

## ORIGINAL ARTICLE

### A COMPARATIVE CLINICAL STUDY OF BUPIVACAINE 0.25% WITH CLONIDINE AND ROPIVACAINE 0.25% WITH CLONIDINE IN PAEDIATRIC CAUDAL BLOCK FOR CIRCUMCISION

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**ABSTRACT: BACKGROUND:** Caudal epidural block is one of the most popularly used regional techniques in paediatric patients. Various drugs in different concentrations have been used for the technique. Local anaesthetic like Ropivacaine produces differential neuraxial blockade with less motor block and reduced cardiovascular toxicity. To increase the duration of action of local anaesthetics and thereby analgesia extending to the post-operative period, various adjuvants like clonidine an  $\alpha_2$  agonist has been used. Post-operative pain is the main concern in circumcision. Lower concentration of local anaesthetics can be used for the procedure as motor blockade is not required. Hence we have compared Bupivacaine 0.25% combined with  $1\mu\text{g}/\text{kg}$  of clonidine and Ropivacaine 0.25% combined with  $1\mu\text{g}/\text{kg}$  clonidine at a volume of  $0.5\text{ml}/\text{kg}$  in children undergoing circumcision. **AIMS AND OBJECTIVES:** To assess the safety, efficacy, onset and duration of analgesia of 0.25% Bupivacaine and 0.25% Ropivacaine when equal volumes of Clonidine is added as an adjuvant in paediatric caudal block. **MATERIAL AND METHODS:** The Current Study is a comparative randomized study where sampling method was purposive sampling. Statistical analysis was done using student's t test and chi square test. 60 children aged between 1 to 6 years weighing  $< 20$  Kgs posted for circumcision were divided into two groups of 30 each. GROUP I received 0.25% Bupivacaine  $0.5\text{ml}/\text{kg}$  +  $1\mu\text{g}/\text{kg}$  Clonidine and GROUP II received 0.25% Ropivacaine  $0.5\text{ml}/\text{kg}$  +  $1\mu\text{g}/\text{kg}$  Clonidine. Intra-operatively, onset of analgesia was noted. Post-operatively, duration of analgesia was assessed using the observational pain scale, duration of sedation was assessed using sedation score and the duration of motor block was assessed using modified bromage scale. **RESULTS:** The onset of action in Group I (Bupivacaine) and II (Ropivacaine) was  $7.06\pm 0.69$ mins and  $6.5\pm 0.73$ mins respectively. The duration of analgesia was  $477.5\pm 39.01$ mins in group I (Bupivacaine) and  $437\pm 23.21$ mins in group II (Ropivacaine). **CONCLUSION:** There was no significant difference in the onset of action, duration of sedation and vital parameters between the two groups. Bupivacaine with Clonidine produced longer duration of analgesia compared to Ropivacaine with Clonidine. Hence 0.25% Bupivacaine  $0.5\text{ml}/\text{kg}$  with Clonidine  $1\mu\text{g}/\text{kg}$  is a better choice than 0.25% Ropivacaine  $0.5\text{ml}/\text{kg}$  with Clonidine  $1\mu\text{g}/\text{kg}$  for short surgical procedures like circumcision.

**KEYWORDS:** Caudal block, Clonidine, Bupivacaine, Ropivacaine, Circumcision.

**INTRODUCTION:** Historically, children have been under treated for pain because of the wrong notion that they neither suffer nor feel pain or respond to or remember the painful experiences to the same degree as adults did.<sup>1</sup> It is now established that newborn infants, even preterm, can appreciate pain and react to it with tachycardia, hypertension and neuro endocrine response.<sup>2</sup>

Post-operative pain relief in children is challenging. Regional anaesthetic techniques reduce the overall intra-operative requirement of both inhaled and intravenous anaesthetic agents and allow

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more rapid return of consciousness while providing effective post-operative pain relief with minimal sedation.<sup>3</sup>

Caudal epidural block is one of the oldest and the most popular regional block performed in paediatric anaesthesia.<sup>4</sup> It provides excellent intra-operative and post-operative analgesia in patients undergoing short surgical procedures below the umbilicus.<sup>5</sup>

Bupivacaine and Ropivacaine are the long acting amide local anaesthetics used for paediatric caudal block with various concentrations ranging from 0.125% to 0.5% and 0.2% to 0.75% respectively.<sup>6</sup> Profound motor block and systemic toxicity are the problems encountered with higher concentrations and volumes of local anaesthetics which can be minimized by reducing the concentration and dosage of the drugs.

