

## Comparison of Clonidine and Fentanyl When Used With Bupivacaine in Caudal Anaesthesia for Prolongation of Postoperative Analgesia in Paediatric Patients



### Medical Science

**KEYWORDS :** Caudal epidural anaesthesia, clonidine, Fentanyl.

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### ABSTRACT

**BACKGROUND:** This prospective double blind, randomized study was undertaken to compare Clonidine and fentanyl as an adjuvant to bupivacaine in caudal anaesthesia for prolongation of postoperative analgesia in paediatric patients.

**Materials and Methods:** A total of 60 ASA grade I and II patients aged between 2 and 10 years who were undergoing elective lower abdominal and urogenital surgeries were randomly assigned into one of the two groups, containing 30 patients each. Group C received 1 ml/kg of 0.25% bupivacaine with 1 mcg/kg clonidine in normal saline and Group F received 1ml/kg of 0.25% bupivacaine with 1 mcg/kg fentanyl in normal saline as single shot caudal epidural anaesthesia. The efficacy of fentanyl and clonidine in terms of quality and duration of analgesia were recorded over the period of 24 hours postoperatively.

**RESULTS:** The mean duration of analgesia was significantly longer in group C than in group F ( $p < 0.05$ ). The requirement of rescue medication at 10 hours in group F was 43% and group C was 16% where as at 18 hours in group F was 63% and group C was 30% which was found to be statistically significant ( $p < 0.05$ ). There was no statistically significant differences in systolic, diastolic, mean blood pressure and heart rate observed in the 24 hour postoperative period among both the groups.

**Conclusion:** 1mcg/kg clonidine significantly increases the quality and duration of analgesia in comparison to 1mcg/kg fentanyl when used as an adjuvant with 1ml/kg of 0.25% bupivacaine as single shot caudal epidural anaesthesia, without any serious side effects.

### INTRODUCTION

Caudal epidural block is the most commonly used regional techniques in paediatric anaesthesia and is popular due to its simplicity and high success rate.<sup>1,2</sup> Post operative analgesia through the caudal epidural route with bupivacaine in children is firmly established in infraumbilical surgery.<sup>3,4</sup> Analgesia provided by the bupivacaine is limited.<sup>5</sup> This lead to the use of various other caudal additives such as opioids, midazolam, clonidine, ketamine and tramadol.<sup>6,7</sup> The main site of action of epidurally administered fentanyl is substantia gelatinosa on the dorsal horn of spinal cord.<sup>8</sup> Clonidine on the other hand is an alpha 2 agonist and act as an analgesic and sedative. So in this study we compare the efficacy of fentanyl and clonidine in terms of quality and duration of analgesia they produced when added with bupivacaine for single shot caudal epidural anaesthesia in paediatric patients.

### MATERIAL AND METHODS

After approval from institutional ethical committee and obtaining consent, 60 ASA grade I and II patients aged between 2 and 10 years who were undergoing elective lower abdominal and urogenital surgeries were enrolled for this prospective, randomized double-blind study which was conducted in National Institute Of Medical Sciences and Research medical college and hospital, jaipur. After careful pre anaesthetic examination patients were kept fasting for 6 hours prior to surgery and were pre-medicated with oral midazolam 0.5mg/kg body weight. All procedures were carried under general anaesthesia. Exclusion criteria included history of allergy to any of study drugs, history of any respiratory illness, presence of sacral deformity or any localized infection. Patients were randomly allocated into two groups by computer generated random number chart. Group F patients received 1ml/kg of 0.25% bupivacaine with 1 mcg/kg fentanyl in normal saline. Group C patients received 1 ml/kg of 0.25% bupivacaine with 1 mcg/kg clonidine in normal saline. The drug was loaded by an anaesthesiologist who did not participate in the study. General anaesthesia was induced with 50% N<sub>2</sub>O, 50% O<sub>2</sub> and 8%

sevoflurane, no intra operative sedatives or opioids were administered. All blocks were performed in the left lateral position, using a 23 gauge hypodermic needle, under strict aseptic precautions. Patients with an anal wink reflex were presumed to have incorrect drug placement and were not included in the study. After surgery residual neuromuscular blockade was reversed and all patients were transferred to post operative room and observed for 24 hours.

