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Comparative Study of Efficacy of Caudal Ropivacaine plus Dexmedetomidine Vs Ropivacaine Alone For Postopertive Analgesia in Children Undergoing Infraumbilical Surgeries

Harshavardhana HS[1], Swarna Gowri S[2] , Priyanka Krishnamurthy[3]

[1,2]Assistant Professor, [3]Post Graduate, Dept of Anaesthesiology, Bangalore Medical College and Research Institute, Bangalore 560002, India.

Abstract

Introduction: Caudal analgesia is reliable, safe and has become most popular and commomly performed regional blocks in pediatric infraumbilical surgeries but has a short duration of action without adjuvants. Dexmedetomidine a potent alpha 2 adernergic agonist, provides better hemodynamic stability and longer post operative analgesia than many other adjuvants. Ropivacaine a amide local anaesthetic, provides pain relief with less motor blockage with reduced central and cardiotoxic effects than bupivacaine. Hence study conducted with 2 groups ropivacaine alone (R) and ropivacine plus dexmedetomidine (RD) an adjuvant. *Aims:* Primary objective is to compare post operative analgesia between two groups, secondarily sedation. *Methods:* prospective, randomized study was carried out in 60 patients of ASA grade 1 and 2, aged between 2 and 8 yrs weighing <20 kg, scheduled in elective infraumbilical surgeries. In our study patients were divided into two groups of 30 each with the help of computer generated table of random numbers. Group R received 0.2% ropivacaine 1 ml/kg and Group RD received ropivacaine 0.2% 1 ml/kg plus dexmedetomidine 1 mcg/kg. Mean duration of caudal analgesia, mean duration of sedation and any other side effects were recorded in both the groups and compared. *Result:* The mean duration of caudal analgesia in group RD was 10.41 hrs while group R was 5.89 hrs and difference is statistically significant ($p<0.001$) and quality of sleep was better in group RD. *Conclusion:* Addition of dexmedetomidine to caudal blocks significantly prolongs post operative analgesia with arousable sedation without significant side effects.

Keywords: Caudal; Paediatric; Ropivacaine; Dexmedetomidine.

Introduction

Pediatric patients are undertreated in terms of pain. In addition to various differences between children and adults, there are barriers unique to pediatric patients which interfere with effective postoperative pain control [1]. The impact of painful experience on young nervous system is so significant that long term effects can occur, including a lowered pain tolerance for months

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Corresponding Author: Swarna Gowri S. Assistant Professor, Dept of Anaesthesiology, Bangalore Medical College and Research Institute, Bangalore 560002, India.

E-mail: harsha.hs624@gmail.com

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after a pain producing event [2]. The benefits of adequate analgesia include attenuation of the surgical stress response, decreased perioperative morbidity, improved outcome of surgery, facilitates rehabilitation and accelerates recovery from surgery [3,4]. Regional anaesthesia techniques can be used as sole anaesthetic technique or adjuvant to general anaesthesia for intra-operative and post operative analgesia. Caudal epidural analgesia is the most common regional technique performed in children [5]. Ropivacaine is a long acting amide local anaesthetic used for caudal anaesthesia. It provides pain relief with less motor blockage but has a improved safety profile over bupivacaine with reduced central nervous and cardiotoxic effects, thus making it more suitable for caudal analgesia [6]. Prolongation of caudal analgesia using a single shot technique has been achieved by addition of various adjuvant, such as epinephrine, opioids, ketamine and alpha-2 agonists [7]. Dexmedetomidine is a highly selective alpha agonist with sedative and analgesic properties. It has alpha2/alpha1 selectivity ratio of 1600:1 which is 8 times more potent than clonidine 200:1.

Various studies are being done to evaluate the use of dexmedetomidine in regional anaesthesia to improve quality and duration of analgesia [8]. Very few studies have been done to evaluate the effect of dexmedetomidine in caudal anaesthesia in children with Ropivacaine. Hence this study was to compare dexmedetomidine with ropivacaine and ropivacaine alone in children under going infraumbilical surgeries.

Materials and Methodology

After obtaining clearance from institutional ethical committee and informed consent from all the parents of patients, this study was conducted over a period of 6 month. Sixty pediatric patients of either gender, belonging to ASA I and II aged between 2 to 8 yrs scheduled for elective infra umbilical surgeries under general anaesthesia were enrolled for the study. Patients with bleeding disorders, spinal anomalies, anticipated difficulty airway and heart blocks, patients with liver and renal diseases were excluded from study. The patient and the observer were blinded to the study drugs. The patients were allocated to either of the two groups ropivacaine group (R) and ropivacaine plus dexmedetomidine (RD) by computer generated randomization technique.

