

Comparison of 0.25% Bupivacaine Plus 2 µg/kg Dexmedetomidine with 0.25% Ropivacaine Plus 2 µg/kg Dexmedetomidine for Caudal Block in Pediatric Lower Abdominal Surgeries: A Randomized, Double-Blinded Study

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Abstract

Introduction: Caudal dexmedetomidine has been used over last few years as an adjuvant with a local anesthetic to prolong the duration of post-operative analgesia in pediatric lower abdominal surgeries. The aim of this study was to compare the duration of post-operative analgesia and sedation with 0.25% bupivacaine plus 2 µg/kg dexmedetomidine versus 0.25% ropivacaine plus 2 µg/kg dexmedetomidine for caudal block in pediatric lower abdominal surgeries.

Materials and Methods: 60 patients of the American Society of Anesthesiologists physical Status I and II, aged 1-6 years undergoing lower abdominal surgeries, were enrolled for the study and divided into two groups as per lottery. In group ropivacaine plus dexmedetomidine (RD) ($n = 30$), 0.25% ropivacaine 1 ml/kg with dexmedetomidine 2 µg/kg in 1 ml normal saline (NS) and in group in bupivacaine plus dexmedetomidine (BD) ($n = 30$), 0.25% bupivacaine 1 ml/kg with dexmedetomidine 2 µg/kg in 1 ml NS, were administered caudally following endotracheal intubation. Following completion of surgery and extubation, all patients were monitored in post-anesthesia care units and duration of post-operative analgesia and sedation was assessed by face, legs, activity, cry, pull score, and Ramsay sedation scale, respectively.

Result and Observation: The duration of caudal analgesia recorded was 16.633 (15.881-17.385) h BD group and 14.7 (14.06-15.43) h in RD group, and the difference is a statistically highly significant ($P < 0.001$). The mean duration of sedation in BD group was 270 (240-300) min and in RD group was 266 (236.27-295.73) min, but the difference is statistically insignificant ($P > 0.05$). We did not evaluate the emergence time and emergence behavior score, time to first micturition in the post-operative period.

Conclusion: 1 ml/kg of 0.25% BD 2 µg/kg in 1 ml NS provide longer duration of post-operative analgesia (but similar duration of sedation) than 1 ml/kg of 0.25% ropivacaine 1 ml/kg with dexmedetomidine 2 µg/kg in 1 ml NS for caudal block for lower abdominal surgeries in pediatric-aged 1-6 years.

Key words: Bupivacaine, Caudal analgesia, Caudal dexmedetomidine, Pediatric lower abdominal surgery, Post-operative period, Ropivacaine

INTRODUCTION

Historically, children have been under treated for pain because of the wrong notion that they neither suffer nor

feel pain or respond to or remember the painful experiences to the same degree as adults do.¹ It is now established that newborn infants, even pre-term, can appreciate the pain and react to it with tachycardia, hypertension, and neuroendocrine response.² As pain is very difficult to assess in the pediatric population, post-operative pain is often undertreated in this age group.³ Regional anesthetic techniques reduce the overall intraoperative requirement of both inhaled and intravenous (IV) anesthetic agents for general anesthesia and allow more rapid return of consciousness while providing effective post-operative pain relief with minimal sedation.⁴

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The caudal epidural block is a commonly used regional anesthetic technique for intraoperative as well as post-operative analgesia for infra-umbilical surgeries in pediatric age group. It is one of the oldest and the most popular regional block performed in pediatric anesthesia.⁵ It is preferred due to its safety and ease of administration and reliable post-operative analgesia for abdominal surgeries.⁶ The main disadvantage of caudal analgesia is the short duration of action after a single injection.⁷ Caudal catheters for continuous infusion or repeated doses are not preferred in children due to the increased risk of infection.⁸

Both bupivacaine and ropivacaine are long-acting, amide local anesthetic with almost similar pK_a (8.1). Ropivacaine, in comparison to bupivacaine blocks pain transmitting A-delta and C fibers to a greater degree than A-beta fibers controlling motor function.^{9,10} It has a wider margin of safety, is less cardiotoxic and neurotoxic and similar duration of analgesia.^{11,12} As compared with bupivacaine, ropivacaine undergoes lower systemic absorption from the caudal epidural space in children, so persists for longer duration.¹³

