

Effectiveness of Clonidine as an Adjuvant to Ropivacaine in Caudal Epidural Anesthesia for Infraumbilical Surgery in Children

Dr. Sudhakar Dwivedi¹, Dr. Subhash Kumar Agrawal², Dr. Avtar Singh Yadav³, Dr. Hansraj Baghel⁴

¹Professor and head, ²Associate Professor, ³Professor, ⁴Assistant Professor

Department of Anaesthesia, Shyam Shah Medical College, Rewa, Madhya Pradesh

***Corresponding Author:**

Dr. Subhash Kumar Agrawal

Associate Professor, Department of Anaesthesia, Shyam Shah Medical College, Rewa, Madhya Pradesh

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ABSTRACT

Aims and Objective: To evaluate the efficacy of clonidine 1µg/kg B.W. with Ropivacaine (0.25%) in caudal block for postoperative analgesia in paediatric patients.

Material and methods: The study was conducted on 60 paediatric ASA grade I and II patients of age group 1-6 years of either sex scheduled for elective infra-umbilical surgeries. Group A (control group) (n=30) received 0.25% Ropivacaine hydrochloride (1ml/kg) B.W. and Group B (n=30) received 0.25% Ropivacaine hydrochloride (1ml/kg) along with inj. Clonidine hydrochloride 1µg/kg B.W.

Result and Conclusion: Addition of clonidine (1µg/kg BW) with Ropivacaine 0.25% for caudal block in children significantly prolongs the duration of post operative analgesia.

Keywords: Caudal block, Ropivacaine, Clonidine

INTRODUCTION

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 behaviours¹.

The greatest advance in paediatric pain medicine is the recognition that untreated pain is a significant cause of morbidity and mortality after surgical trauma².

Several advances in developmental neurobiology and pharmacology, research of new analgesics in the last two decades have helped the paediatric

anaesthesiologist in managing pain in children more efficiently. Regional blocks provide excellent post-operative analgesia and attenuation of stress response in children. It is safe, easy to perform and cost effective.

Caudal anaesthesia is the oldest, and at present the most common epidural technique in children¹⁵. Single dose injection in caudal space is the most effective and most prevalent form of regional block in children³. This method is easy, reliable and safe especially in children weighing less than 20 kg. Caudal block is 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. Caudal block is a simple method with low rate of complications⁴.

Clonidine is an imidazoline derivative with α_2 agonistic activity. After its administration into the

subarachnoid or epidural space, clonidine provides a substantial anti-nociceptive effect by acting on the α_2 receptors in the dorsal horn of spinal cord and brain stem nuclei implicated in pain. Although in adults clonidine is used primarily to achieve haemodynamic stability and blunt the stress response, in children the primary focus is on the quality of recovery from anaesthesia. In both age groups, clonidine is used for prolongation of a regional block ^{5,6}. A considerable amount of clinical experience with clonidine in caudal block now exists in both adults and children.

MATERIAL AND METHODS

The present study was a prospective randomized study and was conducted after obtaining informed consent and approval of the institutional ethics committee, on 60 patients of ASA I and II of age group 1-6 yrs of either sex who were admitted for elective infra umbilical surgeries. The patients were randomly divided into two groups:-

Group A (control group) (n=30) received 0.25% Ropivacaine hydrochloride (1ml/kg) B.W.

Group B (n=30) received 0.25% Ropivacaine hydrochloride (1ml/kg) along with inj. Clonidine hydrochloride 1 μ g/kg B.W.

Proper preanesthetic check up of all patients was done. With all standard premedication and monitoring child was brought to the operation theatre table and baseline value of heart rate, blood pressure, electrocardiogram and spo₂ were recorded before induction.

Induction of anaesthesia was achieved with inj. Propofol 2 mg/kg B.W. intravenously and inj. succinylcholine 1mg/kg B.W. intravenously along with 1-2% sevoflurane with oxygen using Jackson

Rees circuit. Patients were intubated with an appropriate sized endo tracheal tube, bilateral air entry checked and tube fixed with stretchoplast. Anaesthesia was maintained with oxygen, nitrous oxide, sevoflurane and intermittent dosage of inj. Atracurium besylate intravenously.

