



## Anesthesiology

## COMPARISON OF TWO DIFFERENT DOSES OF CLONIDINE WITH ULTRASOUND GUIDED CAUDAL FOR POST OPERATIVE PAIN RELIEF IN CHILDREN.

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**ABSTRACT**

Caudal was performed under ultrasonogram guidance, to avoid multiple needle pricks, for reducing intravascular or intrathecal complications and for improving the success rate of assessing epidural space in the first attempt. A prospective randomized double blinded study was done to compare efficacy of two different doses of clonidine with bupivacaine using ultrasound guided caudal block in children. They were divided into 2 groups Group 1 : 1ml/kg of 0.25% bupivacaine + 1mics/kg of clonidine Group 2 : 1ml/kg of 0.25% bupivacaine + 2 mics/kg of clonidine Assessment of pain by FLACC SCALE was done at 2, 6, 8, and 10 hours postoperatively. According to the study, duration of post operative analgesia was prolonged with clonidine 2 mics/kg than clonidine 1 mics/kg group with a mean of 9 hrs vs 7.1hrs, the number of doses of rescue analgesia was reduced in clonidine 2 mics/kg group as well as FLACC scale score remain statistically significant at 10 hrs between two groups. The hemodynamic parameters were well maintained in both groups, there was no incidence of respiratory depression, hypotension and bradycardia. Hence Clonidine 2 mics/kg can be safely used in paediatrics as it has prolonged duration of post operative analgesia as well as it is devoid of side effects.

**KEYWORDS :** Pediatric surgery, clonidine, caudal block, ultrasound guided, analgesia, complications

**1. INTRODUCTION**

An unpleasant sensory and emotional experience is defined as pain, which is associated with actual or potential tissue damage. It is distinct from other modalities such as touch, warmth, and cold. It is a subjective sensation which can only be experienced and not expressed, especially in children. Humanitarian is the foremost treatment of any pain. It is important in children who depend on their parents for their well being. There is drastic change and improvement over the concept of postoperative pain relief especially in the paediatric age group.[1] All the methods of pain relieving techniques has some disadvantages which limits their use in children such as need of cautious use of opioids because of its respiratory depression effects, some analgesics cannot be given after general anaesthesia because of their adverse effects like vomiting and aspiration and due to fear of needles in case of parenterally administered analgesics. Hence regional anaesthetic techniques was selected which decrease significantly not only post operative pain and but also systemic analgesic requirements. The simplest, safest technique among the regional techniques in paediatric surgery was caudal, it was selected for this study as it has a high success rate. Caudal was performed under ultrasonogram guidance, to avoid multiple needle pricks, for reducing intravascular or intrathecal complications and for improving the success rate of assessing epidural space in the first attempt.[2] In children, epidural space allows rapid spread of drugs longitudinally, and thereby postoperative pain is treated effectively. In children one of the most acceptable and popular method of providing intra- and post-operative analgesia for infra umbilical surgeries is caudal block. The most commonly used local anaesthetic for caudal analgesia is bupivacaine. Shorter duration of action of about four to six hours during 'single shot technique' is the main disadvantage of Bupivacaine.[3] For prolonging the duration of post operative analgesia with bupivacaine several adjuvants like opioids, ketamine, midazolam, clonidine and neostigmine are used. The most commonly used adjuvant with bupivacaine is clonidine for caudal analgesia. It is an alpha 2 agonist and it has been used for both central neuronal blocks and peripheral nerve blocks with bupivacaine for prolonging its action. This study was performed under ultrasound guidance in elective sub umbilical surgeries to assess the efficacy of different doses of clonidine with bupivacaine for postoperative analgesia in children. Clonidine is an mixed  $\alpha_1$  and  $\alpha_2$  agonist but has a greater affinity for  $\alpha_2$  adrenergic receptors. The hypnotic and analgesic effects are mediated by  $\alpha_2$  receptors. Clonidine improves the quality of anaesthesia, provides a more stable cardiovascular course during anaesthesia, mainly due to its sympatholytic effect and it reduces dosage of anaesthetic drugs. Analgesic action is due to its stimulatory effect on inhibitory alpha 2 receptors and reduce the central neural transmission. It inhibits the release of substance -p.

