

Effect of Addition of Dexmedetomidine to Caudal Ropivacaine on Emergence Agitation and Post-Operative Analgesia in Children Undergoing Lower Abdominal Surgeries under General Anesthesia

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Abstract:

Background: Caudal epidural anesthesia has many applications, including surgical anesthesia in children and adults, as well as the management of acute and chronic pain conditions. The addition of various adjuvants (such as epinephrine, opioids, ketamine, alpha-2 agonists) to the local anesthetics during caudal block can improve the quality of anesthesia while providing consistent analgesia and thus reducing the risk of emergence delirium. We aimed to compare caudal ropivacaine alone versus combining dexmedetomidine to caudal ropivacaine in controlling pain in children and thereby preventing emergence delirium, a distressing adverse effect of anesthesia.

Methods: In this prospective, randomized, parallel group study, sixty children (aged 1-6 years) belonging to American Society of Anaesthesiologists physical status I & II scheduled for elective lower abdominal surgeries were randomly assigned into two groups:

Group RD (n=30) – Caudal 0.25% Ropivacaine 1ml/kg with Dexmedetomidine 2µg/kg;

Group R (n=30) – Caudal 0.25% Ropivacaine 1ml/kg, volume according to body-weight and type of surgery. Caudal block was given after induction of general anaesthesia using sevoflurane. The patient was observed for appearance of post-anaesthetic agitation (Watcha score), duration of analgesia, pain scores (FLACC, CHIPPS SCALE), intra-operative and post-operative complications.

Results: The mean duration of analgesia in RD group (13.66 ± 0.79) hours was significantly higher than in R group (8.32 ± 0.66) hours. The WATCHA score for emergence delirium was significantly lower in RD group (1.47 ± 1.13) compared to R group (2.57 ± 1.04) with a p-value of < 0.001 . Post-operative pain scores (CHIPPS and FLACC Score) were drastically lower in RD group.

Conclusion: Dexmedetomidine when added to Ropivacaine as adjuvant to caudal blocks, prolongs duration of analgesia and prevents emergence agitation in pediatric patients.

Keywords: Dexmedetomidine, Caudal, Emergence Agitation, Pediatric, Lower Abdominal Surgery.

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Introduction

The caudal block is the most commonly used technique of central neuraxial blockade in children. [1] The technique is simple and easy to perform for most, with few complications. It is recommended for most surgical procedures below the umbilicus, including inguinal hernia repair, urinary and digestive tract surgery, and orthopaedic procedures

on the pelvic girdle and lower extremities. Agonists of alpha-2 adrenergic receptors (dexmedetomidine, clonidine) are increasingly used as additives to caudal block. [2,3] They offer several benefits in children when added to local anesthetics, it increases the duration of block & improves the

quality of anesthesia without eliciting hemodynamic disorders. [2,4]

Sudden emergence from anesthesia into an unfamiliar environment and elevated post operative pain have been proposed as a cause of emergence delirium. [5] A child with emergence delirium is in a dissociated state of consciousness in which the child is irritable, uncompromising, uncooperative, incoherent and inconsolably crying, kicking & thrashing. It is distressing to the staff and parents, arousing parental dis-satisfaction, self-injury, dislodging dressings, iv lines and drains. A recent study showed that propofol, ketamine, alpha-2 adreno-receptor agonists, fentanyl were effective in reducing the risk of emergence delirium presumably by delaying emergence and reducing post operative pain. [6]

Since the use of dexmedetomidine in paediatric literature is in the form of small studies and case reports, we here have taken up this study to shine more light on the effects of this novel drug. [7,8]

The main interest of my study is to compare the effects of caudal dexmedetomidine with ropivacaine on emergence agitation, post operative analgesia and intra-operative hemodynamic in pediatric population. [9]

Materials & Methods

After obtaining approval from the institutional ethical committee, a total of 60 patients, belonging to ASA physical status I and II, aged 1-6years posted for lower abdominal surgeries were enrolled in the study. A thorough pre-anesthetic evaluation of the patients was done and written, informed consent was taken from the guardians of the patients during pre-anesthetic checkup. Child's medical conditions, previous anaesthesia experience, psychological context of the child and family, careful physical examination and routine lab investigations were noted.

