ISSN No:-2456-2165

Adjuvent Clonidine with Ropivacaine in Caudal Block Improves Postoperative Analgesia in Paediatric Patients

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Abstract:-

Context: To study and compare Postoperative analgesia with Plain Ropivacaine 0.25% and Plain Ropivacaine 0.25% with Clonidine 1µg/kg in pediatric patients.

Aim:to determine the efficacy of clonidine as an adjuvant to caudal anaesthesia with ropivacaine
Settings and Design:

Methods and Material: In single blinded study, 80 ASA I/II patients of 2-9 yr age undergoing infraumbilical surgery were studied. 40 patients allocated to RC group were given with 0.25% Ropivacaine with 1µ/kg of Clonidine(0.5ml/kg) caudally and compared with rest 40 in R group which were given with 0.25% Plain Ropivacaine (0.5ml/kg). Haemodynamic parameters like heart rate blood pressure studied intraoperatively, Pain score with FLACC (Face Legs Activity Cry Consolability) scoring and sedation score were observed postoperatively at 1, 2, 3, 4, 8, 12, 24hrs. Rescue analgesia was provided by Diclofenac suppository 1 mg/kg.

Statistical analysis used: Unpaired t-test and ANOVA

Results: Significantly prolonged duration of postoperative analgesia was observed in RC group than in R group (Significant difference in pain score was observed at hrs postoperatively, with no significant difference in intraoperative Heart rate, blood pressure and postoperative sedation score and adverse effects in both groups.

Conclusion: The combination of Ropivacaine with Clonidine in caudal anesthesia in pediatric patients significantly improves postoperative analgesia without causing significant haemodynamic instability, postoperative sedation and residual motor blockade.

Keywords:- *Ropivacaine, Clonidine, Caudal Analgesia.*

I. INTRODUCTION

Pain is defined by the taxonomy committee of international association for the study of Pain (IASP) as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage".[1]

Post operative pain relief in a child is a main concern to the Anesthesiologist as the lack of ability to express contribute to failure to recognize and treat the pain aggressively and adequately in infancy and early childhood.

Caudal block is most popular and commonly performed regional blocks in pediatric anaesthesia[2]. It is a safe and reliable in way that can be used with general anesthesia for intra-operative and postoperative analgesia inpatients undergoing short duration procedures which are infra- umbilical[3].

Clonidine, an alpha 2 adrenergic agonist is known to produce analgesia, duration is dose dependent[5]. It was used as an adjuvant with doses between 1µg/kg to 3µg/kg in pediatric caudal block. Clonidineis used as an additive with local anesthetics like Lignocaine, Bupivacaine and Ropivacaine in caudal block to increase the intra-operative anaesthesia and postoperative analgesia, thereby reducing the toxicity of local anesthetics. procedures where post operative analgesia is the main requirement , lower concentrations and volumes of local anaesthetics with lower doses of Clonidine can be used, so as to avoid side effects. So, we have decided to study postoperative analgesia when clonidine added as an adjuvant to Ropivacaine Compared with only Ropivacaine in caudal block for infraumbilical surgeries in pediatric patients.

II. METHODOLOGY

The present study is a prospective Randomized controlled single blinded study. 80 patients aged between 2 years and 9 years of either gender belonging to ASA Class I or Class II posted for elective infra-umbilical surgeries were selected for the study. Patients with history of local infection at caudal region, bleeding diathesis, neurological disease or spinal disease were excluded. The study was conducted from January 2013 to October 2014. The study population (n=80) were randomly divided into 2 groups with 40 patients in each group (n=40).

ISSN No:-2456-2165

Study design: Comparative Randomized Single Blinded study
Statistical analysis: Using Student's t test and chi-square test

Method of collection of data:

Data was collected in prescribed proforma. Pediatric patients in the age group between 2 years and 9 years of either gender belonging to ASA class-I or class-II posted for elective infra-umbilical surgeries without any co-morbid diseases are grouped by Computer generated randomization into two groups (n=40).

Preoperative assessment was carried out in detail with investigations and written informed consent of parent was taken.

Procedure:

Patients were premedicated with oral midazolam 0.5 mg/kg 30 min prior to induction of anesthesia, IV Access secured and inj. Atropine 0.02 mg/kg given .The intraoperative monitors included Electrocardiogram, Pulse-oxymetry, NIBP. induction was done with 4-8% sevoflurane and Oxygen. Fentanyl 2µg/kg administered intravenously for analgesia. Anesthesia maintained with 1-2% sevoflurane in oxygen-nitrous oxide (1-3) mixture. The airway was maintained by Mask or Supraglottic airway.