**2. AIM OF THE STUDY**

1. To Compare the efficacy of two different doses of clonidine with caudal bupivacaine.
2. Pain was assessed by FLACC scale.
3. Time of rescue analgesia (duration of analgesia) and the number of doses of rescue analgesia.
4. To evaluate the complications.

**3. MATERIALS AND METHODS.**

A prospective randomized double blinded study was done to compare the effect of two different doses of clonidine with bupivacaine using ultrasound guided caudal block for post operative pain relief in children. After getting informed consent from the patient's parents, this study was carried out in 50 children posted for infraumbilical surgeries with a duration of (approx. 30-60 min). The age group of these children are from 2- 6yrs with the weight of 5-15kgs were selected for the study.

**INCLUSION CRITERIA:**

1. ASA I or II
2. Age- 2-6yrs
3. Both sexes.

**EXCLUSION CRITERIA :**

1. h/o allergy to local anaesthetics,
2. coagulation disorder.
3. spinal deformity like sacral abnormalities, spina bifida.
4. Any cardiac or neurological diseases.
5. local sepsis.

**They were divided into 2 groups**

**Group 1 :** 1ml/kg of 0.25% bupivacaine + 1mics/kg of clonidine  
**Group 2 :** 1ml/kg of 0.25% bupivacaine + 2 mics/kg of clonidine

In the operation theatre, monitors like pulse oximetry, NIBP were attached.

Baseline values of parameters like MAP, PR, SPO<sub>2</sub> were recorded. Iv line secured and ringer lactate were started as per calculated fluid requirements.

Premedicated with inj. atropine 0.02mg/kg, induction was done with standardised doses of inj. thio 5mg/kg and inj. fentanyl 2 mics/kg and inj. atracurium 0.5 mg/kg and intubated with appropriate size endotracheal tube. Maintained with 60% nitrous oxide and 40% oxygen and sevoflurane (1-2%). Patients were positioned in left lateral position. After aseptic precautions, caudal space identified using Ultrasound and single shot caudal block was performed with 23 G needle. Group : 1 patient receives clonidine 1mics/kg with bupivacaine

0.25 % 1ml/kg.Group :2 patient receives clonidine 2 mics/kg with bupivacaine 0.25% 1ml/kg. Technique of Needle placement using USG :Initially using transverse plane of imaging the sacral hiatus is identified sacral hiatus is located between an upper hyperechoic line representing the sacrococcygeal membrane and an inferior hyperechoic line representing the dorsum of the pelvic surface (base) of the sacrum.Rotate the probe longitudinally to capture the sacrococcygeal membrane, a relatively thick linear hyperechoicband, sloping caudally.Insert the needle under longitudinal view which allows for optimal viewing along the needle. after placement with in the epidural space, spread of local anaesthetic is viewed as dilation of the caudal space and localized turbulence. At the end of the operation,residual neurological blockade was reversed with appropriate doses of neostigmine and atropine, and extubated.

**INTRAOPERATIVE MONITORING:** Heart rate, MAP,SPO2 were recorded throughout the operation at an interval of five minute Decrease in heart rate and MAP more than 30 % from the baseline values were treated accordingly.

**POST OPERATIVE MONITORING:** Heart rate and blood pressure were measured at 15, 30, 60, 90mins , 2hrs, 4hrs, 6hrs, 8hrs and 10 hrs postoperatively.

Assessment of pain by FLACC SCALE was done at 2, 6, 8, and 10 hours postoperatively.The time of arrival to POCU to the first time when FLACC score was greater than 4 was noted as the duration of adequate caudalanalgesia.

When the FLACC score was greater than 4,RESCUE ANALGESIA was given Paracetamol suppository was used as rescue medicine with a loading dose of 40 mg/kg followed by 20 mg/kg every six hours.The number of doses of rescue analgesia and the time to which first rescue analgesia was given were recorded.

**COMPLICATIONS :**

- vomiting,respiratorydepression,hypotension,bradycardia were also noted.
- Respiratory depression was defined as a decrease in oxygen saturation less than 93%, requiring oxygen by face mask.
- Hypotension was defined as systolic blood pressure less than 70 mm Hg
- bradycardia was defined as a heart rate less than 80 beats/min.

