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Original Article

Dexamethasone versus Dexmedetomidine as Adjuvant to Ropivacaine 0.2% in Caudal Analgesia in Pediatric Infraumbilical Surgeries: A Prospective, Randomized, and Double-Blind Study

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Abstract

Background: Caudal analgesia is a good, reliable, and safe technique commonly used for intra- and post-operative analgesia in pediatric patients undergoing infraumbilical surgeries. Various adjuvants are being used to improve the quality and duration of single-shot local anesthetic injection. We aimed to compare the analgesic efficacy of dexamethasone versus dexmedetomidine added as an adjuvant to ropivacaine 0.2% in pediatric caudal blocks.

Methods: After approval from the institutional ethics committee and written informed consent of the parents, 60 children of age group 2-8 years, the American Society of Anesthesiologists Grade I and II, scheduled for elective infraumbilical surgeries were divided into two equal groups in a prospective, randomized, and double-blind study. Group A (n = 30) received ropivacaine 0.2% 1 mL/kg with 0.1 mg/kg of dexamethasone and Group B (n = 30), received ropivacaine 0.2% 1 mL/kg with 2 μg/kg of dexmedetomidine. Post-operative pain was assessed by modified objective pain scale score and face, legs, activity, cry, consolability score, and sedation by Ramsay sedation scale.

Results: The mean duration of analgesia was 478.04 ± 61.22 min in Group A, whereas in Group B, it was 724.81 ± 36.30 min (P = 0.0001). Sedation scores between the two groups were comparable. Group B shows increased sedation score (III or IV) significantly in the first 2 h when compared to Group A. No significant difference was observed in the incidence of hemodynamic changes or side effects.

Conclusion: We conclude that dexmedetomidine is a better adjuvant to ropivacaine in single-shot caudal anesthesia for pediatric infraumbilical surgeries with significant post-operative pain relief, resulting in a better quality of sleep and a prolonged duration of arousable sedation with unremarkable side effects when compared with dexamethasone.

Key words: Adjuvant, Caudal analgesia, Dexamethasone, Dexmedetomidine, Ropivacaine

INTRODUCTION

Pediatric surgical procedures are followed by pain that leads to fear, agitation, anxiety, restlessness, and hemodynamic instability in children. To overcome these effects of pain and to improve the quality of analgesia, various regional anesthetic techniques have gained popularity.

Caudal block is one of the most reliable and commonly used regional analgesic techniques to provide intra- and post-operative analgesia in pediatric infraumbilical surgeries. It can be given as single-shot injection or continuous infusion through a caudal epidural catheter. Single-shot caudal was the most commonly preferred technique as the latter is associated with increased incidence of infection due to high risk of fecal contamination of catheter.[1]

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However, the disadvantage of single-shot caudal is less duration of action of local anesthetics. Hence, to increase the efficacy of caudal analgesia, various adjuvants such as opioids, steroids, neostigmine, and α_2 agonists[2-4] have been added to local anesthetics to provide prolonged post-operative analgesia.

Ropivacaine a long acting, S-enantiomer of the amide local anesthetic structurally related to bupivacaine, is considered safe in pediatric population as it produces differential neural blockade, with less motor blockade with reduced cardiovascular and neurological toxicity.[5]

Epidural steroids produce analgesia by their property of anti-inflammatory action, edema reduction, and shrinkage of the connective tissue.[6] Dexamethasone is a high potency, long-acting glucocorticoid with powerful anti-inflammatory as well as analgesic properties.[7] It potentiates analgesia of the caudal block by regulating transcription factor nuclear factor-kB and inhibits central sensitization after surgery.[8,9]

Dexmedetomidine is a highly selective α_2-adrenoreceptor agonist with sedative and analgesic effects. It enhances local anesthetic effect without producing side effects,[10,11] which makes it a good adjuvant to local anesthetics. When compared to other sedatives, it produces sedation without significant respiratory compromise even at high doses.[12]

There are studies demonstrating that the use of dexmedetomidine as adjuvant in caudal block could prolong post-operative pain relief children in successfully.[13,14]

This study was designed to compare the analgesic efficacy of dexamethasone (0.1 mg/k body weight) versus dexmedetomidine (2 μg/kg body weight) added as adjuvants to ropivacaine 0.2% (1 ml/kg) in caudal analgesia in pediatric infraumbilical surgeries, in terms of the duration of post-operative analgesia, post-operative sedation, quality of surgical anesthesia, and to monitor the side effects if any.

MATERIAL AND METHODS

Design and Sampling

Design

This was a prospective, randomized, and double-blind study.

Study period

The duration of the study period was 7 months (between January 2017 and July 2017).