After securing airway patient turned to left lateral position and caudal anaesthesia was performed by 23G IV needle with 0.25% Ropivacaine (0.5 ml/kg) in control group and 0.25% Ropivacaine with 1 µg/kg of clonidine(0.5 ml/kg) in Study Group under all aseptic precautions and patients were turned to supine position immediately after the injection. on pin prick method the 15% variation in the heart rate was chosen as the response variable to confirm the dermatomal level and The degree of motor blockade was assessed by Modification in Bromage scale in which tone of the muscles was assessed at ankle, knee and hip joints and flaccid tone is considered as complete motor blockade.

Haemodynamic parameters like Heart rate(HR), systolic(SBP) and diastolic blood pressure(DBP), were monitored preoperatively and intraoperatively at 0,5,15,30,45,60,90,120 min . Intravenous fluid was administered as per body weight and fasting status in the form of isolyte-P solution. The Pain score and Sedation score was assessed postoperatively, Pain score was assessed by Face ,Legs, Activity, Cry, Consolability (FLACC) scale and was noted at 1,2,3,4,8,12,24 hr postoperatively and if complained of pain.

FLACC SCALE[18](Table no.3)

Criteria	Score 0	Score 1	Score 2
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, uninterested	Frequent to constant quivering chin, clenched jaw
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, distractible	Difficult to console or comfort

0:- No Pain
1-3 :- Mild Pain
4-7 :- Moderate pain
8-10 :- Severe Pain

The time from caudal placement of drug to **FLACC>3** was taken as duration of analgesia. Rescue analgesia was provided with Diclofenac suppository 1 mg/kg.The **SEDATION SCORE[12]** was graded as **0 :-** Awake, **1 :-** Mild (arousable by voice),**2:-** Moderate (arousable by pain), **3 :-** Unarousable which was recorded 1,2,3,4,8,12,24 hours postoperatively.

All patients were monitored during the surgery and perioperative period till complete sensory and motor recovery, employing Multi parameter monitors which displays Heart rate, Systolic Blood Pressure (SBP) Diastolic Blood Pressure (DBP), ECG and SPO_2. Intra operatively Heart Rate, Blood Pressure, monitoring was done at 0, 5, 15, 30, 45, 60, 90, 120 minutes intraoperatively and after extubation in Recovery Room.

Adverse effects: Patients were monitored for any signs of cardiovascular effects like hypotension, bradycardia and arrhythmias, and signs and symptoms of central nervous system stimulation .Patients were observed for any hypersensitivity reactions for the drug.

ISSN No:-2456-2165

Statistical analysis:-Descriptive statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean ± SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5 % level of significance. Student t test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups. Chi-square has been used to find the significance of study parameters on categorical scale between two or more groups.

III. RESULTS

80 patients were studied of which 40 patients in R(control) group and 40 in RC(test) group. There was no statistical significant difference in demographic characteristics like age, weight, genderTypes of surgeries, heart rate, systolic and diastolic blood pressure in both the groups.

Postoperative analgesia in this study was noted with the help of FLACC Scale, which is given below; score >3 taken as Dead line suggesting the Pain threshold and so that the time at which score >3 is taken as **Duration of analgesia** and **Rescue analgesia** was given with **Diclofenac suppository 1 mg/kg**. Mean Duration Of analgesia in **R Group** was **251.50±45.69 Min**. and in **RCGroup** was **600.25 ± 57.13.** That is Duration of analgesia was much more prolonged in RC Group than in R Group, as the P value is **0.001**. which is Highly Significant statistically.

FLACC Score was noted postoperatively and the point at which FLACC Score is **>3** is considered as **Duration Of Analgesia**. The FLACC score estimated at various intervals **1,2,3,4,8,12,24** Hrs after surgery. The mean FLACC Score shown significant difference in scores at **3rd and 4th** hour that is R Group at 3 rd hour scored **2.350±0.70** and RC Group **1.500±0.51** similarly R Group after 4th hour scored **3.375±0.78** and RC Group **1.800±0.41** with **P value <0.001** which statistically significant. Also, values at **8th and 12th** hour were R Group with **4.125±0.52**; **4.575±0.75** and RC Group with **2.150±0.58; 3.800±0.61** which were Highly significant with P value <0.0001. So, from above data it is quiet clear that duration of analgesia is prolonged in RC Group than in R Group.