Continuous monitoring of intra operative heart rate, ECG and pulse oximetry was done and blood pressure was recorded at interval of every 10 minutes. Post operatively heart rate, blood pressure and respiratory rate were measured every 15 minutes. Objective pain assessment was made by using a 5- point scale, modification of the pain/discomfort scale. Where facial expression used for scoring, laughing score 1; happy, contented and playful score 2; calm and sleep score 3; mild-moderate pain- crying, grimacing restless can be distracted with toy, food or parent score 4; severe pain- crying, screaming, inconsolable score 5.

Pain score of 4 or 5 were given paracetamol suppository 15-20mg/kg as rescue analgesic. Side effects, if any were recorded. SpO<sub>2</sub> <93% was defined as respiratory depression and supplemental oxygen was given.

The data are expressed as distribution of cases with respect to hemodynamic parameters, total duration of analgesia, comparison of pain scores and side effects. Incidence of study results were analyzed using students t test and categorical data was analyzed by chi square test. The level of significance was taken up as  $p < 0.05$ .

### RESULTS

The results were analysed in relation to age, sex, weight of the patient, duration of surgery, recovery to first analgesia time, systolic, diastolic, mean blood pressure and heart rate in 24 hours in postoperative period and post operative complication like nausea and vomiting hypotension, brady-

cardia, pruritis and constipation.

The two groups were comparable with respect to age, gender distribution, weight, duration and type of surgeries. (Table:1) The mean duration of analgesia was significantly longer in group C than in group F ( $p < 0.05$ ). (fig:1) The requirement of rescue medication at 10 hours in group F was 43% and group C was 16% where as at 18 hours in group F was 63% and group C was 30% which was found to be statistically significant ( $p < 0.05$ ) (Table:2) There was no statistically significant differences in systolic, diastolic, mean blood pressure and heart rate observed in the 24 hour post-operative period among both the groups. Post operative nausea and vomiting occurred in 2 patients in group F but no such incident seen in group C. Pruritis developed in 1 patient in group C. However other complications like hypotension, bradycardia and constipation did not observed in any of the two groups. (Table:2)

**DISCUSSION**

Caudal epidural block is the most common neuraxial block administered in children. To decrease the dose of bupivacaine for avoiding local anaesthetic toxicity, and to prolong the duration of analgesia various adjuncts are added. 6,7,9

In our study we found that the addition of 1 mcg/kg of clonidine to caudal bupivacaine 0.25% significantly decrease the need for rescue analgesia in the immediate postoperative period which is in consistent with those reported by several other studies. 10-16

In children, a mixture of 0.25% bupivacaine with 1 - 2 µg/kg clonidine has been seen to improve the duration and quality of analgesia provided by caudal block. Although results differ widely, the duration of analgesia provided range from 6.3 hours to 16.4 hours for 1 µg/kg to 5.8 hours and 9.8 hours for 2 µg/kg. One study has shown a mean duration of analgesia of 20.9 ± 7.4 hours in children receiving caudal clonidine with bupivacaine, but a dose of 5 µg/kg of clonidine was used in this study. 16 In various studies the duration of action of clonidine varies which could be due to many reasons like, dose of clonidine used, differences in pre-medication and volatile anaesthetic used, type of surgery, indications for rescue analgesia, assessment of pain, and statistical analysis.

In our study the duration of analgesia in clonidine group was 10 hours, which was consistent with the study done by Lee JJ et al 11 where they concluded that clonidine when added to bupivacaine improves the efficacy of caudal analgesia in children. Several adjuvants have been used to prolong the duration of analgesia of bupivacaine for caudal analgesia in children. Opioids, ketamine and midazolam are some of the commonly used drugs. 14 The use of opioids is associated with an increased incidence of pruritis and post-operative nausea and vomiting. 17 But with Clonidine the advantage is that it prolongs the duration of analgesia without an increase in the incidence of respiratory depression, pruritis and urinary retention which are commonly seen with neuraxial opioids.