**4.RESULTS :**

The information collected regarding all the selected cases were recorded in a Master Chart. Data analysis was done with the help of computer using Epidemiological Information Package (EPI 2010) developed by Centre for Disease Control, Atlanta.Using this software range, frequencies, percentages, means, standard deviations, chi square, 't' value and 'p' values were calculated. 't' test was used to test the significance of difference between quantitative variables and Yate's and Fisher's chi square tests for qualitative variables. A 'p' value less than 0.05 is taken to denote significant relationship.Age of the children between 2-6 yrs with the mean of 3.48 ± 1.12 in group 1 and 3.52 ± 1.08 in group 2 are comparable and statistically not significant.Patients characteristics like sex were comparable and statistically not significant.

**Table 1 :DURATION OF POST OPERATIVE ANALGESIA**

Group	Duration of Post Operative Analgesia (hours)		
	Range	Mean	SD
Group 1	5.5 - 8	7.0	0.71
Group 2	8 - 10	9.02	0.55
'p'	<0.0001 Significant		

The mean duration of post op analgesia between the group 1 and group 2 are 7 ± 0.71 hrs and 9.02 ± 0.55 hrs and is found to be statistically significant with the p value of <0.0001.

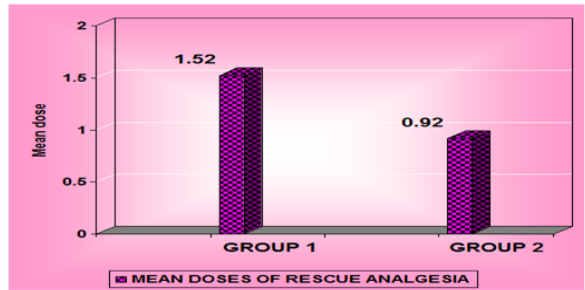
**Table 2 : NUMBER OF DOSES OF RESCUE ANALGESIA.**

Doses of Rescue Analgesia	Group 1		Group 2	
	No	%	No	%
0	4	16	10	40
1	10	40	8	32
2	5	20	6	24
3	6	24	1	4

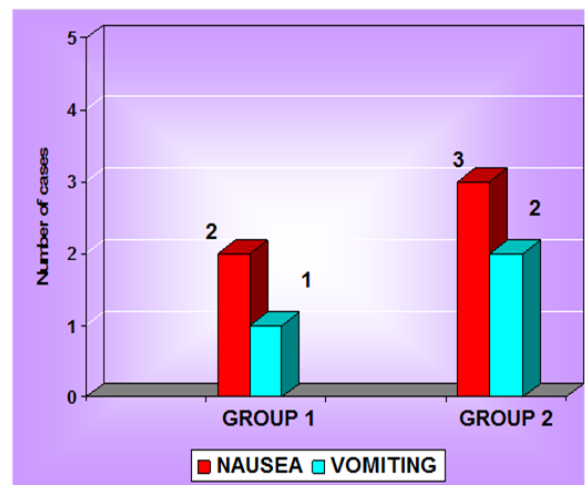
Mean	1.52	0.92
SD	1.05	0.91
'p'	0.0354 Significant	

The number of doses Rescue analgesia between the group 1 and group 2 are 1.52 ± 0.92 and 1.05 ± 0.91 and is found to be statistically significant with the p value of <0.0354.

**Figure 1: NUMBER OF DOSES OF RESCUE ANALGESIA**



**FIGURE 2: COMPLICATIONS**



**5. DISCUSSION**

Caudal analgesia remains unique in the cornerstone of paediatric anaesthesia for providing analgesia in the intraoperative and post operative period, especially in children undergoing perineal, infra umbilical and lower extremity surgery. Virushali Chandrashekar Ponde (Indian Journal of Anaesthesia 2012 ) in his review article ,quoted about recent advances and development in paediatric central neuraxial anaesthesia such as use of ultrasound guidance and electrical stimulation . The correct needle placement in electrical stimulation is indicated by contraction of anal sphincter. These advancement upgrade neuraxial block still effective and safer. Eventhough caudal block is very simple technique ,it also has its own complications like intraosseous, intravascular and intrathecal. Conventional or blind technique is assessed by loss of resistance technique which is subjective variable. Use of ultrasound or electrical stimulation confirms the correct needle placement which avoids blind injury to bony structures . In this study caudal block was performed under ultrasound guidance. Among the drugs used for caudal block ,Bupivacaine remains the local anaesthetic used most commonly, ropivacaine which is similar to bupivacaine but has less motor blockade is being used extensively. Many additives have been added with bupivacaine to increase its duration of action . Adjuvants like ketamine which is preservative free, morphine, fentanyl, clonidine , midazolam , dexmedetomidine ,epinephrine have been added. We in this study combined clonidine with bupivacaine , clonidine was selected as it offers many advantages over opioids . clonidine is a selective α2 agonists. Clonidine decreases central sympathetic drive by stimulating the inhibitory α2 receptors and decrease the nor- adrenaline release ,this sympatholysis will reduce intraoperative requirements of analgesics and inhalational anaesthetics. Sympatholysis effect causes sedation, where child can be aroused to full consciousness. It is also devoid of respiratory depression, pruritis and urinary retention which is seen with