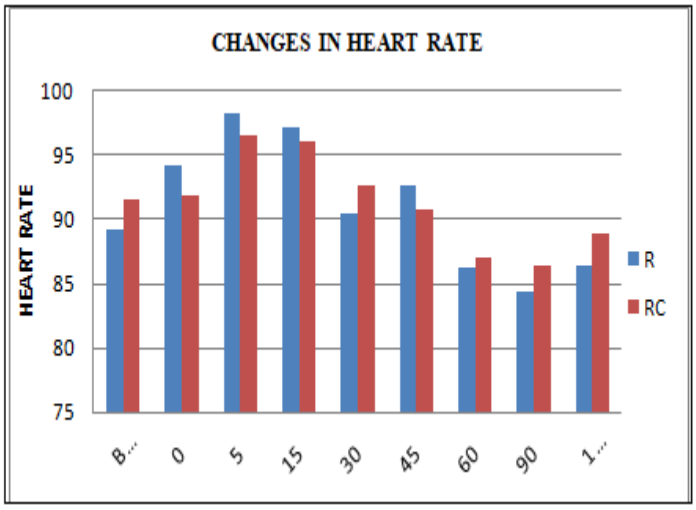
Types of surgeries:-

Table 1

SURGERY	R GROUP (no of patients)	RC GROUP (no of patients)
Circumcision	08	10
Herniotomy	19	17
Orchidopexy	04	03
Haemangioma excision	01	02
Others	07	08
Total	**40**	**40**

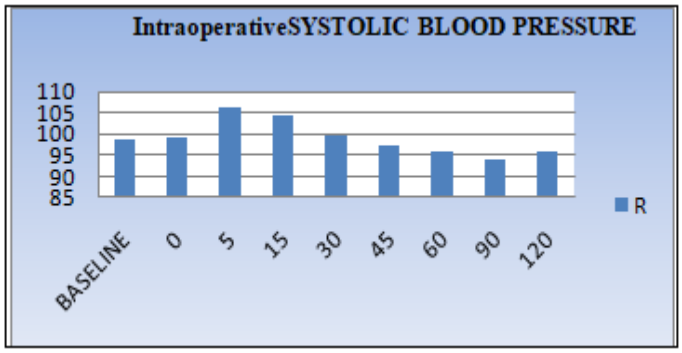
Intraoperative Heart rate

Table 2



Intraoperative Systolic blood pressure:-

Table 3

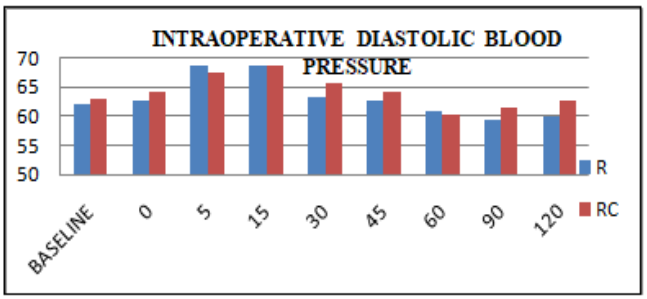


ISSN No:-2456-2165

Intraoperative Diastolic blood pressure:-

Level Of Caudal Block	R-Group(%)	RC-Group(%)
T8	06(15%)	06(15%)
T9	12(30%)	11(27.5%)
T10	22(55%)	23(57.5%)

