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COMPARATIVE STUDY OF CAUDAL ROPIVACAINE WITH CAUDAL ROPIVACAINE AND DEXMEDETOMIDINE IN PEDIATRIC LOWER ABDOMINAL SURGERIES

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ABSTRACT: PURPOSE: The objectives of this study were to compare the effects of caudal dexmedetomidine combined with Ropivacaine to provide postoperative analgesia in children and also to establish its safety in the pediatric patients. **METHODS:** In a randomized, prospective, parallel group, double-blinded study, 80 children of 1 year to 6 years posted for lower abdominal surgeries were recruited and allocated into two groups: Group RD (n=40) received 0.25% Ropivacaine 1 ml/kg with dexmedetomidine 2 µg/kg, making the volume to 0.5 ml and Group R (n=40) received 0.25% Ropivacaine 1 ml/kg + 0.5 ml normal saline. Induction of anesthesia was achieved with Inj. Ketamine 2mg/kg + Inj. Succinylcholine 2mg/kg. Intubated with appropriate-sized Endotracheal tube and caudal block was performed in all patients. Maintained with 66% nitrous oxide in Oxygen and isoflurane 0.2-0.4%. Post-operative pain assessed with FLACC score. **RESULTS:** The duration of postoperative analgesia recorded a mean of 339 minutes (5.6hrs ± 2.4 hrs.) in Group R compared with 884 minutes (14.7 hrs. ± 5hrs) in Group RD, with a p value of <0.001. Group RD patients achieved a statistically significant higher FLACC score compared with Group RD patients. The peri-operative hemodynamics were stable among both the groups. **CONCLUSION:** Caudal dexmedetomidine (2 µg/kg) with 0.25% Ropivacaine (1 ml/kg) for pediatric lower abdominal surgeries provides significant postoperative pain relief and better quality of sleep and a prolonged duration of arousable sedation.

KEYWORDS: Analgesia, anesthesia, caudal Dexmedetomidine, ropivacaine, post-operative period.

INTRODUCTION: There has been a continuing search for a completely satisfactory method for pain relief in children. This technique need to be safe, with low incidence of side effects, and to produce analgesia of adequate duration. It's also advantageous if the technique is simple and without later complications. In the case of day care surgery an added requirement is early recovery. Children undergoing surgery for inguinal hernia, hydrocele, phimosis, undescended testis represent a large number of outpatient's surgical cases.

The traditional use of Narcotics for pain control is associated high incidence of nausea and vomiting, an increased incidence of respiratory depression and pain associated with intramuscular injection, thus delaying discharge from hospital.

The regional anesthesia has become an accepted part of anesthesia for pediatric outpatient surgery. This technique alone or combined with light General anesthesia provides significant pain relief without narcosis, while minimizing detrimental physiological alteration. It minimizes the total requirement of inhalational or intravenous anesthetic drugs, hastens awakening, allows early ambulation, and thus shortens recovery room stay. The most frequently used regional anesthetic technique in children is the caudal epidural injection, usually combined with light General anesthesia,

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thus reducing intra operative need for inhalational agents, attenuate the stress response to surgery, facilitate a rapid, smooth recovery and provide good immediate postoperative analgesia. In order to decrease intra and postoperative analgesic requirements after single shot caudal epidural blockade, various additives such as morphine, fentanyl, clonidine and ketamine with local anesthetics have been investigated. The use of caudal route¹ for providing postoperative analgesia has become a standard practice in many hospitals. The ease of placing a caudal block, its safety and reliability in providing good post-operative analgesia are well known.

Ropivacaine, a long acting amide local anesthetic related structurally to bupivacaine, has been used for pediatric caudal anesthesia. It provides pain relief with less motor blockade and is less cardiotoxic than bupivacaine, which makes it a more suitable agent for caudal epidural analgesia, especially following day care surgery. Dexmedetomidine is an alpha 2 agonist having an eight fold greater affinity for alpha 2 adrenergic receptors than clonidine and much less alpha 1 effects. A major advantage of dexmedetomidine is its higher selectivity compared with clonidine for alpha 2A receptors which is responsible for the hypnotic and analgesic effects. The objective of this study is to compare the effect of dexmedetomidine combined with caudal ropivacaine to provide postoperative analgesia in children undergoing lower abdominal surgeries

METHODS:

STUDY DESIGN: Randomized, prospective, parallel group, double blinded study

RANDOMISATION: Simple randomized sampling was done by lottery method

INCLUSION CRITERIA: ASA grade 1 & 2 patients between 1 to 6 yrs. of age undergoing lower abdominal surgeries were included.

