

A COMPARATIVE STUDY OF EFFICACY OF PLAIN ROPIVACAINE WITH ROPIVACAINE AND CLONIDINE FOR POSTOPERATIVE CAUDAL ANALGESIA IN PAEDIATRIC PATIENTS

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ABSTRACT: AIM: To evaluate the efficacy of plain ropivacaine 0.25% with that of ropivacaine 0.25% and clonidine 2µg/kg for post-operative analgesia caudally in paediatric patients undergoing subumbilical surgeries. **MATERIALS AND METHODS:** 50 paediatric patients aged between 2-9 years of ASA-I and II, divided into two groups. After giving GA, caudal block is performed in both the groups for post-operative analgesia. Group A receiving plain ropivacaine 0.25%, Group B receiving ropivacaine 0.25% and clonidine 2µg/kg, duration of analgesia, requirement of rescue medication, sedation score, hemodynamic effects and any adverse effects are compared between the two groups. **RESULTS:** Mean duration of analgesia in Group A is 484.04 minutes, In Group B with addition of clonidine is 771.12 minutes. No of doses of rescue medication required Group A 12 patients required single dose and 2 doses in 8 patients, In Group B 7 patients required single dose and one patient required 2 doses. **CONCLUSION:** Clonidine as an adjunct to ropivacaine prolongs the duration of analgesia decrease the need of postoperative rescue analgesia with stable hemodynamics.

KEYWORDS: Clonidine, Caudal analgesia, Ropivacaine, Paediatrics, Subumbilical surgeries.

INTRODUCTION: Pain is a protective mechanism designed to alert the body to potentially injurious stimuli. The international association for the study of pain has defined it as "an unpleasant sensory and emotional experience, associated with actual or potential tissue damage". The alleviation of pain has been the focus of continuing human effort. There is a lot of evidence that states that pain was untreated and underrated in children especially in infants in the past; however this trend is rapidly changing. Regional anaesthesia is now an accepted practice in paediatric anaesthesia where by postoperative pain relief can be obtained without recourse to systemic opioid analgesics.

Pain is subjective and therefore it cannot be proven that babies feel pain. However there is unequivocal evidence that nociceptive pathways are present even in preterm infants, and the stimulation of these pathways results in behavioral, physiological, metabolic and hormonal changes consistent with pain.

Local anaesthetics have been routinely used for regional blocks in children. Clonidine, an alpha-2 adrenergic agonist, has been used as an adjunct to local anaesthetics for caudal analgesia. This study was conducted to see the efficacy of Clonidine as an adjunct to Ropivacaine in post-operative pain relief following caudal analgesia for subumbilical surgeries in paediatric patients (age 2-9 years). We compare postoperative pain relief as well as the requirement of rescue analgesia and also look for postoperative complications as compared to local anaesthetics alone.

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AIM OF THE STUDY: To evaluate the efficacy of clonidine 2 μ /kg with 0.25% ropivacaine compared to 0.25% ropivacaine in paediatric patients undergoing subumbilical surgeries by caudal route.

The use of local anaesthetics such as Lignocaine, Bupivacaine, Ropivacaine etc., either alone or in combination with adjuvants such as Pethidine, Clonidine, Magnesium, Neostigmine and Ketamine have been evaluated and researched extensively.

Clonidine, an alpha-2 adrenergic agonist can be safely administered in caudal analgesia and is being used as an adjunct to local anaesthetics to increase the duration of analgesia.

In our study we performed caudal analgesia in 2 groups of paediatric patients to compare the efficacy of Clonidine as an adjuvant to Ropivacaine versus Ropivacaine alone in children undergoing subumbilical surgeries. The caudal analgesia remains the most popular and commonly used, reliable and safe technique in paediatric analgesia.

MATERIALS AND METHODS: After obtaining institutional ethical committee approval and informed consent from parents, this prospective, randomised, double-blinded, controlled study was conducted in King George Hospital, Visakhapatnam. 50 patients under ASA- I and ASA-II scheduled to undergo elective sub umbilical surgeries were included in this study. Preoperative examination was done and informed consent from parents was obtained. The patients were randomly allocated into two groups. Group A (Control Group), Group B (Study Group).

After premedication with atropine and pre-oxygenation patients were induced with Inj. thiopentone sodium 5mg/kg, Inj. fentanyl 1-2 μ gm/kg intubated with appropriate size endotracheal tube after giving Inj. suxamethonium 2mg/kg and anesthesia maintained with N₂O:O₂ mixture and Inj. Atracurium.

