



**ORIGINAL RESEARCH PAPER**

**Anesthesiology**

**COMPARATIVE EVALUATION OF DIFFERENT DOSAGE OF CLONIDINE WITH ROPIVACAINE 0.25% IN CAUDAL BLOCK FOR POSTOPERATIVE ANALGESIA IN PAEDIATRIC PATIENTS**

**KEY WORDS:** Ropivacaine, analgesia,caudal block,paediatric patients.

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**ABSTRACT**

**Background:** Caudal block is the most effective and most prevalent form of regional block in children, suitable especially for infra-umbilical surgeries like abdominal, perineal and lower limb surgeries, where it can provide intra operative as well as post-operative analgesia. Aim was to evaluate and compare the efficacy of different dosage of clonidine (1µg/kg and 2µg/kg B.W.) with ropivacaine(0.25%)in caudal block for paediatric patients. **Materials & method:** 90 paediatric patients of ASA grade 1 and 2 of age group 1-6 years of either sex scheduled for elective infra-umbilical surgeries divided into three groups A, B, and C . **Group A (control group) (n=30)** : 0.25%ropivacaine hydrochloride(1ml/kg) B.W. **Group B (n=30)** : 0.25% ropivacaine hydrochloride(1ml/kg)+inj.clonidine hydrochloride 1µg/kg B.W . **Group C (n=30)** : 0.25%ropivacaine hydrochloride(1ml/kg) + inj.Clonidine hydrochloride 2µg/kg B.W. Caudal block was given and Patients were observed for post operative analgesia using FLACC scores. **Results:** Clonidine 2µg/kg BW with ropivacaine 0.25% for caudal block provide much longer duration of post operative analgesia as compared to clonidine 1µg/kg BW with ropivacaine 0.25% (13 hrs. as compared to 11 hrs.). **Conclusion:** Addition of clonidine (1µg/kg BW to2µg/kg BW) with ropivacaine 0.25% for caudal block in children significantly prolongs the duration of post operative analgesia (11-13 hrs.).

**Introduction**

The International Association for the study of pain defines pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage <sup>1</sup>”. Pain perception in children is complex and often difficult to assess. Children suffer post-operative pain in the same way as adults; the main difference is that factors such as fear and anxiety can further exaggerate physical pain in children. However, in spite of its frequency, pain in infants, children, and adolescents is often underestimated and under treated. It has also been shown that infants and children, who experience pain in early life, show long-term changes in terms of pain perception and related behaviours<sup>2-4</sup>.

The greatest advance in paediatric pain medicine is the recognition that untreated pain is a significant cause of morbidity and mortality after surgical trauma<sup>5</sup>. Regional blocks provide excellent post-operative analgesia and attenuation of stress response in children. It is safe, easy to perform and cost effective. Caudal block is the most effective and most prevalent form of regional block in children, suitable especially for infra-umbilical surgeries like abdominal, perineal and lower limb surgeries, where it can provide intra operative as well as post-operative analgesia.

**Aims & Objective**

Aim was to evaluate and compare the efficacy of different dosage of clonidine (1µg/kg and 2µg/kg B.W.) with ropivacaine(0.25%)in caudal block for paediatric patients.

**Materials & method**

After getting clearance from Institutional Ethics Committee (IEC), 90 paediatrics patients with ASA grade I and II, of age group 1-6 yr of either sex scheduled for elective infra-umbilical surgeries were selected for the study.

Those who were excluded from the study:

1. History of allergic reactions to local anaesthetics and clonidine.
2. Local infection of the caudal area.
3. Bleeding diathesis.
4. Sacral bone abnormalities.
5. Spina bifida.

A thorough preoperative evaluation was done including history, general physical examination, systemic examination, airway assessment and spine. The patients were randomly allocated into three groups A, B, and C of 30 each.

**Group A (control group) (n=30)** : 0.25%ropivacaine hydrochloride(1ml/kg) B.W.

**Group B (n=30)** : 0.25% ropivacaine hydrochloride (1ml/kg)+inj.clonidine hydrochloride 1µg/kg B.W .

**Group C (n=30)** : 0.25%ropivacaine hydrochloride(1ml/kg) + inj.Clonidine hydrochloride 2µg/kg B.W.

Once the child was brought to the operation theatre table, baseline value of heart rate, blood pressure, electrocardiogram and spo<sub>2</sub>were recorded before induction. Patients under GA was given caudal block. After caudal block was performed all the vitals parameter were recorded again.Monitoring was performed continuously and data were recorded at every 15min intervals till the end of surgery. Block was considered adequate when there was no increase in heart rate and systolic blood pressure by 30%, after surgical incision compared to pre-operative values.At the end of surgery anaesthesia was reversed Once the vitals were stable and the child was awake, the child was shifted in to the postoperative recovery room and monitored for 2 hours with spo<sub>2</sub>,non invasive blood pressure and heart rate.After that child was shifted to the ward.Any other complications were also noted.