EXCLUSION CRITERIA: Patients with known allergy to the study drugs, coagulopathy, infection at the site of caudal block, history of developmental delay, neurological diseases and skeletal deformities were excluded.

ALLOCATION: Institutional ethical committee and review board's approval obtained. After getting written informed consent from the parents, the children were randomly allocated into two groups. Group R (n=40) was taken as Ropivacaine group and Group RD (n=40) as Ropivacaine + Dexmedetomidine group.

STUDY GROUPS:

Group R: (n= 40) caudal 0.25% Ropivacaine 1ml/kg + 0.5ml NS.

Group RD: (n= 40) 0.25% Ropivacaine 1ml/kg with Dexmedetomidine 2mcg/kg, making the volume to 0.5ml

MASKING: The Anesthesiologist who administered the drug and the observer were blinded to the study. Sterile syringes containing drug were loaded by another anesthesiologist not participating in study. Intraoperative monitoring and post-operative observation was done by the same anesthesiologist who administered the caudal but was unaware of the content of the syringes.

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PRE OPERATIVE EVALUATION: Age, Body weight and baseline vital parameters of all children were recorded. Relevant history were recorded. Complete physical examination and airway assessment were done. Blood Hemoglobin percentage, blood sugar, urea, serum creatinine and urine analysis were done. All patients were premedicated with oral midazolam 0.5mg/kg 1 hour prior to induction. Induction was done with Inj. ketamine 2mg/kg+ Inj. Suxamethonium 2mg/kg. Appropriate sized endotracheal tube were inserted. Anesthesia was maintained with 66% N₂O in oxygen and isoflurane 0.2-0.4%. Caudal block was performed in left lateral position in all patients according to the group. No other narcotics, sedatives or analgesics were used intraoperatively. Standard monitoring done during anesthesia and surgery. Heart rate, Mean arterial pressure, and Oxygen saturation were recorded before surgery and every 5min till the end of surgery.

Surgery	Group R	Group RD
Inguinal hernia	15(37.5%)	15(37.5%)
Circumcision	10(25%)	10(25%)
Urethroplasty	6(15%)	6(15%)
Cystolithotomy	4(10%)	5 (12.5%)
Orchidopexy	5(12.5%)	4(10%)

TABLE 1: SURGICAL PROCEDURES

Using the FLACC pain score (Table 2) each patients pain intensity was assessed at the end of surgery and then at 2hrs, 4hrs, 6hrs, 8hrs, 12hrs, 16hrs, 20hrs after operation. If the FLACC pain score was 4 or more syrup paracetamol 15mg/kg was administered. The duration of analgesia was also recorded (Figure 1) (from the time of caudal injection to the time at which FLACC score was 4 or more). Complications such as postoperative nausea and vomiting (PONV), Respiratory depression, urinary retention, hypotension and bradycardia were also noted. Respiratory depression was defined as a decrease in oxygen saturation of less than 95% requiring supplemental oxygen. Bradycardia was defined as HR below 80beats per minute for <1 year, below 60 beats per minute for ages >1year. Failure of caudal block was defined as any increase in HR or MAP more than 20% of the pre incision values. In our study we encountered 3 failed caudal blocks. These cases were eliminated from the study.

Parameter	Finding	Points
Face	No particular expression or smile	0
	Occasional grimace or frown withdrawn, disinterested	1
	Frequent to constant quivering chin, clenched jaw	2
Leg	Normal position or relaxed	0
	Uneasy, restless, tense	1
	Kicking or legs drawn up	2
Activity	Lying quietly, normal position, moves easily	0
	Squirming, shifting back and forth, tense	1
	Arched, rigid or jerking	2

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Cry	No cry(awake or asleep)	0
	Moans or whimpers occasional complaints	1
	Crying steadily, screams or sobs, frequent complaints	2
Consolability	Content relaxed	0
	Reassured by occasional touching hugging or being talked to, distractable	1
	Difficult to console or comfort	2

Table 2: FLACC SCORE TO ASSESS POST OPERATIVE ANALGESIA²

FIGURE 1: FLACC SCORE

STATISCAL ANALYSIS: Done with unpaired student t test. p value of <0.001 was considered highly significant.