To prolong the duration of action and to improve the quality of intra-operative and post-operative analgesia of local anaesthetics, various adjuvants have been used.

Clonidine, an  $\alpha_2$  adrenergic agonist has been used as an adjuvant using different dosages ranging from 0.5 $\mu$ g/kg to 3 $\mu$ g/kg in paediatric caudal block to improve the intra-operative and post-operative analgesia and to reduce the dose of local anaesthetics.<sup>7,8</sup>

Post-operative analgesia is of utmost importance in short surgical procedure like circumcision. Since motor blockade is not necessary, lower concentrations and volumes of local anaesthetics with additives can be used for intra operative and post-operative analgesia.

Hence, we have compared Bupivacaine 0.25% combined with 1 $\mu$ g/kg of clonidine and Ropivacaine 0.25% combined with 1 $\mu$ g/kg clonidine at a volume of 0.5ml/kg in children undergoing circumcision.

### AIMS AND OBJECTIVE:

1. To assess the safety and efficacy of 0.25% Bupivacaine and 0.25% Ropivacaine when Clonidine is added as an adjuvant in paediatric caudal block.
2. To compare the onset and duration of analgesia between the two study groups.

**MATERIALS AND METHODS:** After obtaining Institutional Ethical committee approval, this prospective randomized comparative study was conducted on 60 children in the age group 1- 6 years posted for circumcision after fulfilling both inclusion and exclusion criteria. They were divided into 2 groups; Group I received 0.25% bupivacaine 0.5ml/kg + 1 $\mu$ g/kg clonidine and Group II received 0.25% ropivacaine 0.5ml/kg + 1 $\mu$ g/kg clonidine. The study was conducted in the Department of Anaesthesiology with co-operation from the department of Paediatric Surgery at KIMS hospital and Research centre, Bangalore from December 2011 to September 2013. Sampling Method used was purposive sampling.

**STATISTICAL ANALYSIS:** Using Student's t test and chi-square test. P< 0.05 was considered statistically significant.

### INCLUSION CRITERIA:

1. ASA physical status-I.
2. Children between 1 to 6 years posted for circumcision.

**EXCLUSION CRITERIA:**

1. Body weight > 20 kgs.
2. Children with pre-existing neurological or systemic disorders.
3. Bleeding diathesis.
4. Infection at the site of block.
5. Abnormalities of the spine and or sacrum.
6. Allergy to local anaesthetics.
7. Patients on anticoagulants.

On admission, a thorough preoperative evaluation of the patient was done. A written informed consent was taken from the parents after explaining the procedure, its advantages and disadvantages. Basal vital parameters like heart rate, blood pressure and Oxygen saturation and ECG were recorded. Inj. Atropine 0.01mg/kg IV and Inj. Midazolam 0.03mg/kg IV were given as premedication. Patients were induced with Propofol 2mg/kg IV and maintained on spontaneous ventilation with Oxygen, Nitrous Oxide and Halothane.

The child was put in the left lateral position and under aseptic precautions the sacral hiatus was identified. Caudal epidural space was identified by using the loss of resistance technique and Whoosh test and the study drug was deposited after confirming negative aspiration for blood and CSF.

Intra-operatively, the onset of action of the study drug and duration of surgery were noted. Heart rate, blood pressure and SPO<sub>2</sub> were recorded before and after induction and every 5 mins thereafter till the surgery was over. Doses of Propofol if needed were noted.

Post-operatively, the vital parameters were recorded every 15 mins and also the duration of sedation, duration of analgesia, any complications like bradycardia, hypotension, dry mouth, retention of urine, respiratory depression, nausea, vomiting etc. were noted in each group.