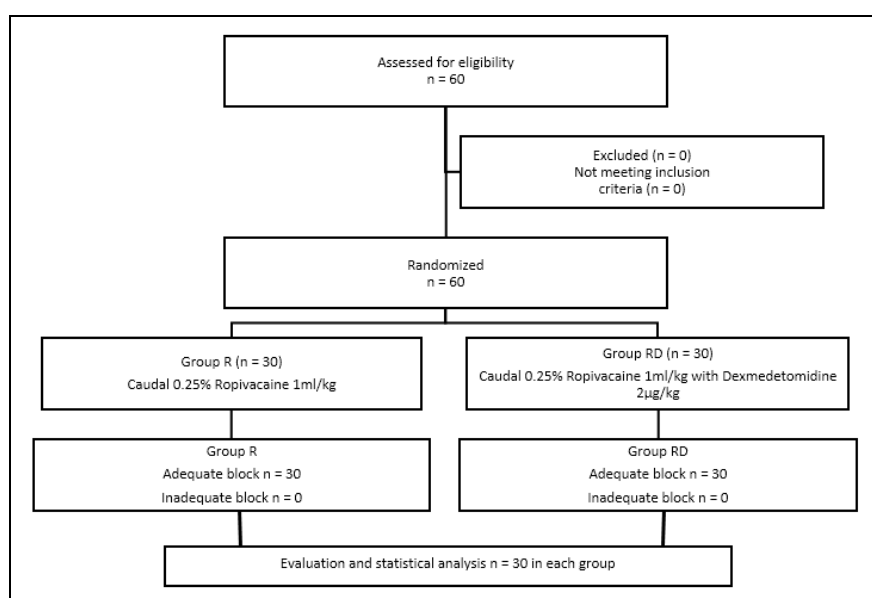


Figure 1: Consort Diagram

Patients with known allergy to the study drugs, infection at block site, suspected coagulopathy, congenital anomalies of lower back, parent/guardian refusal, and prior history of agitation were excluded from the study. On the day of surgery, no premedication was given since certain drugs such as midazolam, atropine are found to be associated with emergence agitation, hence avoided. The patients were shifted to the OT and a multipara monitor & iv fluids were connected. Pre-operative vitals like heart rate, mean arterial pressure and oxygen saturation were noted. Parental presence during anesthetic induction was avoided. Physical restraint and holding, if required was performed under the direction of experienced

anesthesia staff. Induction of anesthesia was achieved using 8% sevoflurane in Nitrous Oxide-Oxygen mixture (50:50) and fresh gas flow of 6 l/min, through Jackson-Rees's modification of Ayre's T-piece. Trachea was intubated after a single dose of atracurium 0.5mg/kg using an appropriate size cuffed or uncuffed endotracheal tube, then sevoflurane concentration was reduced to 3%.

Then the patient was placed in the lateral decubitus position and caudal block performed under sterile conditions using a 23G needle and standard loss of resistance technique. When no midline bulge was observed on introducing 1ml of air, and after negative aspiration for blood or CSF, one of the

following drug combinations were injected into the caudal epidural space. Group RD (n=30) – Caudal 0.25% Ropivacaine 1ml/kg with Dexmedetomidine 2µg/kg and Group R (n=30) – Caudal 0.25% Ropivacaine 1ml/kg, volume according to body weight and type of surgery. Block was considered successful when increase in heart rate and mean arterial pressure in response to skin incision was less than 20% of preoperative values. No narcotics, analgesics or sedatives were administered intraoperatively. If there was movement on incision or tachycardia intra operatively, the block was considered failed. These cases were excluded from the study

The occurrence of intra operative hypotension - defined as decrease of systolic pressure by >30% from the pre-operative value requiring medical intervention was noted. Delayed anesthetic emergence defined as > 20min elapsing from the end of surgery to exiting the operation theatre was also noted. Post-extubation the child was then transferred to the recovery room for 1 hour where heart rate oxygen saturation blood pressure was monitored half-hourly. All children had at least one parent in attendance during recovery. Watcha scale [10] was used to determine emergence agitation. We noted the maximum score during the first hour and scores at four fixed endpoints: 15, 30, 45 and 60 minutes after administration of inhalational anesthetic ceased. Post-anesthetic agitation was defined as a total score of >=3 at any time.

Using the pediatric FLACC [11] (face, legs, activity, cry, consolability) pain scale and CHIPPS [12] (Children and Infant Post-Operative Pain Scale) scales, each study participant's pain was

assessed upon arrival in and at the time of discharge from the PACU, and then every 4 hours for the first 24 hrs after operation. If the FLACC pain scale score and CHIPPS score at any time exceeded four and three respectively, analgesia was supplemented with diclofenac sodium suppository (1~2 mg/kg) or iv paracetamol 12mg/kg. Duration of analgesia defined as the time from caudal block to the first dose of rescue analgesic, was recorded. The primary objective was the incidence of post anesthetic agitation (i.e. a watcha scale score of >=3).