RESULTS: The duration of post-operative analgesia recorded a mean of 339 minutes (5.6 ± 2.4 hours) and in Group R compared with 884 minutes (14.7 ± 5 hours) in Group RD, with a p value of <0.0001. There was a significant difference between the groups in the FLACC score measured in the postoperative period. Group R patients achieved significantly higher FLACC score compared with Group RD patients, Where 35 out of 40 children achieved a FLACC score of 4 at 6th hour compared with 0 patients in Group RD children, whereas group RD children had FLACC score of 4 at 16th hour of postoperative period (Figure 1). R group children were agitated and restless compared to RD group children who were calm and co-operative. The pre-op, intra-op and post-operative hemodynamic changes between the groups were comparable and were not statistically significant and therapeutic interventions were not required.

DISCUSSION: When compared to Bupivacaine, Ropivacaine has a wide margin of safety, less motor blockade,^{3,4} less cardiovascular or neurological toxicity⁵ but has same duration of action. It can be used safely for regional anesthesia and analgesia in pediatrics.

Dexmedetomidine enhances the effects of local anesthetics without increasing the adverse effects. Respiratory effects are also minimal. When compared to Clonidine, Dexmedetomidine is a more selective alpha 2 adrenoreceptor agonist, it allows its uses in high doses without the adverse vascular effects of activation of alpha 1 receptors. Its sedative effect can be reversed by atipamezole. These properties make Dexmedetomidine useful for sedation and analgesia during the whole

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perioperative period. Routes of administration are Intravenous, Intrathecal, epidural. More recently investigations in children have described the pharmacokinetics as well as a number of pharmacodynamic effects in controlled trials. Dexmedetomidine provides sedation that permits arousal with gentle stimulation.

Et-Hennawy et al.⁶ administered dexmedetomidine and clonidine, both in a dose of 2mcg/kg as adjuvant with 0.25% bupivacaine caudally. They found that the duration of analgesia was significantly higher in the group receiving bupivacaine-dexmedetomidine mixture (median (95%CI):16 hours (14-18) or Bupivacaine-clonidine mixture (median (95%CI):12 hours(3-21) than the group receiving bupivacaine alone (median (95% CI):5 hours (4-6).

Neogi et al.⁷ compared clonidine 1 mcg/kg and dexmedetomidine 1 mcg/kg as adjuncts to ropivacaine 0.25% for caudal analgesia in children and concluded that addition of both clonidine and dexmedetomidine with ropivacaine administered caudally significantly increases the duration of analgesia. The patients stayed hemodynamically stable and there were no undue side effects. The mean duration of analgesia was 6.32±0.46 hours in ropivacaine group, 13.17±0.68 hours in clonidine group and 15.26±0.86 hours in dexmedetomidine group. The prolongation of duration of analgesia was significant in both clonidine and dexmedetomidine groups when compared to ropivacaine alone administered group. The incidence of adverse effects were statistically insignificant between these groups.

In our study the duration of postoperative analgesia in ropivacaine group is 339 minutes (5.6 hrs±2.4 hours) and in ropivacaine with dexmedetomidine group 864 minutes (14.7 hours± 5 hours) with a p value of <0.00010⁸. Group R patients achieved a statistically significant higher FLACC score compared with Group RD patients. The preoperative intraoperative, postoperative hemodynamic variables between the groups were comparable and were not statistically significant and therapeutic interventions were not required. No episodes of clinically significant postoperative complications such as PONV, respiratory depression, urinary retention, bradycardia, urinary obstruction were observed. Dexmedetomidine provides a prolonged post-operative analgesia, and it has a good safety profile. It provides stable hemodynamics. It is in concordance with the reports published by other studies.

CONCLUSION: Addition of dexmedetomidine 2mcg/kg with 0.25% ropivacaine 1 ml/kg⁹ provided significantly prolonged post-operative analgesia upto 14.5 hours, and it provided a better quality of sleep. Perioperative hemodynamics were stable. No episodes of post-operative complications were observed. With this we conclude that dexmedetomidine is a safe and effective adjuvant for caudal analgesia in pediatric patients.

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