The use of various adjuvants, such as epinephrine, opioid, clonidine, dexamethasone, ketamine, and α_2 agonists, has been done in prolonging the duration of single shot caudal analgesia in children.¹⁴ In recent years, studies are being conducted to evaluate the use of dexmedetomidine as adjuvant in regional anesthesia to improve the quality and duration of analgesia. Dexmedetomidine is a novel and highly selective α_2 agonist. It has an eight-fold greater affinity for α_2 adrenergic receptors than clonidine and much less α_1 effects. It has sympatholytic, analgesic, and sedative effects and is remarkably free from side effects except for manageable hypotension and bradycardia.^{15,16} Dexmedetomidine acts on the spinal cord, by activating of α_{2A} and α_{2C} adrenoceptors, situated in superficial dorsal horn neurons, directly reducing pain transmission by reducing the release of pronociceptive transmitter, substance P, and glutamate from primary afferent terminals and by hyperpolarizing spinal interneurons via G-protein-mediated activation of potassium channels.¹⁵ Prolongation of sensory blockade in caudal anesthesia by dexmedetomidine can also be attributed to its vasoconstrictor effect on blood vessels which in turn prevents its systemic uptake.

Very few studies have been done to evaluate the effect of dexmedetomidine as adjuvant to bupivacaine or ropivacaine in caudal analgesia in children. So, in this study, we have compared 1 ml/kg of 0.25% bupivacaine plus 2 µg/kg dexmedetomidine with 1 ml/kg of 0.25% ropivacaine plus 2 µg/kg dexmedetomidine for caudal analgesia in children undergoing lower abdominal surgeries.

Aims and Objective

1. To compare duration of post-operative analgesia of dexmedetomidine (2 µg/kg) plus 0.25% bupivacaine (1 ml/kg) with dexmedetomidine (2 µg/kg) plus 0.25% ropivacaine (1 ml/kg) for pediatric caudal block
2. To compare duration of sedation of dexmedetomidine (2 µg/kg) plus 0.25% bupivacaine (1 ml/kg) with dexmedetomidine (2 µg/kg) plus 0.25% ropivacaine (1 ml/kg) for pediatric caudal block
3. To evaluate any other relevant observations, if they arise.

MATERIALS AND METHODS

This prospective, randomized, parallel, double-blinded study, after obtaining institutional ethical clearance and informed parental consent, included 60 patients of American Society of Anesthesiologists (ASA) physical Status I and II, aged 1-6 years undergoing lower abdominal surgeries. In our study, we included children between 1 and 6 years of age as there is difficulty in identifying caudal epidural space in children >7 years due to the fusion of sacral vertebrae and reduction in the size of sacral hiatus.¹⁷ Study exclusion criteria included ASA physical Status III and IV, a history of developmental delay or mental retardation, which could make observational pain intensity assessment difficult, a known or suspected coagulopathy, a known allergy to any of the study drugs and any signs of infection at the site of proposed caudal block. The children were randomly allocated into two groups as per lottery. In Group RD ($n = 30$), 0.25% ropivacaine 1 ml/kg with dexmedetomidine 2 µg/kg in 1 ml normal saline (NS) and in Group BD ($n = 30$), 0.25% bupivacaine 1 ml/kg with dexmedetomidine 2 µg/kg in 1 ml NS, were administered caudally. We have used 1 ml/kg of 0.25% ropivacaine or 0.25% bupivacaine as the local anesthetic drugs in our study which has been supported by evidence from further studies.¹⁷⁻²¹ The selected caudal dose of dexmedetomidine (2 µg/kg) was based on previous study reports in pediatric patients.^{19,20} Sample size calculation was done based on data obtained from two previous pilot studies^{19,20} taking into account the duration of analgesia from these two studies and using the online calculator available at <http://www.stat.ubc.ca/~rollin/stats/ssize/n2.html>. It was calculated that a sample size of 28 people per group would permit a Type 1 error of $\alpha = 0.05$ with power of 0.8 (statistical difference was defined as $P < 0.05$). So, we took a sample size of 30 patients per group. All health-care personnel providing direct patient care, the subjects, and their parents or guardians were blinded to the caudal medications administered. The anesthesiologist who administered the caudal drugs were blinded to the study groups as well as the drugs used. Sterile syringes containing study drugs

were prepared by another anesthesiologist not concerned or participating in the study. The intraoperative and post-operative monitoring was done by the same anesthesiologist who administered the caudal drugs but was unaware of the content of the syringes.