Table 4

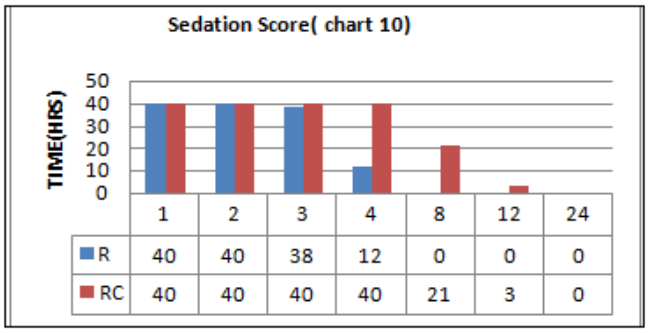


Level of caudal block:-

Table 5

Sedation score:-

Table 6

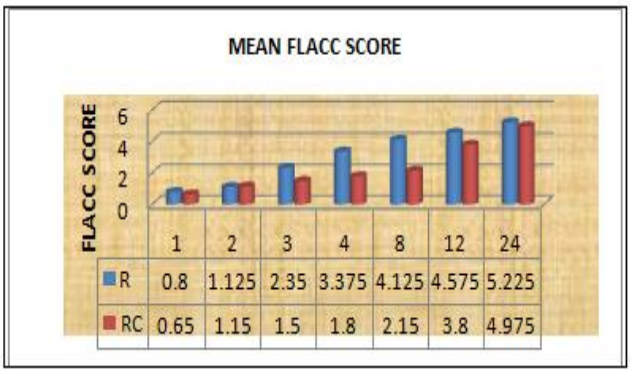


Postoperative FLACC score :-

Table 7

TIME (HRS)	MEAN FLACC SCORE		P VALUE	SIGNIFICANCE
	R GROUP	RC GROUP		
1	0.800±0.46	0.650±0.48	0.16	**Not significant**
2	1.125±0.46	1.150±0.48	0.81	**Not significant**
3	2.350±0.70	1.500±0.51	<0.001	**Significant**
4	3.375±0.78	1.800±0.41	<0.001	**Significant**
8	4.125±0.52	2.150±0.58	<0.0001	**Highly significant**
12	4.575±0.75	3.800±0.61	<0.0001	**Highly significant**
24	5.225±0.66	4.975±0.66	0.09	**Not significant**

Table 8



IV. DISCUSSION

Recently in last few years we have seen many advances in the treatment of acute pain in children. Caudal blockade is presently most popular regional block used in pediatric anaesthesia for infra-umbilical surgeries. This technique is use dwidely for many procedures alone or in with general anaesthesia. Itallows early recovery from anaesthesia with effective post-operative analgesia. The main disadvantage of this technique is the short duration of action following singleshot caudal. To avoid epidural catheter, which has the risk of infection, various additives to local anaesthetic solutions have been used with single shot caudal.[14,15]

Hence, recently various studies have reported caudal opioids and otherdrugs in children to improve postoperative analgesia. Though the use of caudalopioids prolonged the duration of analgesia, but was associated with other opioid induced adverse effects likerespiratory depression, pruritis, urinary retention, nausea and vomiting. so, otherdrugs like clonidine have been administered to improve analgesia in the postoperativeperiod while avoiding the adverse effects of opioid.[16]

In the present study, there was no significant difference in the two groups with regard to age, weight and Gender.

In this study, we have chosen 0.25% Ropivacaine which provides good analgesia and clonidine 1µg/kg which prolongs the duration of analgesia significantly to avoiding the side effects like excesssedation, Bradycardia and Hypotension associated with higher doses of clonidine.

As In present study volume of the drug same i.e. 0.5 ml/kg in both groups no significant difference found in the level of caudal block in both groups that is average upto T10(55% in R and 57.5% in RC), T9(30% in R and 27.5% in RC), T8(15% in both R and RC group) . Even addition of 1 microgram/kg of clonidine in RC group didn't change the adequacy of level achieved Observations of present study are comparable with the study conducted by S.J Bajwa et al[11] in the year 2010 and In 2012 Arpita laha et al[13]

Excessive sedation was not observed as no patients in this study scored >2. All the children in group R and RC were sedated for a period of 3 hours. 40(100%) of the children in group RC and 12(30%) in group R were sedated at the end of 4th hour. There was no significant sedation in the post-operative period leading to respiratory depression. The sedation score was either 1 or less in all the patients after 12 Hour. The duration of sedation corresponded closely with the duration of analgesia which was comparable with studies of J J Lee et al[17] Cook et al[6] in 1995.

FLACC Scale has been used to equate pain and discomfort in young children with changes in standardized behavioural and physiologic parameters. Supplementary analgesic with rectal Diclofenac 1 mg/kg were given to patients with pain score more than 3, There was no incidence of pain score >3 in 1st and 2nd hour in either groups. At the end of 3rd,4th hour the pain score was significantly high in R group than RC group with p value <0.01which is significant. Similarly at the end of 8th,12th hour the difference was very much significant i.e. mean pain score was much increased in R group than RC group with p value<0.0001 which is highly significant. The difference was not significant between the 2 groups in the remaining time interval with regards to analgesic efficacy. **In 2005 Locatelli et al[8]** observed the postoperative pain using the children and in fants postoperative pain scale (CHIPPS) which includes: crying, facial expression, posture of the trunk, posture of the legs and motor restlessness. **In 2006 Y. Kawaraguchi et al[9]** evaluated the postoperative analgesia in caudal block using theChildren's Hospital of Eastern Ontario Pain Scale (CHEOPS) 30 min afterextubation and at 1, 2, 4, 6, 12 and 24 h. CHEOPS includes cry, facial expression,verbal response, torso and leg position.**El Hennawy et al[10] in 2009** used the FLACC pain scale to assessthe duration of analgesia which includes face, legs, activity, cry and consolability.