Statistical Analysis

The data were collected and entered into Microsoft excel version 2007 and further analysed in the SPSS software (IBM corporation) version 27.0. All the categorical variables were expressed in terms of number and percentages. Association between two categorical variables were determined by using Chi-squared or Fischer exact test. All the quantitative variables were expressed in terms of mean and standard deviation. Comparison of mean depending on the distribution. Normality of the quantitative variables were checked using Shapiro-Wilks between two groups was done using independent sample t-test or Mann-Whitney U test before applying statistical test. P value less than 0.05 was considered statistically significant.

Results

Demographically, both the groups were comparable. Mean age of the study participants in RD group was 3.70 ± 1.60 years compared to 3.53 ± 1.75 years in R group (Table 1). This difference in age was not statistically significant (P value = 0.702).

Table 1: Demographic profile of the study participants

| Variables | | RD group | R group | χ^2 / t value | P value |
|------------------------------|-------------|-----------------|-----------------|--------------------|---------|
| Age in years (mean \pm SD) | | 3.70 ± 1.60 | 3.53 ± 1.75 | 0.384 | 0.702 |
| Age category (n, %) | < 2 years | 9 (30.0) | 10 (33.3) | 0.105 | 0.949 |
| | 2 – 4 years | 10 (33.3) | 9 (30.0) | | |
| | > 4 years | 11 (36.7) | 11 (36.7) | | |
| Gender (n, %) | Male | 16 (53.3) | 17 (56.7) | 0.067 | 0.795 |
| | Female | 14 (46.7) | 13 (43.3) | | |

Pre-operative hemodynamic profile were similar in both groups. (Table 2)

Table 2: Comparison of pre-operative hemodynamics of the study participants in both the group

| Variables | RD group (mean \pm SD) | R group (mean \pm SD) | t value | P value |
|---------------------------------------|--------------------------|-------------------------|---------|---------|
| Heart rate (bpm) | 110.93 ± 8.02 | 114.47 ± 8.65 | -1.64 | 0.106 |
| Mean arterial pressure | 83.07 ± 9.46 | 85.17 ± 7.71 | 0.942 | 0.350 |
| Oxygen saturation (SPO ₂) | 98.13 ± 0.77 | 98.07 ± 0.78 | 0.331 | 0.742 |

The duration of analgesia was significantly higher in group RD, thus delaying the need for rescue analgesics in the immediate post-operative period. (Table 3, Figure 2.)

Table 3: Comparison of duration of surgery and analgesia parameters between the groups

| Variables | RD group (mean ± SD) | R group (mean ± SD) | t value | P value |
|------------------------------|-------------------------|------------------------|---------|---------|
| Duration of surgery in mins | 42.20 ± 5.3 | 42.27 ± 6.7 | -0.43 | 0.966 |
| Duration of analgesia in hrs | 13.66 ± 0.79 | 8.32 ± 0.66 | 28.05 | < 0.001 |

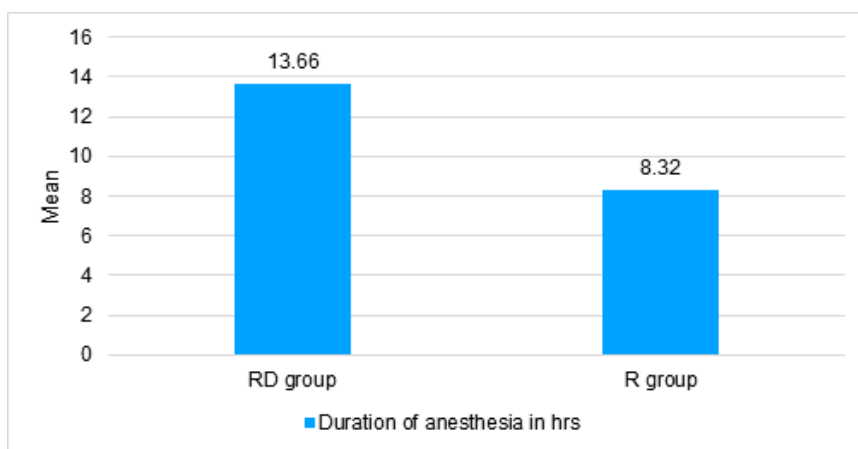


Figure 2: Comparison of duration of analgesia between the groups

The Watch a score was significantly lower in RD group (1.47 ± 1.13) compared to R group (2.57 ± 1.04) with a p-value of < 0.001. (Table 4)

