



## COMPARATIVE STUDY OF PEDIATRIC CAUDAL ADJUVANTS DEXMEDITOMIDINE AND CLONIDNE FOR LOWER ABDOMINAL SURGERIES:A RANDOMIZED CONTROL TRIAL.

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### ABSTRACT

**Background:** Caudal block is the commonest technique for pediatric analgesia. But the caudal block with ropivacaine has short duration of action. So addition of adjuvants like dexmedetomidine or clonidine to caudal block will increase the duration of analgesia.

**Aim:** The aim of the study is to compare the efficacy of the adjuvants dexmedetomidine and clonidine with ropivacaine in pediatric caudal anaesthesia for lower abdominal surgeries.

**Materials and methods:** Study was conducted among 60 pediatric patients between age group 1 and 6. The caudal block was administered with inj. ropivacaine 0.25% 1ml/kg with inj. clonidine 1µg/kg (group RC) and inj. ropivacaine 0.25% 1ml/kg with inj. dexmedetomidine 1µg/kg (group RD) after induction of general anaesthesia. Haemodynamic parameters were noted before during and after surgical procedure. The duration of post operative analgesia, the rescue analgesic dose required, pain score and side effects were also recorded.

**Results:** The mean duration of effective analgesia in group RD was 14.98±0.85 h versus 10.2±0.9h in group RC with p value of 0.0001 which is statistically significant. There is no significant difference occurs in haemodynamic parameters and side effects between these groups.

**Conclusion:** Dexmedetomidine as an adjuvant to ropivacaine increases the duration of caudal analgesia than clonidine in infraumbilical surgeries.

**KEYWORDS :** Caudal analgesia, pediatric patients, ropivacaine, dexmedetomidine, clonidine, post operative period.

### INTRODUCTION:

The caudal epidural block is the commonest, reliable and safe technique in pediatric analgesia for infra umbilical surgeries. The main disadvantage of caudal block is short duration of action after single injection [1]. The caudal catheter administration is not popular because of concern about infection. So the addition of adjuvants like ketamine, adrenaline, opioids and  $\alpha_2$  agonists to single shot technique will prolong the duration of analgesia. [2]

Both clonidine and dexmedetomidine belong to  $\alpha_2$  agonist group. Dexmedetomidine has 1600 times greater affinity to  $\alpha_2$  receptor. These drugs interact with local anaesthetics by three possible mechanisms. First, by blocking A $\delta$  and C fibres as a consequence of an increase in potassium conductance in isolated neurons, thus intensifying local anaesthetics conduction block [3]. Secondly, by causing local vasoconstriction decreasing the local anaesthetics spread and removal around neural structures. This effect is mediated by the drug action on post synaptic  $\alpha_2$  receptor [4]. Thirdly, it combines with spinal local anaesthetics or used in peripheral nerve block intensifies and prolongs the analgesia. [5]. Spinal  $\alpha_2$  adrenergic agonist may also induce analgesia by activating spinal cholinergic neurons resulting acetyl choline release. Dexmedetomidine has 8-fold greater affinity for  $\alpha_2a$  receptor than clonidine, which is responsible for the hypnotic and analgesic effect of this drug.

Considering the above facts we designed this study to compare the analgesic effects and side effects of dexmedetomidine and clonidine added with ropivacaine for pediatric caudal analgesia in infraumbilical surgeries.

### MATERIALS AND METHODS:

After obtaining institutional ethical committee approval, written informed consent was obtained from parents of the children belonging to this study.

#### Study design:

This was a randomized, prospective, parallel group double blinded study.

#### Sample size:

Sixty patients were studied.

#### Inclusion criteria:

ASA 1 and 2 patients between 1 and 6 years of age undergoing lower abdominal surgeries were included.

#### Exclusion criteria:

Patients with known allergic to study drugs, suspected coagulopathy, infection at the site of caudal block, history of developmental delay, neurological disease and skeletal deformities were excluded.

#### Allocation:

The patients were randomly allocated in to two groups.