The duration of analgesia was assessed by using the subjective pain scale in children more than 3years of age who can verbally express pain and observational pain scale for rest of the children who cannot verbally express pain. If the child complained of pain or if the pain score is  $\geq 3$ , the child received Paracetamol suppository 15mg/kg as a rescue analgesic. Sedation was assessed using Sedation score. Motor block was assessed by Modified Bromage scale.

**OBSERVATIONAL PAIN SCALE:**

CRITERION		SCORE
Heart rate	>10% to < 20% of preoperative	0
	20% to 30% of preoperative level	1
	>30% of preoperative level	2
Blood pressure	>10% to < 20% of preoperative level	0
	20 % to 30% of preoperative level	1
	>30% of preoperative level	2
Crying	Not crying	0
	Crying but responds to tender loving care	1
	Crying and does not respond to tender loving care	2

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**RESULTS:** In this randomized comparative study, the demographic parameters were comparable between the two study groups.

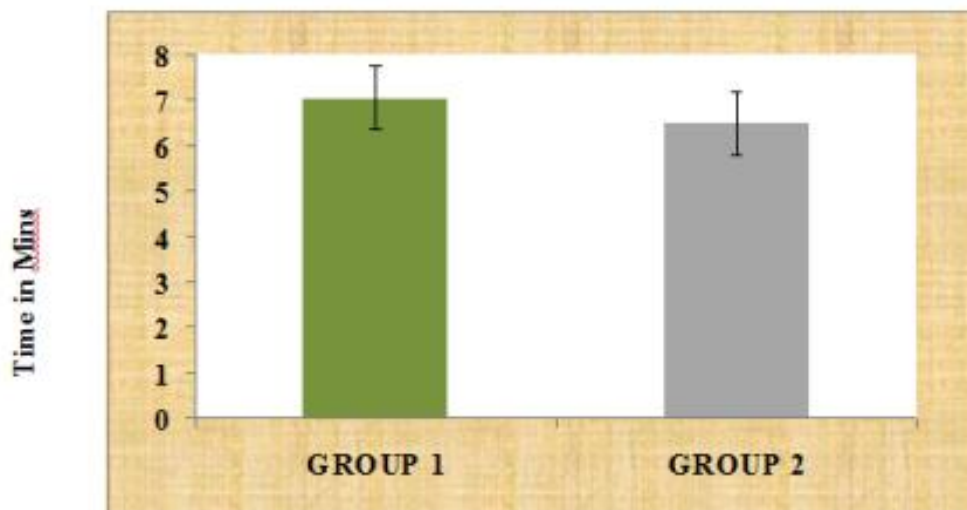
**ONSET OF ACTION:** The mean onset of action in group I was  $7.06 \pm 0.69$  mins and in group II was  $6.5 \pm 0.73$  mins as represented in Table 1 and Figure 1.

Onset of action In minutes	Group1	Group 2	P value
Mean	$7.06 \pm 0.69$	$6.5 \pm 0.73$	0.284

**Table 1: Mean Onset of action**

Group 1: 0.25% Bupivacaine 0.5 ml/kg +  $1 \mu\text{g}/\text{kg}$  clonidine.

Group 2: 0.25% Ropivacaine 0.5 ml/kg +  $1 \mu\text{g}/\text{kg}$  clonidine.



**FIGURE 1: Mean onset of action**

Group 1: 0.25% Bupivacaine 0.5 ml/kg +  $1 \mu\text{g}/\text{kg}$  clonidine.

Group 2: 0.25% Ropivacaine 0.5 ml/kg +  $1 \mu\text{g}/\text{kg}$  clonidine.

This was not statistically significant ( $p = 0.284$ ).

**DURATION OF SURGERY:** Mean duration of surgery in group I was  $26.83 \pm 4.04$  mins and in group II was  $26.33 \pm 3.45$  mins.