Patients were given intranasal midazolam (0.3 mg/kg) spray as premedication approximately 5 min prior to anesthetic induction. All the baseline parameters, such as the pulse rate (PR), mean arterial pressure (MAP), peripheral oxygen saturation (SpO₂), were observed and recorded. All patients underwent a standard inhalation induction with sevoflurane in oxygen followed by insertion of an IV cannula and administration of a neuromuscular blocking agent to facilitate endotracheal intubation. After endotracheal intubation, patients were placed in the lateral decubitus position, and a single-dose caudal block was performed according to the Group BD or RD under sterile conditions using a 23 G needle and standard loss of resistance technique. Skin incision was allowed 15 min after caudal block were performed. Maintenance of anesthesia was done with sevoflurane-oxygen-N₂O and patients were mechanically ventilated. Heart rate and blood pressure were recorded before the operation and every 5 min interval after the start of procedure until 30 min. An increase in PR or MAP within the 10-15 min of the start of surgical procedure were deemed as a failure of caudal anesthesia, and rescue analgesia in the form of injection fentanyl was administered (2 µg/kg) IV. Failed caudal blocks were excluded from the study. IV fluids in the form of Isolyte-P® solution were administered according to body weight and the fasting status. The total duration of surgery for each case and intraoperative complications were noted. At the end of the surgical procedure, all the anesthetic gasses were turned off, and the patients were extubated after reversal of neuromuscular blockade with injection neostigmine (50 µg/kg) and injection glycopyrrolate (10 µg/kg). All the patients were observed for 24 h in post-anesthesia care units.

MAP, PR, and SpO₂ were recorded at a 15 min, 30 min, and 60 min after extubation and thereafter hourly up to the maximum duration of analgesia.

Using face, legs, activity, cry, consolability (FLACC) score,¹⁹ pain intensity was assessed at 15 min after extubation and thereafter hourly until FLACC score were ≥4 for all patients. If the FLACC pain scale score was noted to be 4 or more, injection paracetamol (15 mg/kg) slow IV was administered as rescue analgesic. The duration of adequate post-operative analgesia was deemed from the time of extubation to the time when the FLACC pain scale score was noted to be 4 or more.

Duration of sedation was assessed by Ramsay sedation scale²² at 15 min, 30 min, and 60 min after extubation and thereafter hourly until the Ramsay sedation score became 1 in all patients. Duration of post-operative sedation was deemed from the time of extubation until Ramsay sedation score was 2 or less.

The occurrence of post-operative complications, such as post-operative nausea vomiting, respiratory depression, hypotension, and bradycardia, were also noted.

Statistical Analysis

Statistical analyzes were carried out using the statistical software “Graph Pad InStat version 3.0.” Data are presented as a mean and standard deviation for the demographic parameter, duration of post-operative analgesia, and duration of sedation. To estimate differences in normally distributed continuous outcome variables, the “unpaired Student’s *t*-test” for independent samples was used. A *P* < 0.05 was considered statistically significant.

RESULTS AND OBSERVATION

Demographic Parameters

In this randomized, prospective, double-blinded study, no difference could be detected between two groups from the data of 60 children regarding the patient profile. Demographic data of patients are given in Table 1. There was no significant difference in the groups in terms of age, body weight, gender distribution, and duration of surgery.

Intraoperative Hemodynamic Variation

Heart rate

As shown in Figure 1, changes in mean heart rate in both the groups are comparable and statistically insignificant (*P* > 0.05). Both the groups showed gradual decreasing trends in mean heart rate from the pre-operative baseline

Table 1: Comparison of demographic parameters

Demographic parameters	Group BD	Group RD	<i>P</i> value
Age (months)	36±6.3	34±6.9	0.2458
Weight (kg)	16±2.3	15.3±3	0.3147
Sex (M:F)	20:10	23:07	
ASA physical status I/II (<i>n</i>)	25:5	24:6	
Duration of surgery (min)	45.5±15.3	44±16.1	0.7128
Surgical procedures			
Colonic pull-through	7	5	
Undescended testicle	3	3	
Lord’s plication	5	6	
Inguinal hernia repair	8	10	
Umbilical hernia repair	2	1	
Colostomy	2	1	
Hypospadias repair	3	4	

BD: Bupivacaine plus dexmedetomidine, RD: Ropivacaine plus dexmedetomidine, ASA: American Society of Anesthesiologists

value up to 30 min intraoperatively, which may be attributable to caudal dexmedetomidine.