After securing endotracheal tube patients were placed in lateral decubitus position and a single dose caudal block was performed according to the group under sterile conditions using a 23 G hypodermic needle and standard "loss of resistance" technique under all aseptic precautions and the patients were turned supine immediately after the injection.

Group 'A' received 1ml/kg of 0.25% Ropivacaine Group 'B' received 1 ml/kg of 0.25% Ropivacaine with 2 microgm/kg clonidine.

The block was given post induction and duration of anesthesia was noted in both the groups. The patients were assessed for 24 hours post operatively. Heart Rate and Blood Pressure were measured for 2 hours in the post-operative period for every 15 min. Pain score was assessed using FLACC scale. F-Face, L-Leg, A- Activity, C-Cry, C-Consolability. 0 — no pain 1-3 mild pain, 4-7 moderate pain, 8-10 severe pain.

The follow up in PACU and ward for FLACC scale was noted separately by anesthesiologist in the PACU and a nurse in the ward who were blinded, and the data was analyzed at the end of the study by a blinded statistician. The post-operative follow up times were 15, 30, 45, 60, 90, 120 minutes for heart rate and systolic blood pressure. The FLACC scale was noted for 0, 1, 2, 6, 12 and 24 hrs postoperatively.

In the post-operative unit, the necessity for rescue medicine was decided by the pain score \geq 4. Rescue medication was provided with syrup. Paracetamol with a dose of 10-15mg/kg.

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In the post-operative period patients were also monitored for adverse effects including respiratory depression, hypotension and bradycardia. Respiratory depression was defined as a decrease of SpO₂ less than 92% requiring supplemental oxygen via facemask.

An intraoperative decrease in the arterial pressure or heart rate more than 15% from the base line was defined as hypotension and bradycardia respectively. From the time of arrival in PACU, to the first time the FLACC pain scale score was noted to be 4 or more was recorded as the duration of adequate caudal analgesia. The number of doses of rescue medication required was recorded over 24 hrs.

STATISTICAL ANALYSIS AND RESULTS: In our study we compared the effectiveness of Clonidine as an adjuvant to Ropivacaine in caudal analgesia for paediatric patients posted for sub umbilical surgeries.

DEMOGRAPHIC DATA: Group A had a mean age of 5.2 yrs, Group B had a mean age of 5.88 yrs.

It was found to be insignificant with a p value of 0.2756.

Age in years	Mean	SD
Group A	5.2	2.16
Group B	5.88	2.2

Table 1

DURATION OF ANALGESIA: The duration of analgesia between the two groups were compared using Mann-Whitney test. It was found that there was a significant difference between Group A and B with a p value of <0.0001 with a mean of 484.04 minutes in Group A and 771.12 minutes in Group B.

Duration of analgesia (min)	Group A	Group B
Mean	484.04	771.12
SD	15.08	22.42

Table 2

RESCUE MEDICATION: The Requirement of rescue medicine was compared between the two groups using Pearson's Chi square test and it was found to be significant with a p value of <0.0001.

Number of doses	Group A	Group B
Zero	5	17
One	12	7
Two	8	1

Table 3

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SEDATION SCORE: The sedation score was compared between the two groups using student T-test. It was found that Group A having a score of 2.32 and group B 2.68 with $p < 0.0714$ which is not quite significant.

Sedation score	Group A	Group B
Mean	2.32	2.68
S.D.	0.8	0.56

Table 4

DISCUSSION: Epidural analgesia after surgery in addition to providing patient comfort can facilitate accelerated recovery anaesthesia approach labeled postoperative rehabilitation by Kehlet. With this approach post-surgical patient receive not only effective pain relief but also early postoperative intake of oral nutrition, reduction in postoperative stress response and organ dysfunction, avoidance of fatigue with lower incidence of DVT, early mobilization and postoperative discharge.

The present study was designed to evaluate the effectiveness of Clonidine as an adjuvant to Ropivacaine for caudal analgesia in children. A total of 50 patients were randomized into two groups A and B. Group A received 1 ml/kg of 0.25% Ropivacaine, while Group B received 1 ml/kg of 0.25% Ropivacaine with Clonidine $2\mu\text{g}/\text{kg}$. Both the groups were then monitored for duration of postoperative analgesia.

Both the groups were comparable with respect to demographic details like age, sex and weight and nature of surgeries.

In our study, the postoperative analgesia was evaluated using the FLACC scale (Merkel SI et al)¹ for the first 24 hours. In our study, as assessed by FLACC scale the postoperative pain was found to be significantly lower in the Group B which received Clonidine as an adjuvant to Ropivacaine than Group A which did not receive Clonidine.