**INTRAOPERATIVE HEMODYNAMIC VARIATIONS: HEART RATE:** The mean basal heart rate in group I was  $129.37 \pm 9.16$ /min and in group II was  $132.72 \pm 11.86$ /min as shown in Table 2. At the end of 30 mins the mean heart rate in group I was  $105.16 \pm 7.44$ /min and in group II was  $105.25 \pm 6.36$ /min. There was a minimal fall in heart rate which was not statistically significant.

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HR (bpm)	GROUP 1	GROUP 2	P value
0 min	129.37+9.16	132.72+11.86	0.235
5min	124.23+8.52	126.86 +10.40	0.344
10min	119.66+8.57	121.58+ 9.47	0.325
15min	115.23+8.83	117+ 9.25	0.428
20min	110.86+8.47	112.44+ 8.46	0.567
25min	107.56+7.81	108.44+ 8.21	0.315
30min	105.16+7.44	105.25 +6.36	0.364

**Table 2: Comparison of heart rate in two groups of patients**

Group 1: 0.25% Bupivacaine 0.5 ml/kg +1µg/kg clonidine.

Group 2: 0.25% Ropivacaine 0.5 ml/kg +1µg/kg clonidine.

**MEAN ARTERIAL BLOOD PRESSURE:** The basal mean arterial pressure in group I was 69.56±3.52mmHg and in group II was 69.13±3.16mmHg. After 30mins it was 69.45±3.12mmHg and 69.13±3.54mmHg respectively (Table 3). This was not statistically significant.

MAP (mm Hg)	GROUP 1	GROUP 2	P value
0 min	69.56 +3.52	69.13 +3.16	0.362
5min	69.34 +3.75	69.02+ 3.24	0.343
10min	68.76 +2.89	68.23 +2.68	0.635
15min	69.60+ 3.24	69.14+ 3.25	0.346
20min	69.89+ 2.51	69.35 +3.27	0.641
25min	69.58 +2.87	69.34+ 3.68	0.451
30min	69.45 +3.12	69.13+ 3.54	0.678

**Table 3: Comparison of mean arterial blood pressure in two groups of patients**

Group 1: 0.25% Bupivacaine 0.5 ml/kg +1µg/kg clonidine.

Group 2: 0.25% Ropivacaine 0.5 ml/kg +1µg/kg clonidine.

**POST-OPERATIVE HEMODYNAMIC PARAMETERS:** Post operatively, there were no statistically significant variations in hemodynamic parameters in both the study groups.

**DURATION OF SEDATION:** The mean duration of sedation in group I and group II was 139.12±14.22mins and 138.66±13.21mins respectively as shown in Table 4.

Duration of sedation	Group 1	Group 2	P value
Mean	139.12+14.22	138.66+13.21	0.147

**Table 4: Duration of sedation**

Group 1: 0.25% Bupivacaine 0.5 ml/kg +1µg/kg clonidine.

Group 2: 0.25% Ropivacaine 0.5 ml/kg +1µg/kg clonidine.

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**DURATION OF ANALGESIA:** Table 5 represents the duration of analgesia in both the groups. In our study the mean duration of analgesia in group I was 477.5±39.01mins, whereas in group II the mean duration of analgesia was 437±23.21mins which was statistically significant. (p< 0.001)