Group RD (n=30) : receiving 0.25% ropivacaine 1 ml /kg with dexmedetomidine 1µg/kg.

Group RC (n=30) : receiving 0.25% ropivacaine 1ml/kg with clonidine 1µg/kg.

All patients underwent pre-anaesthetic check up the day before surgery and all routine and specific investigations were noted. The children were kept nil by mouth 6 hours prior to surgery. An intravenous line was secured, and Isolyte p was started. Standard monitors like ECG, pulse oximeter, non invasive blood pressure were applied.

All children were premedicated with inj. atropine 0.02 mg / kg, inj. ondansetron 0.1mg/kg and oral midazolam 0.5mg/kg body weight. All base line parameters like PR, BP and SpO<sub>2</sub> were recorded. After induction of anaesthesia ETT of appropriate size was intubated. Then caudal block was performed in all patients according to the group. Maintenance of anaesthesia with oxygen, nitrous oxide, and sevoflurane mixture. PR, BP, and SpO<sub>2</sub> were monitored at 5 minutes interval till the end of surgery. The hypotension requiring fluid bolus and bradycardia requiring atropine were noted.

At the end of the surgery all anaesthetic gases were turned off and the patients were extubated in a fully awake condition. The PR, BP, SpO<sub>2</sub> and pain sedative score were recorded postoperatively at 4 hour interval for 24 hours. The pain and sedation score was

Opening of eyes spontaneously = 3

Opening of eyes to verbal commands = 2

Opening of eyes to physical shaking = 1

Not arousable = 0

The pain intensity was assessed with FLACC pain score. If the score was 4 or more, syrup paracetamol 15mg/kg was administered. The duration of analgesia (from the time of caudal injection to time at which FLACC score was 4 or more) was also recorded. All the observations

were recorded and all the results were analysed. Statistically data were presented as a mean±standard deviation. A value of P ≤0.05 was considered as a statistically significant difference with unpaired students t-test.

**RESULTS:** As per the (table 1 ) mean age, weight, sex distribution in both groups are nearly same without any significant differences. P ≥0.05

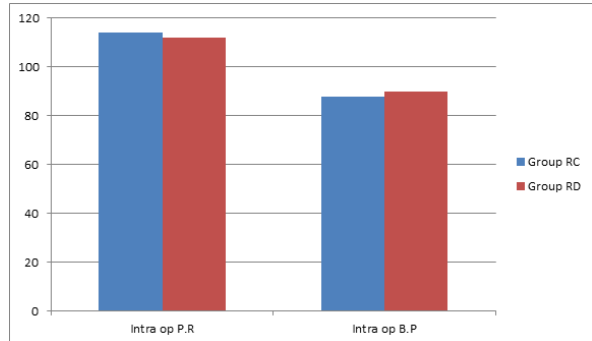
**TABLE -1 DEMOGRAPHIC DATA**

VARIABLES	GROUP- RC	GROUP-RD	P value
Age in years Mean ±SD	4.76±2.33	5.34±2.26	0.33
Weight in KG Mean ±SD	13.26±4.16	14.12±4.21	0.42

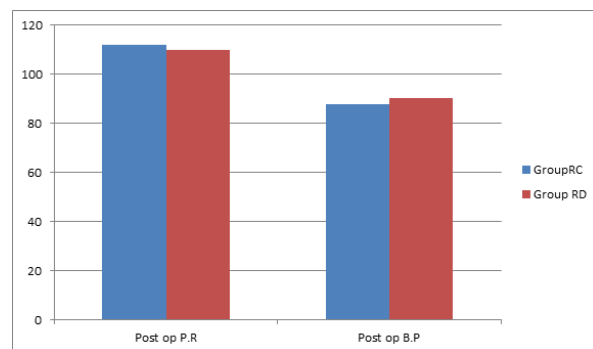
**TABLE -2 shows no significant difference between the groups with mean intraoperative and postoperative BP,PR.**