Blood pressure

As shown in Figure 2, changes in MAP in both the groups are comparable and statistically insignificant ($P > 0.05$). Both the groups showed gradual decreasing trends in MAP from the pre-operative baseline value up to 30 min intraoperatively, which may be attributable to caudal dexmedetomidine.

Post-operative Hemodynamic Variation

Heart rate

As shown in Figure 3, changes in post-operative mean heart rate in Group BD and Group RD are comparable from 15 min until the 13th h and are statistically insignificant ($P > 0.05$). The mean heart rate at the 5th h was slightly higher than the mean heart rate at the 4th h in both the groups, which was probably due to the patients becoming awake in both the groups (the mean duration of sedation in Groups BD was 270 ± 30 min and in

Group RD was 266 ± 29.73 min). There was statistically significant ($P > 0.05$) difference in mean heart rate between the two groups at the 14th, 15th, and 16th h. This rise in heart rate in Group RD at the 14th, 15th, and 16th h was probably due to pain (the duration of analgesia in Group BD was 16.633 ± 0.752 h and in RD Group was 14.7 ± 0.64 h).

Blood Pressure

As shown in Figure 4, changes in post-operative MAP in Group BD and Group RD are comparable from 15 min until the 16th h and are statistically insignificant ($P > 0.05$). The MAP at the 5th h was slightly higher than the MAP at the 4th h in both the groups, which was probably due to the patients becoming awake in both the groups (the mean duration of sedation in Groups BD was 270 ± 30 min and in Group RD was 266 ± 29.73 min). There was a slight increase in MAP at the 16th h in the Group RD and 18th h in Group BD, which may be attributable to pain (the duration of analgesia in Group BD was 16.633 ± 0.752 h and in RD Group was 14.7 ± 0.64 h).

Duration of Post-operative Analgesia

As shown in Table 2 and Figure 5, the duration of post-operative analgesia in Group BD was 16.633 ± 0.752 h and in RD Group was 14.7 ± 0.64 h, and the difference is statistically significant ($P < 0.0001$).

FLACC score (Figures 6 and 7)

As shown in Figure 6, most patients in Group BD had FLACC score of 4 at 17th and 18th hr. But as shown in