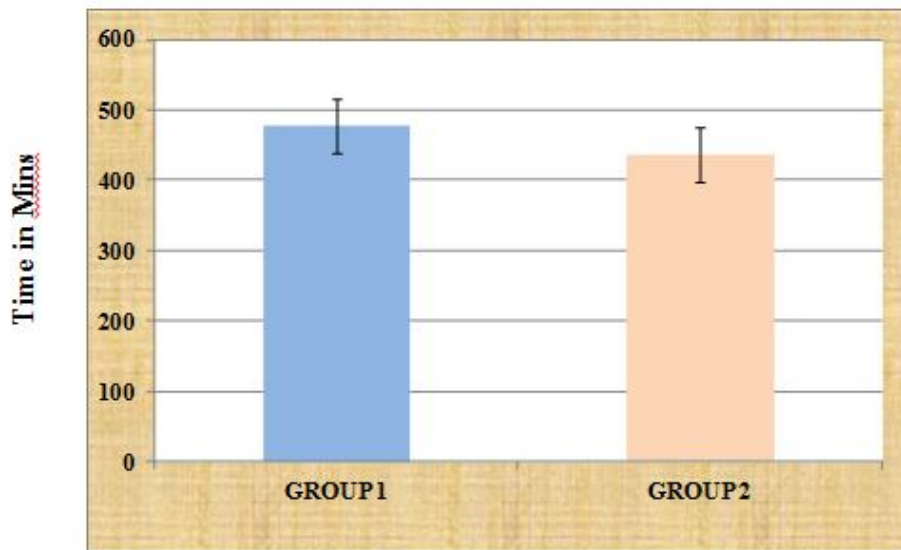
Duration of Analgesia	Group1	Group 2	P value
Mean	477.5 + 39.01	437+23.21	<0.001

**Table 5: Duration of analgesia**

The difference in duration of analgesia between the two groups is statistically significant (p<0.001).

Group 1: 0.25% Bupivacaine 0.5 ml/kg +1µg/kg clonidine.

Group 2: 0.25% Ropivacaine 0.5 ml/kg +1µg/kg clonidine.



**FIGURE 2: Duration of analgesia**

Group 1: 0.25% Bupivacaine 0.5 ml/kg +1µg/kg clonidine.

Group 2: 0.25% Ropivacaine 0.5 ml/kg +1µg/kg clonidine.

**COMPLICATIONS:** In our study, only one case (3.3%) in group I had retention of urine for >12hrs which was not statistically significant.

**DISCUSSION:** Circumcision can be performed under various anaesthetic techniques like General anaesthesia, Neuraxial blocks and Regional local blocks.

The origin of pediatric regional anaesthesia goes back to 1899 when August Bier, the father of regional anaesthesia, studied the Cocainization of spinal cord in a 11 year old boy<sup>9</sup>. Regional anaesthesia produces excellent postoperative analgesia and attenuation of the stress response in infants and children.

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The advantages of regional anaesthesia are that it provides complete block of sensory transmission, hence offers complete pain relief and it can be extended to the post-operative period.<sup>10</sup>

In our study, we included children between 1- 6 years of age as there is difficulty in identifying caudal epidural space in children greater than 7 years due to the fusion of sacral vertebrae and reduction in the size of sacral hiatus.<sup>11</sup>

Bernard et al<sup>12</sup> in 1989 observed high failure rates in children above 7 years of age.

The volume of local anaesthetic required is directly proportional to the weight, larger volume of the drug increases the cephalad spread leading to higher levels of block.<sup>12</sup> Hence we have included children weighing less than 20 kgs in our study. Our study can be correlated with Constant et al<sup>13</sup> 1998 who studied the efficacy of caudal blockade in children weighing less than 25 Kgs.

Onset of analgesia differs with various local anaesthetics, adjuvants and different induction methods used. In our study the mean onset of action was 7.1mins in group I and 6.5mins in group II.

The onset of action observed by Locatelli et al<sup>14</sup> in 2004 was 8mins in those given caudal Bupivacaine 0.25% and Levobupivacaine 0.25%, and 7 mins in those given Ropivacaine 0.25% which is in par with our study.

In contrast to our study, Ivani et al<sup>15</sup> in 2000 observed the onset of action as 10min for those given caudal Ropivacaine 0.2% without adjuvant and 9 min for those given Clonidine 2µg/kg as adjuvant. They observed longer onset of action as the concentration of Ropivacaine used was 0.2%.

Different authors have adopted different scales to assess pain. Some methods are easy and some are difficult to assess. We have chosen the subjective pain scale for children aged more than three years of age who can verbally express pain and observational pain scale for children less than three years of age who cannot verbally express pain.

The duration of analgesia depends on the type of local anesthetics used and the concentration of the adjuvant used.

In our study, the mean duration of analgesia was 477.50±39.01mins in group I, whereas in group II the mean duration was 437.0±23.21mins.