**TABLE-2 HEMODYNAMIC DATA:**

PREOPERATIVE VITALS (mean±SD)	Group RC	Group RD	P value
PULSE	115.6±11.58	115.4±10.22	0.943
BP(in mmHg)	91.04±8.46	91±6.81	0.98
INTRA OPERATIVE VITALS (mean±SD)	Group RC	Group RD	P value
PULSE	114±9.8	112±11.5	0.47
BP(in mmHg)	88.3±5.44	89.9±6.84	0.3201



POSTOPERATIVE VITALS (mean±SD)	Group RC	Group RD	P value
PULSE	112±8.85	110±9.3	0.39
BP	88.1±6.13	90.4±6.01	0.147

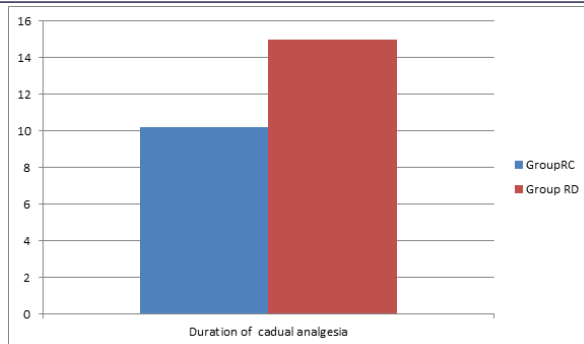


As per table(3) the mean duration of caudal analgesia in group RC was 10.2±0.9

The mean duration of caudal analgesia in group RD was 14.98±0.85. It shows the duration was significantly prolonged in group RD (P0.0001)

**TABLE-3 DURATION OF CAUDAL ANALGESIA**

	GROUP RC	GROUP RD
MEAN DURATION OF CAUDAL ANALGESIA(hrs)	10.2±0.9	14.98±0.85
P value	0.0001	



As per table(4) the sedation and pain score was statistically insignificant in both groups with p value >0.05

**TABLE-4:PAIN AND SEDATION SCORE**

SCORE	GROUP RC	GROUP RD
1	6	4
2	9	8
3	15	18

As per table 5 the incidence of nausea, vomiting, respiratory depression are almost same on both groups.

**TABLE-5: POSTOPERATIVE COMPLICATIONS:**

POSTOP COMPLICATIONS	GROUP RC	GROUP RD
Nausea, vomiting	5	4
Respiratory depression	Nil	Nil

**DISCUSSION:**

The caudal epidural analgesia is one of the most popular and commonly used regional blocks in pediatric anesthesia. It is reliable and safe technique that can be used with general anesthesia for intra operative and postoperative analgesia for intra abdominal and lower limb surgeries.

The main disadvantage of caudal anesthesia is the shorter duration of action after single injection of local anesthetic solution. The use of caudal catheters to administer the repeated doses or infusion of LA is not popular because of the risk of infection. Double caudal technique whereby the caudal is topped up at the end of the procedure has recently been advocated.

Ropivacaine has a wider margin of safety, less motor blockade, less cardiovascular and neurological toxicity. It can be safely used for regional anesthesia in the ambulatory setting in pediatrics. In 1984 the analgesic action of regional clonidine was first demonstrated [6,7]. The use of epidural clonidine in adults led to its evolution in pediatric caudal block. The studies shown caudal clonidine has increase the duration of post operative analgesia [8,9,10]. The dexmedetomidine commonly used as an intravenous agent, can be used epidurally for increasing the post operative analgesia in human [11,12,13].

Clonidine is used for potentiating the analgesic action of various local anaesthetics administered regionally. The aim of our study is to evaluate the efficacy of caudal dexmedetomidine over caudal clonidine when combined with 0.25% solution of ropivacaine. The results showed that the caudal bolus injection of 0.25% ropivacaine 1ml/kg dexmedetomidine 1µg/kg provides better analgesic action than caudal bolus inj. 0.25% ropivacaine 1ml/kg with clonidine 1µg/kg.