Duration Of Analgesia

In Present study the duration of analgesia was significantly prolonged in Ropivacaine-clonidine group (**600.25 ± 57.13** min) compared to Ropivacaine alone group (**251.50±45.69** min) in our study. This is similar with a study by **J J Lee and colleagues[17]**, which found that addition of clonidine to local anaesthetic prolongs the duration of analgesia after a single shot caudal block. They reported an increase in the mean analgesia duration (588 ± 120 min) after the addition of clonidine when compared to local anaesthetic alone (312 ± 60 min).**Manickam et al[12] in 2012** studied the efficacy of clonidine with ropivacaine for caudal analgesia in children in subumbilical surgeries Group A received 1 ml/kg of 0.1% ropivacaine, group B received 1 ml/kg of 0.1% ropivacaine with clonidine 1 mcg/ kg, and group C received 1 ml/kg of 0.2% ropivacaine. They found that mean analgesia duration was 243.7 ± 99.29 min(group A), 590.25 ± 83.93 min (group B), and 388.25 ± 82.35 min(group C). The duration of analgesia was significantly prolonged in group B compared to groups A and C. **S.J Bajwa et al[11] in the year 2010** compared caudal Ropivacaine 0.25% and Ropivacaine with clonidine 2microgram/kg for lower abdominal surgeries in pediatric patients. The duration of analgesia was prolonged where Clonidine was added that is 13.4 hours compared to 8.5 hours in control group. The Rescue doses were also significantly lesser in Clonidine group. The incidences of side effects were low. A caudal block with 0.25% of ropivacaine combined with 2 µg/kg of clonidine providedgood analgesia intra-operatively and prolonged post-operative duration of analgesia. This may be the result of dose of clonidine , premedications and inhalational anaesthetics , type of surgery, rescue analgesia; assessment of pain and statistical analysis.**In 2009 Archna et al[7]** observed the duration of analgesia as 270 mins in thosegiven 0.25% Bupivacaine 0.75ml/kg and 615mins in those given Clonidine 2µg/kg asadjuvant. In this study the longer duration of analgesia may be because pain wasassessed by parents, where there was some inconsistency in assessing the duration of analgesia.**In 2012 Arpita laha et al[13]** compared the analgesia between Ropivacaine 0.2%, 1ml/kg and Ropivacaine 0.2%, 1ml/kg added with Clonidine 2microgram/kg for paediatric caudal block. Duration of analgesia in Clonidine group was 975mins compared to 466±0.94 min in Ropivacaine group . In this study all the study population were premedicated with nasal midazolam 0.2mg/kg and of pentazocine 0.05mg/kg which may have increased the duration of analgesia. In contrast to our study the duration of analgesia is significantly increased, wherewe have used 0.5 ml/kg of Ropivacaine 0.25% and Clonidine 1 microgram/kg.

V. CONCLUSION

We conclude that, There was no significant variation in the Hemodynamic parameters like Preoperative and Intraoperative Heart Rate, Systolic Blood Pressure, Diastolic Blood Pressure and Respiratory Rate in Both Groups.

There was no any significant difference found in Dermatomal Level of caudal anesthesia In both Groups. The sedation produced by addition of clonidine corresponded with the duration of analgesia, which was conscious sedation without Respiratory depression. Both Plain Ropivacaine and Ropivacaine along with Clonidine as an adjuvant produced good postoperative analgesia in children. But the duration of analgesia Ropivacaine with Clonidine produced longer duration of analgesia compared to Plain Ropivacaine. There were no significant difference seen related to adverse effects in both the groups. Hence, Adjuvent clonidine 1 µg/kg with Ropivacaine 0.25% is better choice than Plain Ropivacaine 0.25% in caudal block

for infra-umbilical surgeries in pediatric patients for postoperative analgesia without any hemodynamic effects.

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