Ansermino M et al,² evaluated the effect of non-opioid additive Clonidine with local anaesthetics for caudal block in paediatric patients and showed that there was significant reduction in postoperative pain and also prolonged duration of analgesic effect with the use of Clonidine.

Thomal R vetteret al³, examined the effects of Clonidine with 0.2% Ropivacaine on the duration of postoperative analgesia in caudal anaesthesia in 60 children aged 1-6 years undergoing ureteral re implantation and found that the duration of postoperative analgesia was significantly longer in the group A given Ropivacaine and $2\mu\text{g}/\text{kg}$ Clonidine without any side effects than group B receiving Ropivacaine 0.2% and 30microgms/kg morphine.

In our study, in the Clonidine Group B, there was prolonged analgesia for a period of 771.12 minutes (SD -22.42 minutes) in the post-operative period when compared to Groups A where patients had analgesia only for a period of 484.04 minutes (SD-15.22). Negri P et al⁴, showed in their study that Clonidine given caudally with Ropivacaine 0.2 % in a group of children aged 1-5 years undergoing minor surgery compared with Ropivacaine 0.2% alone, increases the duration of postoperative analgesia in paediatric patients by 6 - 7 hours without any clinical side effects.

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In our study the number of patients who received rescue medications was much less in group B than in group A.

Casati et al⁵ evaluated the effects adding small-dose of Clonidine to Ropivacaine for sciatic-femoral block and found that the group with Clonidine had a three hour difference in first request for postoperative pain medication compared to the group without Clonidine. In our study there was a difference of 3.5 hours between two groups with respect to time of requirement of rescue analgesia.

Per-Arne Lonnqvist et al⁶, in his study has proved that the use of Clonidine as an adjunct to local anaesthetic enhances the quality of pain relief and substantially prolongs the duration of analgesia after caudal and epidural blockade in children.

When sedation was compared in both the Groups at 2hrs, majority of children in Group – B were having a score of 3/5 according to Wilson’s grading, whereas majority in Group - B were having 1-2/5, when these results are statistically analyzed by student ‘T’ Test with a P value of <0.0714 not quite significant. This sedation is highly desirable in the post-operative period.

No adverse effects were noticed in both the groups. There was no incidence of bradycardia or hypotension in both groups till 2 hours postoperatively. In our study the heart rate and systolic blood pressure was monitored till 2 hours postoperatively and was found to be stable.

Our study clearly substantiated the use of Clonidine as an adjunct to local anaesthetics in paediatric patients to provide postoperative analgesia without deleterious side-effects.

CONCLUSION: From our study, we conclude that there is significant difference in the duration of analgesia between two groups. Clonidine as an adjuvant to Roivacaine has improved postoperative analgesia with favourable haemodynamics in paediatric caudal analgesia for subumbilical surgeries.

BIBLIOGRAPHY:

1. Merkel SI, Voepel-Lewis T, Shayevitz JR, Malviya S, The FLACC: a behavioral scale for scoring postoperative pain in young children. *Paediatric Nursing* 1997; 23: 293-7.
2. Ansermino M, Basu R, Montgomery C Vandebek C, Nonopoid additives to local anaesthetics for caudal blockade in children: a systemic review. *Paediatric Anaesth* 2003;13: 561-73.
3. Thomas R. Vetter, MD, Daniel Carvallo, MD, Jodie L. Johnson, MD, Michael S. Mazurek, D and Robert G. Presson Jr, MD A Comparison of Single-Dose Caudal Clonidine, Morphine, or Hydromorphone Combined with Ropivacaine in Pediatric Patients Undergoing Ureteral Reimplantation.
4. Ivani G, De Negri P, Conio A, et al. Ropivacaine-clonidine combination for caudal blockade in children. *Acta Anaesthesiol Scand* 2000; 44: 446–9.
5. Casati A, Magistris L, Fanelli G, Small-Dose Clonidine Prolongs Postoperative Analgesia after Sciatic-Femoral Nerve Block with 0.75% Ropivacaine for Foot Surgery, *Anesth Analg*. 2000, 91(2): 388-92.

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- Ivani G, De Negri P, Lonnqvist PA, et al. Caudal anesthesia for minor pediatric surgery: a prospective randomized comparison of ropivacaine 0.2% vs. levobupivacaine 0.2%. *Paediatr Anaesth* 2005; 15: 491–4.

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