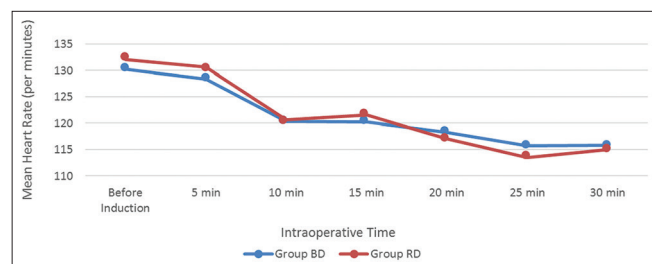


Figure 1: Comparison of intraoperative heart rate

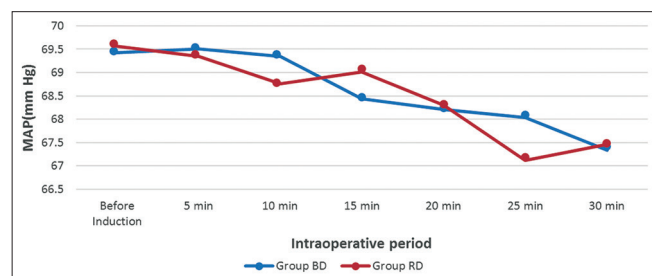


Figure 2: Comparison of intraoperative blood pressure

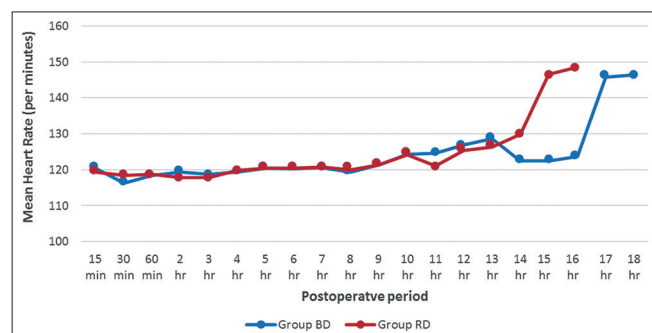


Figure 3: Comparison of post-operative heart rate

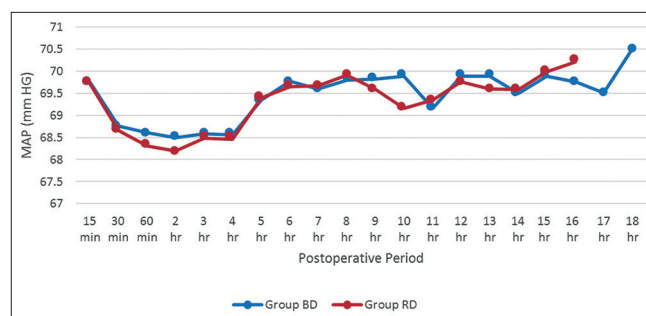


Figure 4: Comparison of post-operative blood pressure

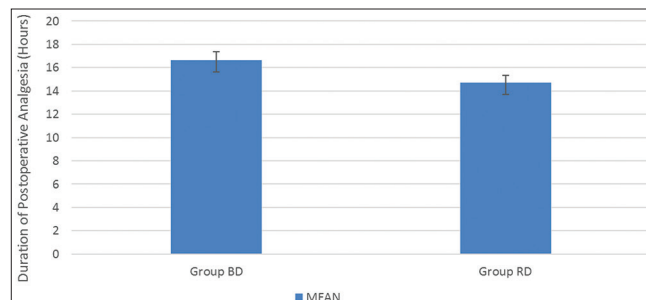


Figure 5: Comparison of duration of post-operative analgesia

Figure 7, most patients in Group RD had FLACC score of 4 at the 15th and 16th hr.

Duration of Sedation

Table 3 and Figure 8 show a comparison of the mean duration of sedation in the Groups BD and Group RD. The mean duration of sedation was greater in Group BD than Group RD, but the difference is statistically insignificant (>0.05).

Ramsay sedation score

As shown in Figures 9 and 10, most of the patients in both Group BD and RD remained co-operative, oriented, and calm at 300 min, whereas most of the patients became anxious and agitated or restless, or both at 420 min.

DISCUSSION

In caudal block, the duration of analgesia depends on concentration and volume local anesthetics as well as the concentration of the adjuvant used. The volume of local anesthetic required in caudal block is directly proportional to the weight; larger volume of the drug increases the cephalad spread leading to higher levels of block.²³

In a study on caudal analgesia using 0.25% bupivacaine, there was significant prolongation in the duration of caudal analgesia following the addition of dexmedetomidine to 0.25% bupivacaine.²⁰ In another similar study using 0.25% ropivacaine, there was a significant prolongation of the duration of analgesia following the addition of dexmedetomidine to 0.25% ropivacaine for caudal blocks.²⁴ El-Feky and El Abd²⁵ used dexmedetomidine (1 µg/kg) or fentanyl (1 µg/kg), and Bhaskar *et al.*²¹ used dexmedetomidine (2 µg/kg) and fentanyl (2 µg/kg) as caudal adjuvant; in

Table 2: Comparison of duration of post-operative analgesia

Duration of analgesia (h)				P value
Group BD		Group RD		
Mean	SD	Mean	SD	
16.633	0.752	14.7	0.64	0.0001

SD: Standard deviation, BD: Bupivacaine plus dexmedetomidine, RD: Ropivacaine plus dexmedetomidine

Table 3: Comparison of mean duration of sedation

Duration of sedation (min)				P value
Group BD		Group RD		
Mean	SD	Mean	SD	
270	30	266	29.73	0.6059

SD: Standard deviation, BD: Bupivacaine plus dexmedetomidine, RD: Ropivacaine plus dexmedetomidine

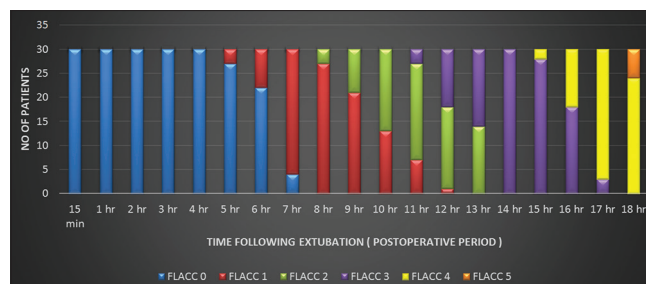


Figure 6: Face, legs, activity, cry, consolability (FLACC) pain score of patients in group bupivacaine plus dexmedetomidine in the post-operative period. Most patients had FLACC score of 4 at 17th and 18th h