Sampling

Pediatric patients in the age group of 2-8 years scheduled for infraumbilical surgeries under general anesthesia in the Department of Pediatric Surgery, Government General and Teaching Hospital, Kakinada, were selected for the purpose of the study.

Sampling procedure

Pediatric patients selected for lower abdominal surgeries were identified in the pediatric surgery ward, and information regarding the diagnosis, data of child, and type of surgery was collected from the inpatient case record.

Study population

Eligible children of the American Society of Anesthesiologist Physical Status I and II of either sex, in the age group of 2-8 years, undergoing elective infraumbilical surgical procedures were included in this study.

Exclusion criteria

Participants with parents refusal, infection at sacral region, bleeding diathesis, pre-existing neurological/spinal diseases, mental retardation, congenital anomaly of lower spine, known allergy to steroids, local anesthetic drugs, sepsis, and cardio-respiratory or other systemic diseases were excluded from the study.

Justification of sample size

The primary outcome of this study was the mean time to first analgesic request. The sample size estimation was determined based on the primary outcome of the study. A pilot study was done with 10 patients per group in which clinically significant difference in the meantime to first request of analgesia between the two groups was 257.85 min which was >25% variation between the groups. In this pilot study, mean duration of analgesia for dexmedetomidine group was 692.39 ± 34.09 min and dexamethasone group was 409.16 ± 59.47 min using $\alpha = 0.05$, $\beta = 0.20$, and power of study being 80%, the sample size was calculated to be 25 per group (using power analysis and sample size software, power and sample size software.com). Hence, we recruited 30 in each group to compensate for dropouts. The subjects included in the pilot study were not taken for the original study.

Ethical issues

The hospital ethics committee approval was sought. All parents/legal guardians were explained about the anesthetic technique and its merits and demerits, and written informed consent was obtained.

Double blinding

An anesthesiologist not involved in the study kept the table of random numbers and prepared and coded the sample drugs according to patients body weight in equal volumes in syringes of either ropivacaine 0.2% with dexamethasone (0.1 mg/kg) making the volume to 1 ml for dexamethasone group or ropivacaine 0.2% with dexmedetomidine (2 μg/kg) making the volume to 1 ml for dexmedetomidine group. As it was a double-blinded study, the anesthesiologist administering anesthesia and doing data collection was blinded to the drug administered.

Group allocation

60 children were randomly allocated into two groups of 30 patients each by a computer generated randomization method, and the group identification slip was put in serially numbered, sealed envelopes to hide allocation.

- Group A (n = 30): Received caudal 0.2% Ropivacaine (1 ml/kg) + dexamethasone (0.1 mg/kg) making the volume to 1 ml.
- Group B (n = 30): Received caudal 0.2% Ropivacaine (1 ml/kg) + dexmedetomidine (2 μg/kg) making the volume to 1 ml.

Patients were kept fasting as per the guidelines before surgery. In the operating room, all the standard monitors (non-invasive blood pressure [NIBP], pulse rate, and blood oxygen saturation level [SPO2]) were connected. Baseline cardio-respiratory parameters were recorded. After securing an IV access, the children were premedicated with injection glycopyrrolate 0.005-0.01 mg/kg IV, injection ondansetron 0.1 mg/kg, and injection midazolam 0.05 mg/kg IV, induction was done with sevoflurane using Jackson Rees circuit, and intubation was facilitated with injection suxamethonium 2 mg/kg IV. Patients were intubated and kept on controlled ventilation on oxygen 50% + nitrous oxide 50%, sevoflurane 1%, and injection atracurium 0.5 mg/kg as an initial dose, followed by maintenance dose of 0.1 mg/kg.

After securing endotracheal tube in place, patients were placed in left lateral position with hips and knees flexed. Under strict aseptic precautions and after identifying sacral hiatus, a 22G short-beveled needle was inserted in the caudal space using loss of resistance technique and confirmed by whoosh test.[15] The injection was made after negative aspiration for blood or cerebrospinal fluid. The caudal drug was given according to the group assigned by an anesthesiologist, who was blinded to the drug administered. The vitals were recorded every 15 min for 1 h, every 1 h for 4 h, and then every 2 h for up to 12 h.

The time of caudal block was noted and surgical incision was allowed after 10 min after administering the caudal block. Block considered failed if increase in heart rate and mean blood pressure more than 15% compared with the baseline values obtained just before surgical incision. On the completion of surgery, the residual effect of muscle relaxant was reversed with injection neostigmine 0.05 mg/kg and injection glycopyrrolate 0.01 mg/kg, and patients were extubated, when fully awake.