Table 4: Comparison of Watcha Scale Score

| Variables | RD group (mean ± SD) | R group (mean ± SD) | t value | P value |
|--------------|-------------------------|------------------------|---------|---------|
| Watcha score | 1.47 ± 1.13 | 2.57 ± 1.04 | -3.91 | < 0.001 |

The FLACC score consistently remained less than 4 in Group RD for 8 hours post-operatively. (Figure 3)

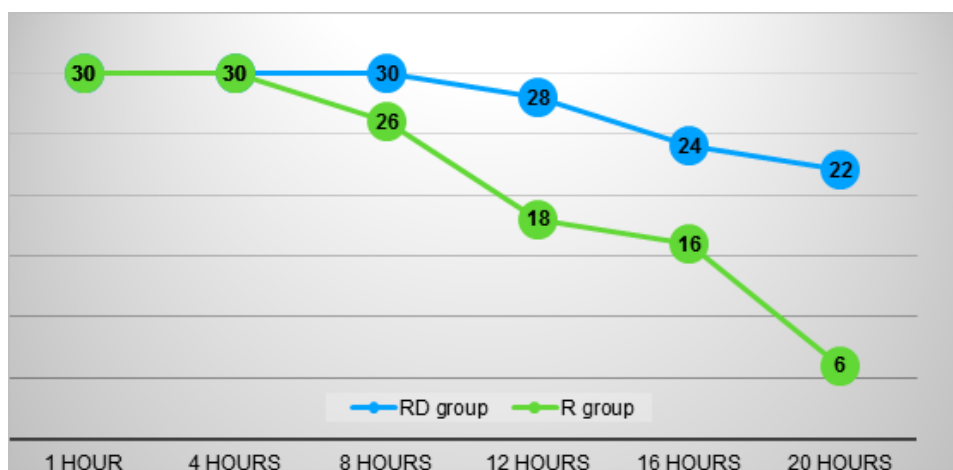


Figure 3: Line diagram showing no. of patient with FLACC score of less than 4 at different time interval

We found a highly significant lower CHIPPS score in RD group compared to R group (P-value < 0.001) (Table 5)

Table 5: Comparison of CHIPPS score in both the groups

| Variables | RD group (mean ± SD) | R group (mean ± SD) | t value | P value |
|--------------|-------------------------|------------------------|---------|---------|
| CHIPPS score | 3.90 ± 1.76 | 7.00 ± 1.57 | -7.16 | <0.001 |

Requirement of rescue analgesic was higher in R group (12 out of 30 i.e 40%) compared to RD group (5 out of 30 i.e 16.7%). This difference was statistically significant (P value = 0.045). (Figure 4)

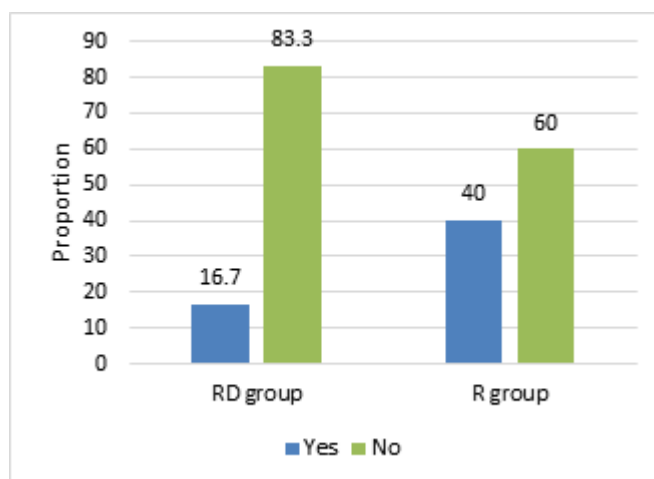


Figure 4: Comparison of rescue analgesia requirement between the group

Hypotension was seen in one patient (3.3%) in RD group while it was seen in two patients (6.7%) in R group. This difference was not statistically significant (P -value = 0.554). Similarly, we did not find any significant difference in terms of respiratory depression, post-operative nausea vomiting and urinary retention between the groups with a p -value of > 0.05 . (Table 6)

Table 6: Comparison of adverse events between the group

| | | RD group N (%) | R group N (%) | χ^2 value | P value |
|----------------------------|-----|-------------------|------------------|----------------|---------|
| Intraoperative Hypotension | Yes | 1 (3.3) | 2 (6.7) | 0.351 | 0.554 |
| | No | 29 (96.7) | 28 (93.3) | | |
| Respiratory depression | Yes | 0 (0) | 0 (0) | - | - |
| | No | 30 (100.0) | 30 (100.0) | | |
| PONV | Yes | 4 (13.3) | 6 (20.0) | 0.480 | 0.488 |
| | No | 26 (86.7) | 24 (80.0) | | |
| Urinary retention | Yes | 1 (3.3) | 1 (3.3) | 0.0 | 1.00 |
| | No | 29 (96.7) | 29 (96.7) | | |