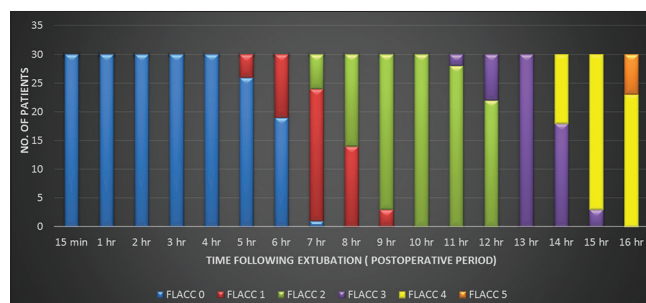


Figure 7: Face, legs, activity, cry, consolability (FLACC) pain score of patients in group ropivacaine plus dexmedetomidine in the post-operative period. Most patients had FLACC score of 4 at the 15th and 16th h

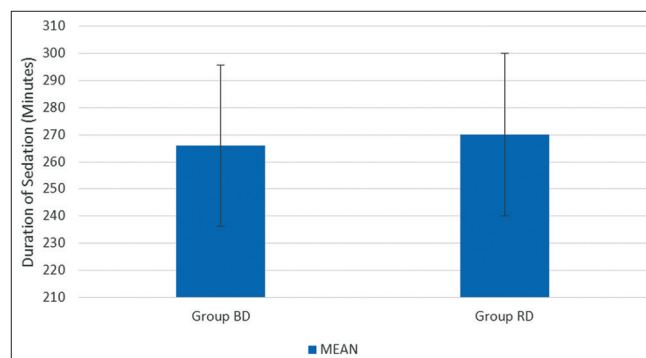


Figure 8: Comparison of duration of sedation (MEAN ± SD)

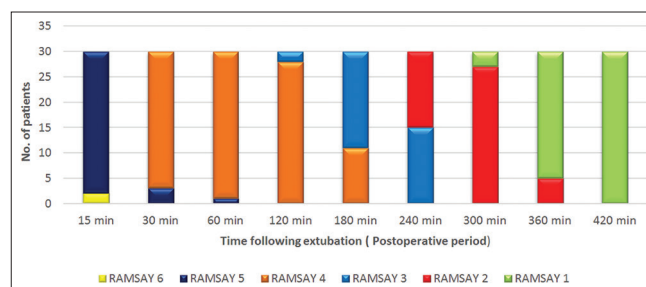


Figure 9: Ramsay sedation score of patients in group bupivacaine plus dexmedetomidine in the post-operative period. Most of the patients remained co-operative, oriented, and calm at 300 min, whereas most of the patients became anxious and agitated or restless, or both at 420 min

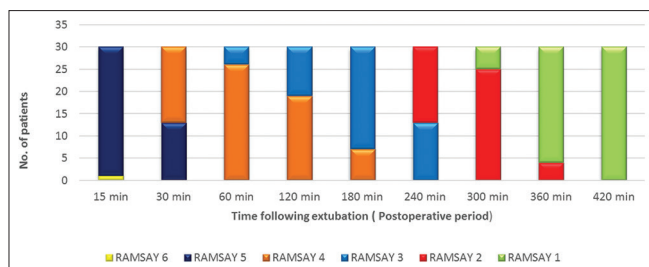


Figure 10: Ramsay sedation score of patients in group ropivacaine plus dexmedetomidine in the post-operative period. Most of the patients remained co-operative, oriented, and calm at 300 min, whereas most of the patients became anxious and agitated or restless, or both at 420 min

both the studies, the duration of caudal analgesia was significantly prolonged with dexmedetomidine as compared to fentanyl, with comparable and stable hemodynamic, lower consumption of post-operative analgesics, and similar levels of sedation. Dexmedetomidine has been used in the range of 1.5-2 µg/kg without any incidence of neurological deficits and without any significant side effect.^{19,22,26}

In our study, we compared the effect 2 µg/kg of dexmedetomidine when added to 1 ml/kg of 0.25% ropivacaine and 1 ml/kg of 0.25% bupivacaine for caudal block in pediatric patients undergoing lower abdominal surgeries and found out that the duration of caudal analgesia recorded was 16.633 (15.881-17.385) h in bupivacaine plus dexmedetomidine (BD) group and 14.7 (14.06-15.43) h in RD group with a highly significant $P < 0.001$.