Patients were shifted to the post-operative anesthesia care unit (PACU), for further monitoring of SPO^2, pulse rate, respiratory rate (RR), and NIBP. The quality of analgesia and sedation was assessed every 15 min till 2 h, every 2nd hourly till 12 h, and every 6th hourly till 24 h until the first dose of rescue analgesia was given. The intensity of pain was measured using the pediatric observational face, legs, activity, cry, consolability (FLACC) pain score with its 0-10 score range and modified objective pain scale (MOPS).[13] The duration of analgesia is defined as the time period between administration of block until FLACC score reached >4.[16] Patients were administered rescue analgesia with paracetamol 15 mg/kg IV on evidence of pain, i.e., if the MOPS score reached a value of >4.

Motor block was assessed in the PACU on awakening by modified Bromage scale.[17] The duration of motor block was calculated from the time of administration of the drug to the time when modified Bromage scale reached the value of 1.

Level of sedation was assessed by Ramsay sedation scale[18] at 30 min and 60 min after extubation and thereafter hourly up to 12 h or until score became I in all patients. Ramsay score of V or VI indicates excessive sedation.

Any adverse events such as hypotension, bradycardia, nausea, vomiting, and respiratory depression were monitored for 24 h and treated accordingly. Post-operative respiratory depression was defined as RR <10/min or decrease in SPO_2 <95% and required supplemental oxygen.

Statistical Analysis

Statistical analysis was performed using GraphPad.com software. Data were analyzed and compared using student's *t*-test, Fisher's exact test, and Chi-square test. Data were represented as a mean and standard deviation. $P < 0.05$ was considered statistically significant and $P < 0.001$ is considered to be highly significant.

Face, legs, activity, cry, consolability behavioral pain assessment

Categories	Score		
	0	1	2
Face	No particular expression or smile	Occasional grimace or frown; withdrawn, disinterested	Frequent to constant frown, clenched jaw, quivering chin
Legs	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 being talked to; distractable	Difficult to console or comfort

Modified objective pain scale[13]

Criteria	Findings	Points
Crying	None	0
	Consolable	1
	Not consolable	2
Movements	None	0
	Restless	1
	Thrashing	2
Agitation	Asleep	0
	Calm	0
	Mild	1
	Hysterical	2
Posture	Normal	0
	Flexed	1
	Holds injury site	2
Verbal	Asleep	0
	No complaints	0
	Complaints but cannot localize	1
	Complaints and can localize	2

Modified Bromage scale

Criterion	Score
No motor block, child moves limbs freely	0
Inability to raise legs	1
Inability to flex knees	2
No movement possible in legs	3

Six point sedation score was assigned as follows:

Ramsay sedation score

Score	Clinical description
I	Anxious, agitated
II	Cooperative, oriented, tranquil
III	Responds only to verbal commands
IV	Asleep with brisk response to light stimulation
V	Asleep with sluggish response to stimulation
VI	Asleep without response to stimulation

RESULTS

A total of 60 patients in the age group of 2 - 8 years were enrolled in the study. Caudal block was successful in all the patients.

Demographic data of patients in both the groups in terms of age, sex, weight, and duration of surgery were similar and comparable (Table 1).

There was no significant difference in the hemodynamic parameters between the two groups in pre- and post-operative periods.

The mean duration of analgesia in Group B was significantly more than in Group A, i.e., 724.81 ± 36.30 min and 478.04 ± 61.22 min ($P < 0.0001$), respectively (Table 2).

When pain scores (FLACC and MOPS) were compared between two groups, it was observed that during the first 4 h after surgery all patients in Group A and Group B had adequate analgesia (FLACC score <4 and MOPS score <4). In Group A, the FLACC and MOPS score reached 4 at 6th h in most of the patients with mean analgesic duration of 478.04 ± 61.22 min (8.9 h). In Group B, the FLACC and MOPS score reached 4 at 12 h in most of the patients with mean analgesic duration of 724.81 ± 36.30 min (12.68 h). Rescue analgesia was administered when MOPS and FLACC ≥4 (Figures 1 and 2).

There was no significant prolongation of motor blockade after the surgery in both the groups (Table 2).