Clonidine produces analgesia via a nonopioid mechanism. [14] Klimscha et al., had studied the effectiveness of caudal clonidine in potentiating the postoperative analgesic effect and found that in small children with a mean age of 3 years who underwent an elective lower abdominal day care surgeries, the addition of clonidine 1-2 µg/kg to ropivacaine 0.25% significantly prolonged the median duration of analgesia and reduced the total dose of postoperative analgesic compared with ropivacaine alone or ropivacaine plus epinephrine 5 µg/ml (P < 0.05). [15] The findings of our study are almost similar with observations of Klimscha et al., as postoperative analgesia was significantly prolonged in the patients receiving dexmedetomidine or

clonidine as an adjuvant to ropivacaine. Clonidine causes dose-dependent post-operative sedation in children as demonstrated by Lund and his colleagues in their study on adding 2 µg/kg clonidine to caudal ropivacaine. In our study, the difference in sedation scores was not statistically significant as the all patients were easily arousable in all the groups which is consistent with the findings of other studies.<sup>[16,17,18]</sup>

Like clonidine<sup>[19,20]</sup> dexmedetomidine also enhance the effects of LA without increasing the incidence of side effects<sup>[21]</sup>. Dexmedetomidine compare to clonidine is a much more selective alpha 2 adrenoceptor agonist for sedation and analgesia without vascular effects from activation of alpha1 receptors. Dexmedetomidine is a shorter acting drug than clonidine and its sedative effects is reversed by atipamazole. These properties render dexmedetomidine suitable for sedation and analgesia during the whole perioperative period.

In children the pharmacokinetics of 10 min iv infusion of dexmedetomidine 0.33, 0.60 or 1microgram/kg yielded a rapid redistribution (alpha phase) half life of 9min and slow (beta phase) elimination phase with half life of 2 hours, similar to adults<sup>[22]</sup>.

Pharmacodynamic effects of dexmedetomidine have been studied thoroughly in adults<sup>[23,24]</sup>. Nowadays investigations on pediatric group described the pharmacokinetics and pharmacodynamic effects in randomised controlled trials<sup>[25-27]</sup>. The advantage of dexmedetomidine than other sedatives is its respiratory effects which is minimal in adults and children. The respiratory rate, co2 tension, spo2 are well maintained with dexmedetomidine sedation in children. The patient awake with gentle stimulation in dexmedetomidine sedation. This can be used in procedures such as MRI in children<sup>[29,30]</sup>. El-Hennawy et al. administered dexmedetomidine and clonidine in a dose of 2micro gram/kg with 0.25% bupivacaine caudally. They found that the duration of analgesia was higher in groups receiving adjuvants (median 95% cl) 16hrs (14-18) in dexmedetomidine and median (95%cl) 12hrs (3-21) in clonidine than the group with plain bupivacaine (median 95% cl) 5hrs<sup>(4-6)</sup>.

Noogi et al compared clonidine 1microgram/kg and dexmedetomidine 1microgram/kg with ropivacaine 0.25% for caudal anesthesia in children. They found that the duration of analgesia was more for adjuvants groups than plain ropivacaine group. The mean duration of analgesia was 6.32±0.46 hrs in ropivacaine group, 13.17±0.68 hrs in clonidine group and 15.26±0.86 hrs hours in dexmedetomidine group. The incidence of adverse effects was statistically insignificant between three groups.

We observed from our study that the duration of postoperative analgesia (table3) in group RC was 10.2±0.90 hrs compared with 14.98±0.85 hrs in group RD with a P value of(0.0001).

No significant postoperative complication such as PONV, respiratory depression, urinary retention, pruritus, hypotension, bradycardia were observed. The results of our observations shows that the addition of dexmedetomidine to ropivacaine provides longer duration of postop analgesia than the addition of clonidine to ropivacaine.

## CONCLUSION:

The caudal dexmedetomidine 1µg/kg with ropivacaine 0.25% 1ml/kg produce the post operative analgesia of 14.98±0.85 hrs when compare to 10.2±0.9 hrs in caudal clonidine 1µg/kg with 0.25%ropivacaine 1ml/kg. So addition of adjuvant dexmedetomidine in pediatric caudal anaesthesia for lower abdominal surgeries provides longer duration of post operative analgesia than adjuvant clonidine.

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