Post-operative analgesia was assessed by using the paediatric observational FLACC (F– Face, L– Leg, A– Activity, C–Cry, C– Consolability)pain scale which was first put forward by Merkelet al (1997).

**TABLE II - FLACC PAIN SCALE**

Category	Scoring		
	0	1	2
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested	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; distractable	Difficult to Console

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

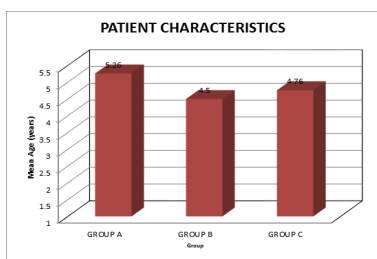
The time from arrival in the post anaesthesia care unit to the first time the FLACC score was more than 4 was recorded and noted as the duration of adequate caudal analgesia. In the post anaesthesia care unit, the necessity for rescue medicine was decided by the pain score. Rescue medication was administered when the FLACC score was  $\geq 4$ . 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 medication given and the time to first administration of rescue medication were also noted.

**Result**

**TABLE I - PATIENT CHARACTERISTICS**

S.No.	Patients Characteristics	GROUP A (control group)	GROUP B	GROUP C	p-value
1	AGE (yrs)	5.26 $\pm$ 0.868	4.5 $\pm$ 1.613	4.76 $\pm$ 1.430	0.08

Table 1: Mean age of three groups were comparable and the difference in age was statistically insignificant. (P value >0.05)



**TABLE II - DURATION OF SURGERY**

Duration of Surgery (mins)	GROUP A	GROUP B	GROUP C	p value
	38.16 $\pm$ 6.628	38.833 $\pm$ 6.90	37.166 $\pm$ 5.200	0.589

Table 2 : The above table shows that the mean duration of surgery in Group A was 38.16 $\pm$ 6.62 min, in Group B was 38.83 $\pm$ 6.90 min and in Group C was 37.16 $\pm$ 5.20 min, which was comparable among all the three groups

**TABLE III - DURATION OF ANALGESIA**

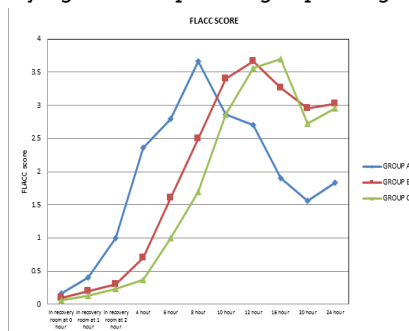
Duration of Analgesia (in hours)	GROUP A	GROUP B	GROUP C	p value
	7.73 $\pm$ 1.81	11.2 $\pm$ 2.65	13.93 $\pm$ 3.73	<0.0001

**TABLE 3:** The above table shows that the mean duration of analgesia in Group A was 7.73 $\pm$ 1.81 hour, in Group B was 11.2 $\pm$ 2.65 hour and in Group C was 13.93 $\pm$ 3.73 hour, which was clinically as well as statistically significant in all the three groups.

**TABLE IV - COMPARISON OF FLACC SCORE IN THREE GROUPS**

S.N o.	Time Interval of FLACC SCORE	GROU P A	GROU P B	GROU P C	p-value		
					AVs B	AVs C	B Vs C
1	In recovery room at 0 hour	0.16 $\pm$ 0.37	0.1 $\pm$ 0.30	0.06 $\pm$ 0.25	0.460	0.207	0.582
2	In recovery room at 1 hour	0.4 $\pm$ 0.85	0.2 $\pm$ 0.40	0.13 $\pm$ 0.34	0.251	0.118	0.493
3	In recovery room at 2 hour	1 $\pm$ 1.17	0.3 $\pm$ 0.65	0.23 $\pm$ 0.37	0.005	0.0012	0.612
4	4 hours after surgery	2.36 $\pm$ 1.18	0.7 $\pm$ 0.79	0.36 $\pm$ 0.49	<0.0001	<0.0001	0.05
5	6 hours after surgery	2.8 $\pm$ 1.21	1.6 $\pm$ 1.19	1.1 $\pm$ 1.07	0.0003	<0.0001	0.05
6	8 hours after surgery	3.66 $\pm$ 1.56	2.5 $\pm$ 1.25	1.7 $\pm$ 1.57	0.0024	<0.0001	0.038
7	10 hours after surgery	2.86 $\pm$ 1.33	3.4 $\pm$ 1.19	2.86 $\pm$ 1.22	0.1031	>0.99	0.088
8	12 hours after surgery	2.7 $\pm$ 1.55	3.66 $\pm$ 1.24	3.56 $\pm$ 1.67	0.010	0.0439	0.793
9	16 hours after surgery	1.9 $\pm$ 1.44	3.26 $\pm$ 1.17	3.7 $\pm$ 1.57	0.0002	<0.0001	0.225
10	20 hours after surgery	1.56 $\pm$ 0.85	2.96 $\pm$ 0.18	2.73 $\pm$ 0.82	<0.0001	0.9941	0.142
11	24 hours after surgery	1.83 $\pm$ 0.59	3.03 $\pm$ 0.18	2.96 $\pm$ 0.18	<0.0001	<0.0001	0.141