Table 1: Demographic characteristics of the studied patients

Data	Mean±SD (*n*=30)		*P*
	Group A	Group B	
Age (years)	3.68±1.46	3.70±1.3	0.955
Weight (kg)	13.96±3.16	14.42±2.8	0.520
Sex (%)			
Male	22 (82.5)	25 (87.5)	0.532*
Female	8 (17.5)	5 (12.5)	
ASA (I/II)	20/10	22/8	0.566†
Duration of surgery (in min)	44.12±14.89	45.35±13.71	0.740

Values are expressed as mean±SD, SD: Standard deviation, or ratio or absolute numbers, Student: *t*-test, *Fischer's exact test, †Chi-square test used ASA status, *P*<0.05 statistically significant, ASA: American society of anesthesiologists

Table 2: Surgical procedures

Surgical procedures	Group A *n*=30 (%)	Group B *n*=30 (%)
Inguinal herniotomy	13 (43.33)	11 (36.66)
Hypospadias	15 (50)	18 (60)
Orchiopexy	02 (6.66)	01 (3.33)

Data expressed in absolute numbers (%)

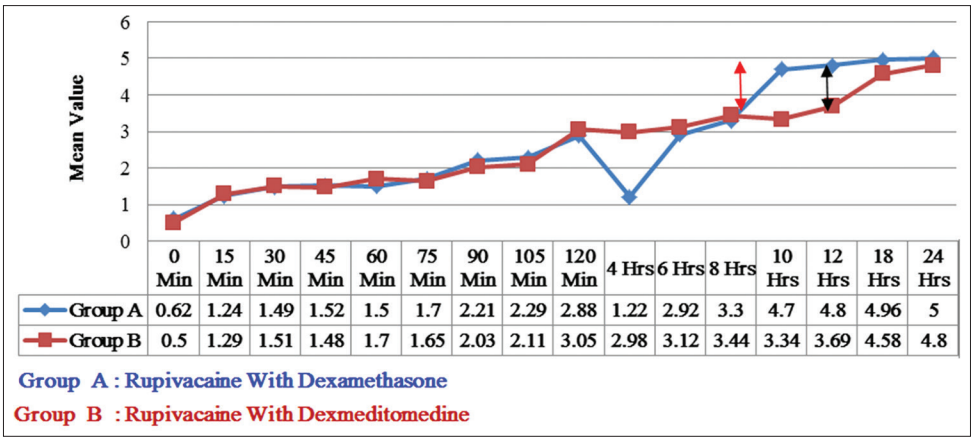

Figure 1: Face, legs, activity, cry, consolability score (mean) pain scores at different time intervals in both groups (adequate analgesia is score <4). *Statistically significant compared with group ropivacaine with dexamethasone

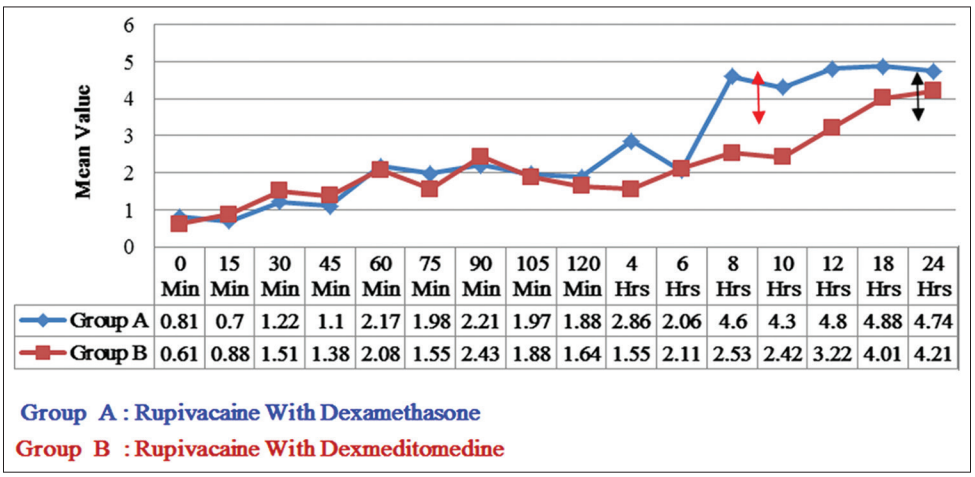

Figure 2: Modified objective pain scale (mean) pain scores at different time intervals in the both group. (Adequate analgesia is score <4). *Statistically significant compared with group ropivacaine with dexamethasone

Sedation scores between the two groups were comparable at 30 min, 1st h, 2nd h, 3rd h, 6th h, and 12th h after surgery. Group B shows increased sedation score (III or IV) significantly in the 1st 2 h when compared to Group A. No patient had sedation score of V or VI (Table 3).

There was no significant difference between the two groups as regard to the incidence of side effects (Table 4). Although one child in Group B developed bradycardia that was managed with injection atropine 0.01 mg/kg IV, one child in Group A had vomiting and treated with injection Ondansetron 0.1 mg/kg IV (Table 4).