A standard anaesthesia technique was followed. Children were premedicated with 0.4 mg/kg midazolam syrup 45 minutes prior to surgery and intravenous access with appropriate size cannula was obtained and Ringer lactate infusion was started as per the calculated fluid requirements. Patients were shifted to operative theatre and baseline values of heart rate (HR), noninvasive blood pressure (NIBP), and pulse oximetry (SpO_2) was noted. Electrocardiogram (ECG) and all vital parameters were monitored throughout the study. General anaesthesia was induced using propofol 2 -2.5 mg over 20-30 sec as tolerated. Loss of eye lash reflex was considered as the end point of induction. At this point Injection Atracurium 0.5 mg/kg given. After three minutes of mask ventilation, endotracheal intubation was performed with appropriate size endotracheal tube. Bilateral air entry was confirmed. Anaesthesia was maintained with sevoflurane delivered in 50% nitrous oxide and 50% oxygen.

The child was positioned in left lateral position and caudal block was performed using aseptic technique with a short beveled 22-23g needle. After negative aspiration for blood and CSF, one of the following drug combination was injected into the caudal epidural space.

Group R received 1 ml/kg of 0.2% ropivacaine with 1 ml normal saline and Group RD received 1 ml/kg of 0.2% ropivacaine plus 1 mcg/kg of dexmedetomedine diluted to 1ml with normal saline.

Dexmedetomidine 100 µg/ml preparation was used. The dosage was calculated according to the patients weight, loaded using an insulin syringe rounded off to the closest unit and diluted to one ml with normal saline.

Patients heart rate and blood pressure were monitored after administration of caudal block every 5 min for the first 30 min and every 15 min subsequently up to 90 min by an observer who was blinded to the study drug.

No narcotics, analgesics or sedatives were administered intraoperatively. An increase in heart rate and mean blood pressure (>20%) with skin incision indicates that caudal block was inadequate, analgesia was supplemented with injection fentanyl 2 µg/kg and the plane of anaesthesia was deepened by increasing Sevoflurane 1-3% These cases were excluded from study as it is implied that block itself had failed. At the end of procedure, neuromuscular blockade was reversed by neostigmine and glycopyrolate. After the surgery, patients were observed in the post anaesthesia care unit and FLACC pain scale assessment was carried out at 1, 2, 3, 4, 6, 8, 12 and 24 hrs after caudal block.

Duration of post-operative analgesia was defined as the time interval between the administration of caudal block and the first requirement of supplementary analgesia for the patient.

When the FLACC pain scale score was more than 4, analgesia was supplemented with diclofenac sodium suppository (1-2 mg/kg) or syrup ibuorofen (4-6 mg/kg). The study concluded when the first supplementary analgesic was administered or at the end of 24 hours, whichever was earlier.

Side effects such as nausea, vomiting, urinary retention, shivering, agitation and deep sedation were noted and recorded.

Results and Statistics

In our study, patients were divided into two groups of 30 each with the help of a computer generated table of random numbers. Data was analyzed using SPS22 version software categorical data was represented in the form of frequencies and proportions. Chi square test was used as test of significance for qualitative data. Continuous data was represented as mean standard deviation.

Both the groups were comparable with respect to age, sex, body weight and duration of surgeries.

There were no significant differences in the heart rates and mean blood pressures between both the groups intraoperatively and postoperatively.

Total duration of post operative analgesia (time to first analgesic requirement) in Group RD was 425.33 ± 33.37 min, whereas in the group R was 219.33 ± 19.06 min. The difference is statistically highly significant ($p<0.001$). About 68% of cases in the Group RD did not require any rescue analgesics. All the cases in the Group R received rescue analgesics within 24 hrs. Group R children had significantly high FLACC score than group RD children. Difference was statistically significant ($p<0.001$). In group R, most of the patients have FLACC score of 4 between 3 to 6 hrs compared to group RD patients having FLACC score of 4 between 7 to 10 hrs of post operative period.

There was no incidence of bradycardia, respiratory depression or urinary retention intra or postoperatively in both the groups. Whereas vomiting was noted in 2 children of group R and 3 children of group RD post operatively. Sedation scores were comparable between the groups.

Table 2: Demographic profile

Variable	Group R	Group RD
Age (months)	49.2 ± 12.2	51.56 ± 21.3
Weight (kg)	14.80 ± 3.23	14.43 ± 3.42
Sex (male/female)	22/08	25/05
Duration of Surgery (min)	52.65 ± 2.12	51.96 ± 28.07

Table 3: Duration of post operative analgesia

	Group	N	Mean	Std. Deviation	p
Duration of analgesia	R	30	219.33	19.061	<0.001
	RD	30	425.33	33.372	