Several mechanisms have been suggested for the clonidine-induced prolongation of caudal analgesia with bupivacaine. The anti-nociceptive action is due to the direct suppression of the spinal cord nociceptive neurons by epidural clonidine. Another mechanism is that clonidine crosses the blood brain barrier and interacts with alpha 2 adrenoceptors at spinal and supra-spinal sites to produce analgesia. Clonidine also suppresses neurotransmission in peripheral sensory A δ and C nerve fibres. The final mechanism sug-

gested is pharmacokinetically mediated: clonidine induces vasoconstriction through α-2b adrenoceptors located at the peripheral vascular smooth muscles. 18

We monitored our patients for a period of 24 hours post-operatively which is in contrast to a few other studies where there was only a six-hour period of observation post-operatively and the rest of the assessment was done by parents. 19,20 Assessment by parents could introduce some inconsistency as parents differ in the way they perceive their children to be in pain and the threshold for administering rescue medications varies between parents. A meta-analysis of 18 trials by Curatalo et al comparing epidural fentanyl, adrenaline and clonidine as adjuvants to local anaesthetics concluded that addition of fentanyl decreased the incidence of pain quantitatively during surgery and is safe. 21

Constant I et al 22 in their study found out that addition of clonidine or fentanyl to local anaesthetics prolong the duration of surgical analgesia after single shot caudal block in children. Yeddanapudi et al 23 concluded that addition of 1 mcg/kg but not 0.5 mcg/kg of fentanyl caudal bupivacaine prolonged the post operative analgesia in children undergoing genitourinary surgery and herniotomy.

**CONCLUSION**

1mcg/kg clonidine significantly increases the quality and duration of analgesia in comparison to 1mcg/kg fentanyl when used as an adjuvant with 1ml/kg of 0.25% bupivacaine as single shot caudal epidural anaesthesia, without any serious side effects.

**TABLE:1 Patient characteristics. Data are Mean+/-SD, number (%)**

PATIENT CHARACTERISTICS		GROUP F (n=30)	GROUP C (n=30)
AGE		5.03±2.44	5.10±2.43
SEX	M	26(86.60)	28(93.30)
	F	4(13.30)	2(6.60)
WEIGHT OF PATIENT(KG)		14.00±2.25	14.90±2.09
DURATION OF SURGERY (MINUTES)		65.54±5.01	65.64±5.06
TYPE OF SURGERY	HERNIOTOMY	20(66.66)	21(70.00)
	ORCHIDOPEXY	7(23.33)	5(16.66)
	CIRCUMCISION	3(10.00)	4(13.33)

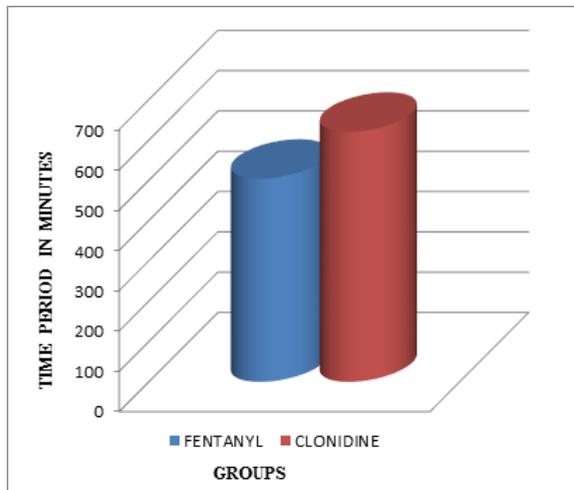
(\* $p < 0.05$  = statistically significant)

**TABLE:2 COMPARISION OF TWO GROUPS**

		GROUP F (n=30)	GROUP C (n=30)
NEED FOR RESQUE ANALGESIA	8 HOUR	13(43.33)*	5(16.66)*
	16 HOUR	19(63.33)*	9(30.00)*
NAUSEA/VOMITING		2(6.66)	-
PRURITIS		1(3.33)	-
BRADYCARDIA		-	-
HYPOTENSION		-	-
(C) CONSTIPATION		-	-

(\* $p < 0.05$  = statistically significant)

Fig: 1 RECOVERY TO FIRST ANALGESIC IN MINUTES



( $p < 0.05$  = statistically significant)

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