In 1994 Lee et al<sup>16</sup> found the duration of caudal analgesia with 0.25% Bupivacaine 1ml/kg as 312mins and with Clonidine 2µg/kg as 588mins. In this study all children received morphine 0.2mg/kg IM as premedication which could have influenced the duration of analgesia.

In 2004 Hansen et al<sup>5</sup> observed the time to first analgesic dose after caudal deposition of the drug was 450mins in those who received Clonidine 2µg/kg as an adjuvant to 0.25% Bupivacaine 0.5ml/kg. In contrast, we observed a similar duration of analgesia, where we have used half the dose of Clonidine that they have used.

In 2005 Upadhyay et al<sup>17</sup> studied 50 children undergoing elective lower abdominal and lower limb surgeries who received 0.25% Bupivacaine 0.75ml/kg alone and in combination with low dose Clonidine 1µg/kg caudally. The duration of analgesia was 10.3hrs in the Clonidine group. This is in contrast to our study, where the duration of analgesia is comparatively less even though the dose of Clonidine used is same.

Different local anesthetics and adjuvants with different concentrations and volumes used for caudal block, drugs used for pre medication and rescue analgesia, various methods to assess pain and statistical analysis may all account for the variability in the duration of analgesia.

In our study, sedation was assessed using an objective score based on eye opening. In our study the mean duration of sedation in group I was 139.12+/-14.22mins and group II was 138.66 +/-13.21mins.

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In a study conducted by S. J. Bajwa et al<sup>18</sup> in 2010 mean duration of sedation was 2.68 +/- 0.56hrs in 0.25 % Ropivacaine group and 2.86 +/- 0.52hrs in 0.25% Ropivacaine and Clonidine (2µ/kg) group which is similar to our study where we have used 1microgram/kg of Clonidine.

In contrast to our study, Lee et al<sup>16</sup> in 1994 observed the duration of sedation as 546mins in those given caudal Clonidine 2µg/kg as adjuvant and 348mins for plain Bupivacaine 0.25% 1ml/kg.

The longer duration of sedation in these cases may be due to the administration of oral Trimeprazine and Morphine IM as premedicants.

In our study, we found no motor blockade in both the groups which was assessed by using the Modified Bromage scale.

Our results correlated with the work of G.Ivani, et al<sup>19</sup> who compared Ropivacaine 0.2% and Bupivacaine 0.25% for caudal analgesia in children in 1998 and demonstrated no motor blockade in either group.

Arpita laha et al<sup>20</sup> in the year 2012 compared the quality of analgesia between Ropivacaine 0.2% 1ml/kg alone and Ropivacaine 0.2% 1ml/kg with Clonidine 2microgram/kg for paediatric caudal block. They did not observe any significant difference in mean heart rate, SBP, DBP between the two groups.

In our study, there was a marginal fall in mean heart rate intra operatively which was not statistically significant. No significant difference in heart rate, SBP, DBP was noted between the two study groups post operatively.

El Hennaway<sup>21</sup> in 2009 observed postoperative nausea and vomiting and urinary retention as side effects in those given caudal Clonidine as an adjuvant. Archna et al<sup>22</sup> in 2009 observed no side effects with the use of Bupivacaine 0.25% and 2µg/kg of Clonidine caudally as an adjuvant.

In our study, we observed 1 case of urinary retention (3.3%) in group I, as complication.

The complications observed in many studies are within the acceptable range.

**CONCLUSION: OUR OBSERVATIONS FROM THE STUDY ARE:** There was no significant difference in the onset of action, duration of sedation and vital parameters between the two groups. With the doses and concentrations of the drugs we used, no motor blockade and no significant complications were observed. Bupivacaine with Clonidine produced longer duration of analgesia compared to Ropivacaine with Clonidine.

Hence 0.25% Bupivacaine 0.5ml/kg with Clonidine 1µg/kg is a better choice than 0.25% Ropivacaine 0.5ml/kg with Clonidine 1µg/kg for short surgical procedures like circumcision.

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