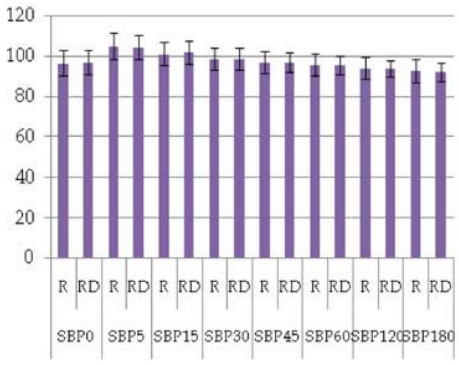

Fig. 1: Changes in Systolic blood pressure

Table 1: FLACC Behavioral Pain Assessment Scale

Categories	Scoring		
	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

Fig. 2: Changes in Heart rate

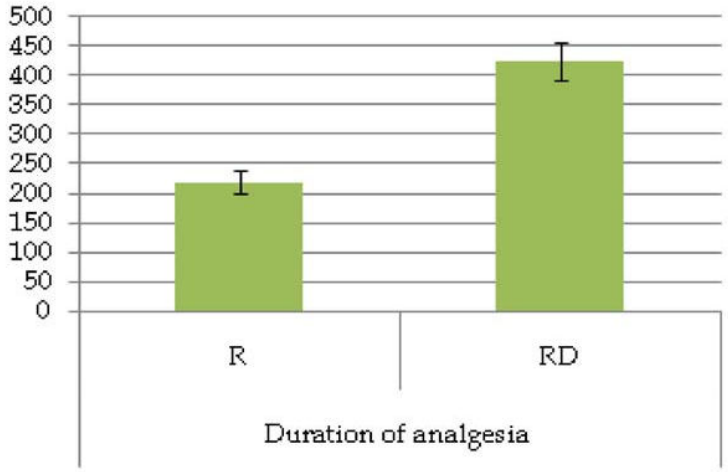

Fig. 3: Showing mean duration of post operative analgesia between the two groups (min)

Discussion

Caudal analgesia in one of the most commonly performed pediatric regional analgesia technique to provide intraoperative and post operative analgesia. It has a very high success rate, reduces the incidence of side effects associated with general anaesthesia, attenuates the stress response, and reduces the hospital stay [9]. Most common disadvantage of caudal block is short duration of action of local anaesthetics. For this reason various adjuvant have been used to prolong the duration of action of local anaesthetics. Various additives used for caudal block are alpha -2 adrenergic agonist's clonidine and dexmedetomidine, opioids like fentanyl, ketamine and epinephrine. Sedation, stable hemodynamics and an ability to provide smooth and prolonged post operative analgesia are the main qualities of alpha-2 adrenergic agonists. Dexmedetomidine is a safe and highly selective alpha-2 agonist, has been described safe and effective additive in many studies. It is available as a preservative free solution.

Ropivacaine is a long acting amide local anaesthetic with greater safety margin and reduced systemic toxicity, although still toxicity has been noted in adults following regional techniques. The main aim of our study was to evaluate the efficacy of caudal dexmedetomidine with ropivacaine in providing intra and postoperative analgesia along with prolongation of post operative duration of caudal block.

Ropivacaine produces lesser post operative motor blockade as compared to bupivacaine when used in lower concentration. There was no apparent motor deficit in our patients probably due to lower concentration of ropivacine used [10].

The analgesic activity of dexmedtomidine is mediated by both supraspinal and spinal mechanisms. It is assumed that central alpha 2 adernorecptors in the locus cerulus and in dorsal horn of the spinal cord are involved in the activity [10].

The dose of dexmedetomidine used in our study was 1 µg/kg. Many studies have used dexmedetomidine in the dose of 0.5 µg /kg, 1 µg /kg, 1.5 µg /kg [11]. They noted in their study patients receiving dexmedetomidine 1.5 µg /kg were more sedated when compared to other groups ($p<0.001$). So in our study caudal dexmedetomidine dose selected at 1 µg /kg.

In this study, the duration of analgesia was significantly prolonged in group RD (425.33 + 33.37 min) compared to group R (219.33 + 19.06 min). The difference between the two groups was highly significant, both clinically and statistically. About 68% of cases in the Group RD did not require any rescue analgesics. All the cases in the Group R received rescue analgesics within 24 hrs. Similar results were noted in studies by our was similar to that conducted by EL-Hennawy et al. [12], Parameshwari et al. [13], Xiang et al. [14], Kauppiah et al. [15].

We choose the FLACC pain score to evaluate post operative pain as it is easy to use, validated and useful for an objective evaluation [16]. Group R children had significantly high FLACC score than group RD children. Difference was statistically significant ($p<0.001$). In group R, most of the patients have FLACC score of 4 between 3 to 6 hrs compared to group RD patients having FLACC score of 4 between 7 to 10 hrs of post operative period.

After addition of dexmedetomidine 1 µg/kg to caudal ropivacaine, the magnitudes of hemodynamics changes between the groups were similar. No respiratory depression or urinary retention was noted. Whereas vomiting was noted in 2 children of group R and 3 children of group RD post operatively, sedation scores were comparable between the groups.

Conclusion

We conclude that single caudal injection of dexmedetomidine 1 µg/kg added to ropivacaine 0.2% offer an advantage over plain ropivacaine 0.2% for post operative pain relief in children undergoing infraumbilical surgeries without increasing the incidence of adverse effects**.**

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