Table 4: The above table shows mean FLACC SCORE at different time intervals. FLACC in group A was found to be significantly higher as compared to group B and group C



**Discussion**

Caudal epidural analgesia is one of the most popular and commonly performed regional blocks in paediatric anaesthesia. It is a reliable and safe technique that can be used with general anaesthesia for intra- and postoperative analgesia in patients undergoing abdominal and lower limb surgery. Furthermore, it is easy to perform in younger children. The main disadvantage of caudal block is the short duration of action after a single injection of local anaesthetic solution. Prolongation of caudal analgesia using a 'single-shot' technique has also been achieved by the addition of various adjuvants. The use of caudal opioids seems to have been superseded by clonidine and dexmedetomidine. The addition of clonidine 1  $\mu$ g/kg and 2  $\mu$ g/kg B.W. to plain bupivacaine 0.25% can extend the duration of 'single-shot' caudal injections with minimal risk of side-effects.

The main interest of our study was compare and evaluate the efficacy of different dosage of clonidine (1µg/kg and 2µg/kg B.W.) with ropivacaine (0.25%) in caudal block for postoperative analgesia in paediatric patients.

In our study 90 patients were randomly allocated into three groups A, B, and C of 30 each. In our study the mean durations of postoperative analgesia was 7.73±1.81 hours in group A, 11.2±2.65 hours in group B and 13.93±3.73 hours in group C. There was a significant difference in the duration of analgesia between three groups (Group A v/s Group B, Group A v/s Group C, Group B v/s Group C). The duration of analgesia was longest in group C (clonidine 2µg/kg B.W.) as compared to group A (0.25% ropivacaine) and group B (clonidine 1µg/kg B.W.) (p< 0.05). Similar results were also observed by **Klimschaetal**<sup>7</sup> (1998) who studied the effectiveness of caudal clonidine in small children. The addition of clonidine 1-2 g/kg to bupivacaine 0.25% significantly prolonged the mean duration of analgesia as compared with bupivacaine alone or bupivacaine plus epinephrine 5 g/ml (P<0.05). The findings of our study are almost similar to the above study as post-operative analgesia was significantly prolonged in the patients receiving clonidine(1-2 g/kg) as an adjuvant.

**Sukhminder J Bajwa et al**<sup>8</sup> (2010) performed the caudal block using ropivacaine 0.25% (Group I) and ropivacaine 0.25% and clonidine 2 g/kg (Group II) and found the prolonged duration of analgesia in group (II) 13.4 ± 3.4 hr. We also observed the similar result.

**S Balasubramanian et al**<sup>9</sup> (2016) studied the two groups were compare ropivacaine ® (0.1%, 1 ml/kg) or ropivacaine with clonidine (RC) (0.1%, 1 ml/kg with 1µg/kg) for caudal block in children. The duration of analgesia was significantly prolonged in group RC with a mean duration of analgesia for 480 min. our result are similar to the above study.

**Jamali et al**<sup>10</sup> (1994) who compared the analgesic effects of clonidine, epinephrine along with 1 ml/kg of 0.25% bupivacaine and found that the duration of analgesia was significantly longer with clonidine (987±573 min).

**Parameswari A et al**<sup>11</sup> (2010) concluded that addition of clonidine 1µg/kg to 1 ml/kg 0.25% bupivacaine significantly increased the duration of analgesia from 288.7±259.1 min to 593.4±423.3 min.

**Upadhyay et al**<sup>12</sup> (2005) concluded that the addition of clonidine to bupivacaine significantly increases the duration of analgesia (p<0.05) from 5.59±0.633 hours in control group to 10.333±0.836 hours in clonidine group.

**Conclusion**

Addition of clonidine (1µg/kg BW to 2µg/kg BW) with ropivacaine 0.25% for caudal block in children significantly prolongs the duration of post operative analgesia (11-13 hrs.). And Clonidine 2µg/kg BW with ropivacaine 0.25% for caudal block provide much longer duration of post operative analgesia as compared to clonidine 1µg/kg BW with ropivacaine 0.25% (13 hrs. as compared to 11 hrs.).

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