Table 3: Caudal block characteristics (min)

Outcome parameters	Mean±SD (*n*=30)		*P*
	Group A	Group B	
Duration of analgesia (min)	478.04±61.22	724.81±36.30	0.0001*
Duration of motor block (min)	129.42±27.13	143.02±23.58	0.486

*Values are expressed as mean±SD, SD: Standard deviation, Student: t-test, *P*<0.05 statistically significant, Group A: Ropivacaine with dexamethasone, Group B: Ropivacaine with dexmedetomidine

DISCUSSION

Pediatric caudal analgesia has gained importance nowadays because, in addition to providing adequate post-operative analgesia, it also reduces the requirement of anesthetics intraoperatively without significant side effects[19] and also helps in improving the outcome after surgery. The use of various additives to local anesthetics improves the quality of block by enhancing the duration of block and provides good quality of surgical conditions with hemodynamic stability and minimal side effects.

In this study, we found that caudal administration of dexmedetomidine 2 μg/kg when added to ropivacaine 0.2% in caudal epidural analgesia achieved good quality of intra- and post-operative analgesia, better quality of

Table 4: Ramsay sedation score during observation period

Time	Median (range)	
	Group A	Group B
End of surgery	2 (1-3)	4 (3-4)
30 min	2 (1-3)	4 (3-4)
1 h	1 (0-1)	3 (2-3)
2 h	1 (0-2)	2 (2-2)
3 h	1 (0-1)	1 (0-2)
6 h	0 (0-0)	0 (0-0)
12 h	0 (0-0)	0 (0-0)

Data expressed in absolute numbers, Group A: Ropivacaine with dexamethasone, Group B: Ropivacaine with dexmedetomidine

Table 5: Side effects

Side effects	Group A *n*=30	Group B *n*=30
Bradycardia	0	1
Hypotension	0	0
Respiratory depression	0	0
Vomiting	1	0

Data expressed in absolute numbers

sleep, significant post-operative pain relief with lesser pain score, and without remarkable side effects in children undergoing infraumbilical surgeries when compared with caudal dexamethasone 0.1 mg/kg.

We preferred ropivacaine, in our study, because it is better tolerated and less toxic compared to bupivacaine,[20] we selected 2-8-year-old children and the dosage of ropivacaine, and we used in our study 1 ml/kg of 0.2% which was considered as safe in this age group and this was consistent with the study done by Wulf *et al.*[21] who evaluated the pharmacokinetics of ropivacaine 0.2% in children and documented as safe dose.

Perineural injection of steroids is reported to influence post-operative analgesia. In our study, addition of dexamethasone to ropivacaine increased the analgesic duration of caudal block, reduced severity of pain without inducing any significant respiratory, and hemodynamic effects.

Kim *et al.*[22] evaluated the analgesic efficacy of caudal dexamethasone combined with ropivacaine and found that post-operative pain scores at 6 and 24 h were significantly lower in dexamethasone group. The findings of their study were similar to our study.

Choudhary *et al.*,[23] in their study, proved that the mean duration of analgesia in ropivacaine with dexamethasone group was significantly more than in ropivacaine group, i.e., 478.046 ± 104.57 min and 248.4 ± 54.1, respectively. In our study, also mean duration of analgesia in ropivacaine with dexamethasone was 478.04 ± 61.22 min, and our value coincides with their value.

Dexmedetomidine is selective α_2 adrenergic receptor agonist which prolongs the duration of analgesia when added to caudal ropivacaine. This effect is due to local vasoconstriction, increased potassium conductance in Aδ and C fibers.

Anand *et al.*[24] administered caudal dexmedetomidine 2 μg/kg with 0.25% ropivacaine 1 ml/kg for pediatric lower abdominal surgeries and achieved significant post-operative pain relief up to 15 h. We used the same dose of dexmedetomidine 2 μg/kg with 0.2% ropivacaine 1 ml/kg and achieved mean duration of analgesia of nearly 13 h. The observations of Anand *et al.* study correlated with our study.

Afonso and Reis.[12] found that sedation caused by dexmedetomidine can be easily reversed with slight stimulation and do not cause respiratory depression even at high doses. In our study, also no child had respiratory depression in the post-operative period which is in agreement with his study.

As regard to sedation score, there was a significant increase in the 1st 2 h in sedation score with prolonged duration of sedation in dexmedetomidine group compared to dexamethasone group which is acceptable to the parent's as the child remains calm.

CONCLUSION

We conclude that dexmedetomidine is a better adjuvant to ropivacaine in single-shot caudal anesthesia for pediatric infraumbilical surgeries with significant post-operative pain relief, resulting in a better quality of sleep and a prolonged duration of arousable sedation with unremarkable side effects when compared with dexamethasone.

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