opioids. CLONIDINE analgesic effect is due to its suppression of nociceptive neurons in spinal cord directly, substance -P release is prevented, prevents the neurotransmission in A $\delta$  and C fibres and due to its interaction with  $\alpha$ 2 receptors in spinal and supraspinal sites. So, we in this study compared the effects of two different doses of clonidine and the following parameters were studied. There was no change in pulse rate, mean arterial pressure and SPO2 during preoperative, intraoperative and postoperative period. The two groups were comparable and the values were found statistically insignificant.

**FLACC SCALE:** FLACC scale was used in this study to assess pain. It was selected as it is easy to perform. The mean number of doses of RESCUE ANALGESIA between group 1 (clonidine 1 mcg/kg with bupivacaine 0.25%) and group 2 (clonidine 2 mcg/kg with bupivacaine 0.25%) are  $1.52 \pm 1.05$  and  $0.92 \pm 0.91$  respectively with a p value of 0.00354 and was found to be statistically significant. So the above findings correlate well with similar studies done by Klimscha et al, Motsch et al and Negri et al. [4][5]

FLACC SCALE was not statistically significant at 2 hrs, 6 hrs, 8 hrs and was found to be statistically significant at 10 hrs with a p value of 0.009.

**MEAN DURATION OF POSTOPERATIVE ANALGESIA:** The mean duration of postoperative analgesia in group 1 (clonidine 1 mcg/kg with bupivacaine 0.25% 1ml/kg) and group 2 (clonidine 2 mcg/kg with bupivacaine 0.25% 1ml/kg) are  $7 \pm 0.71$  hrs and  $9.02 \pm 0.5$  hrs respectively with a p value of  $< 0.001$  which was statistically significant. The findings of this study well correlated with similar other studies done by T.S. Yildiz et al, Archanakoul et al and Lee et al. [6][7] **VOLUME OF LOCAL ANAESTHETICS:** In this study bupivacaine 0.25% was used in the volume of 1ml/kg. Sharpe et al reported that the volume and concentration of bupivacaine must be adequate to bring about the action of clonidine, volume of 0.5ml/kg of bupivacaine will cause clonidine to settle caudally. [8] **COMPLICATIONS:** There was no single occurrence of side effects like respiratory depression, bradycardia and hypotension between the two groups. Incidence of nausea and vomiting between the two groups were statistically insignificant with a p value of 0.5.

This prospective randomized study was conducted in 50 children of age 2-6 yrs posted for infraumbilical surgery. This study was done to compare the effects of two different doses of clonidine using ultrasound guided caudal block for postoperative analgesia in children. They were divided into two groups,

Group 1 receiving bupivacaine 0.25% (1ml/kg) with clonidine 1 mcg/kg.

Group 2 receiving bupivacaine 0.25% (1ml/kg) with clonidine 2 mcg/kg.

Intraoperatively, monitors like MAP, pulse rate and spo2 were observed. In the postoperative period, hemodynamic parameters like pulse rate, spo2 and MAP were noted, pain was assessed by FLACC scale. According to the study, duration of postoperative analgesia was prolonged with clonidine 2 mcg/kg than clonidine 1 mcg/kg group with a mean of 9 hrs vs 7.1 hrs, the number of doses of rescue analgesia was reduced in clonidine 2 mcg/kg group as well as FLACC scale score remain statistically significant at 10 hrs between two groups. In conclusion, the data and statistical analysis suggest that in caudal block clonidine 2 mcg/kg has prolonged duration of postoperative analgesia than clonidine 1 mcg/kg and it also has minimal side effects. Hence Clonidine 2 mcg/kg can be used safely in caudal block for postoperative analgesia in children.

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