Discussion

Pediatric regional blocks, in addition to minimising the potential exposure of the developing brain to extra doses of general anaesthetics, may also improve the post-operative outcomes by attenuation of the stress responses, cardiac stability and reduction in hospital stay. Caudal block ensures a high success rate and a good safety profile. Regional analgesics administered before painful procedures in infants demonstrate a reduction in the magnitude of long-term changes in pain behaviours. The main disadvantage is that the effectiveness of this technique is limited by the duration of action of the local anaesthetics. Introduction of dexmedetomidine has further widened the scope of α -2 agonists in regional anaesthesia. The faster onset of action of local anaesthetics, rapid establishment of both sensory and motor blockade, prolonged duration of analgesia into the post-operative period, dose-sparing action of local anaesthetics and stable cardiovascular parameters makes these agents a very effective adjuvant in regional anaesthesia.

The main interest of our study is to compare the effects of caudal dexmedetomidine with ropivacaine on emergence agitation, post-operative analgesia and intra-operative hemodynamic in paediatric population. The two groups were homogeneous with respect to age, sex, body-weight and duration of surgery. Ropivacaine, in comparison to bupivacaine, has a wider margin of safety, less motor blockade, less cardiovascular or neurological toxicity and similar duration of analgesia. In the light of a pharmacokinetic study demonstrating the safety of caudal ropivacaine 0.2% (1 ml/kg) in 1-8 years old children and other studies support to efficacy of this dose, we considered the same dose in our study. [9,13] Many studies have been performed taking into account doses between 1 μ g/kg – 2 μ g/kg of dexmedetomidine.

Intra-operative hypotension was seen in one patient under RD group and two patients in R group and was corrected with small fluid bolus. We did not find any significant difference in terms of intra operative hemodynamic between the two groups. There was no event of de-saturation or hypercapnia.

Using the pediatric observational FLACC and CHIPPS scale with a 0-10 score range, we assessed the patient's pain intensity. There was significant difference between the groups in the FLACC score measured 4th hourly in the post-operative period. Group R (12 out of 30) patients achieved higher FLACC score (score >4) compared with Group RD (2 out of 30) at 12th hour of post-operative period. In this study, the duration of analgesia was significantly prolonged in group RD (13.6 ± 0.79) hrs than in group R (8.32 ± 0.33) hrs. The no. of cases requiring rescue analgesics within 24hrs was higher in group R (12 out of 30). Similar results were obtained by Neogi et al [14], who compared clonidine $1\mu\text{g}/\text{kg}$ and dexmedetomidine $1\mu\text{g}/\text{kg}$ as adjuncts to ropivacaine 0.2% for caudal analgesia.

Emergence agitation (EA) is a frequent side-effect of sevoflurane anaesthesia in pediatric patients. The alpha-2 receptor agonists may offer advantages in preventing EA because they have both analgesic and sedative properties. The Watcha Score was significantly lower in RD group (1.47 ± 1.13) compared to R group (2.57 ± 1.04) with a p-value of < 0.001. These observations showed that R group children were agitated and restless compared to RD group children who were calm and co-operative during the first hour in the PACU. No episodes of statistically or clinically significant post-operative complication such as respiratory depression, PONV, urinary retention was observed. The results of our study showed that in addition to prolonged post-operative analgesia, dexmedetomidine has a favourable safety profile and stable haemodynamics, which are in concordance with the reports published by several other authors.

Conclusion

Postoperative pain management is becoming an integral part of anesthesia care. Pain is one of the most misunderstood, underdiagnosed, and untreated medical problems, particularly in children.

Various multimodal techniques have been designed for pediatric pain relief. These include both systemic and regional analgesia. The most commonly used regional technique is caudal epidural block. Advantages of the caudal block are early extubation, ambulation, and decreased postoperative analgesic requirements, and early discharge. Our study results allow us to conclude that addition of dexmedetomidine ($2\mu\text{g}/\text{kg}$) to caudal ropivacaine 0.2% at $1\text{ml}/\text{kg}$ significantly promoted analgesia after anaesthetic recovery in children aged 1 to 6 years, undergoing lower abdominal surgeries, with fewer rescue analgesic requirements. Dexmedetomidine further proved to be a good choice as adjuvant to caudal blocks, in prevention of sevoflurane induced emergence agitation in pediatric patients.

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