El-Hennawy *et al.*¹⁹ used dexmedetomidine 2 µg/kg and 0.25% bupivacaine caudally and found the duration of caudal analgesia to be 16 (14-18) h; similarly, Anand *et al.*²⁴ used dexmedetomidine 2 µg/kg with 0.25% ropivacaine and found that the duration of caudal analgesia was 14.5(13.90-15.09) h, in both the studies the duration of analgesia obtained, was similar to our study result.

Manohar and Yachendra²⁷ used 1 µg/kg dexmedetomidine with 0.25% bupivacaine and 0.25% ropivacaine caudally and found the duration of analgesia to be 532.67 (493.66-571.68) min in BD group and 497 (473.79-520.21) min in RD group. The lower duration of analgesia noted in this study was probably due to the use of lower dose 1 µg/kg of dexmedetomidine.

Saadawy *et al.*,²⁰ in a similar study, on caudal analgesia using 0.25% bupivacaine and 1 µg/kg dexmedetomidine showed a longer duration of caudal analgesia of 18.5 (15.7-21.3) h than our study which was probably because of the wider intervals at which pain score was assessed (6, 8, 10, 12,

16, 20, and 24 h post-operatively) and due to this long interval between subsequent determination of pain score, the estimation of analgesic duration may have been faulty.

Bhaskar *et al.*²¹ used ropivacaine 0.2% with 1 µg/kg dexmedetomidine caudally and found the duration of post-operative caudal analgesia to be 714 (565-863) min which is lower than our study analgesia duration, this may be due to the higher age group and body weight of patients in whom pain threshold may be lower than those included for this study compared to the current study or it may be due to the use of 0.2% ropivacaine for the study as compared to 0.25% ropivacaine used in our study.

In our study, the mean duration of sedation in BD group was 270 (240-300) min and in RD group was 266 (236.27-295.73) min. The mean duration of sedation was greater in Group BD than Group RD, but the difference was statistically insignificant.

In a similar study using 1 µg/kg dexmedetomidine with 0.25% bupivacaine and 0.25% ropivacaine, the duration of post-operative sedation obtained was 139.12 (124.9-153.34) min in BD group and 138.66 (125.45-151.87) min in RD group;²⁷ in another study using 1 µg/kg dexmedetomidine with 0.25% bupivacaine a sedation duration of 210 (138-282) min was observed,²⁰ the use of lower dose (1 µg/kg) dexmedetomidine may be accounted for the decreased duration of sedation in both the studies. In our study, the Ramsay sedation score of 2 was attained by most of the patients in both the groups at 300 min and a sedation score of 1 at 420 min post-extubation.

No episodes of clinically significant post-operative complications, such as respiratory depression, hypotension, and bradycardia, were observed in any of the groups except 1 episode of desaturation in 1 baby in Group RD 2 h post-extubation which was managed by oxygen supplementation.

The major limitation of our study apart from being a single center study was that its sample size was small ($n = 30$). Future study on the larger number of patients may strongly prove the hypothesis. Different local anesthetics and adjuvants with different concentrations and volumes used for the caudal block, drugs used for premedication, and rescue analgesia, various methods to assess pain and statistical analysis may all account for the variability in the duration of analgesia. We did not evaluate the emergence time and emergence behavior score, time to first micturition in the post-operative period.

CONCLUSION

There was no significant difference in the vital parameters and duration of sedation between the two Group BD and Group RD. With the doses and concentrations of the drugs we used, no complication was observed except desaturation in 1 baby in Group RD 1 h post-extubation which was managed by oxygen supplementation. 1 ml/kg of 0.25% BD 2 µg/kg in 1 ml NS produced longer duration of post-operative analgesia and similar duration of sedation as compared to 1 ml/kg of 0.25% RD 2 µg/kg in 1 ml NS in caudal block for lower abdominal surgeries in pediatric age group of 1-6 years.

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