The patient was placed in lateral decubitus position with both hip flexed, and the sacral hiatus was palpated. After under all aseptic preparation, a 25 G needle caudal block was performed and all the vitals parameter were recorded again. Heart rate, electrocardiogram, systolic and diastolic blood pressure, and peripheral oxygen saturation (spo₂) were monitored intra-operatively. Monitoring was performed continuously and data were recorded at every 15min intervals till the end of surgery.

If the block was failed child required additional supplemental doses of ketamine for analgesia, the case was excluded from the study and supplemental analgesia in the form of further doses of ketamine was given.

At the end of surgery anaesthesia was reversed with inj. neostigmine 0.08mg/kg B.W. intravenously and inj. glycopyrolate 0.01mg/kg B.W. intravenously. Once the vitals were stable and the child was awake, the child was shifted in to the postoperative recovery room. After arrival to the recovery room, the child was monitored for 2 hours with spo₂, 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** ⁷.

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; distractible	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 ≥ 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.

In postoperative period the level of sedation was assessed by using Ramsay Sedation Scale (RSS).

RAMSAY SEDATION SCALE

Scale	Response
1	Anxious, agitated or restless or both
2	Cooperative, oriented, tranquil
3	Responding to commands only
4	Brisk response to light glabellar tap
5	Sluggish response to light glabellar tap
6	No response to light glabellar tap

All the observation were tabulated and statistical analysis was done with the help of ANNOVA and Student 't' test. p value (<0.05) were considered statistically significant.

OBSERVATIONS AND RESULT

In our study most of demographic profile was similar in both of the groups. **Table-1** shows that the maximum number of patients were operated for herniotomy and suprapubic cystolithotomy in both the groups. **Table -2** shows that the mean duration of surgery in Group A was 38.16 ± 6.62 min, in Group B was 38.83 ± 6.90 min which was comparable. **Table -**

3 shows that the mean duration of analgesia in Group A was 7.73 ± 1.81 hour, in Group B was 11.2 ± 2.65 hour which was clinically as well as statistically significant in between the groups. **Table - 4** shows mean FLACC SCORE at different time intervals. FLACC in group A was found to be significantly higher as compared to group B. **Table -5** shows the mean sedation scores at different time of interval. Sedation scores in group A was found to be statistically significant lower as compared to group B at different time intervals. **Table - 6** shows side effects and complication in both groups. Only three patient had shivering in group A.

TABLE - 1: DISTRIBUTION OF PATIENTS ACCORDING TO TYPE OF SURGERY

Type of Surgery	Group A	Group B
Rectal Polypectomy	3	1
Inguinal Herniotomy	15	17
SuprapubicCystolithotomy	8	9
Others	4	3

TABLE- 2: DURATION OF SURGERY

Duration of Surgery (mins)	GROUP A	GROUP B	p value
	38.16 ± 6.628	38.833 ± 6.90	0.589

TABLE -3: DURATION OF ANALGESIA

Duration of Analgesia (in hours)	GROUP A	GROUP B	p value
	7.73±1.81	11.2 ± 2.65	<0.0001

TABLE - 4: COMPARISON OF FLACC SCORES

S.No.	Time Interval of FLACC SCORE	GROUP A	GROUP B	p-value
1	In recovery room at 0 hour	0.16±0.37	0.1±0.30	0.460
2	In recovery room at 1 hour	0.4±0.85	0.2±0.40	0.251
3	In recovery room at 2 hour	1±1.17	0.3±0.65	0.005
4	4 hours after surgery	2.36±1.18	0.7±0.79	<0.0001
5	6 hours after surgery	2.8±1.21	1.6±1.19	0.0003
6	8 hours after surgery	3.66±1.56	2.5±1.25	0.0024
7	10 hours after surgery	2.86±1.33	3.4±1.19	0.1031
8	12 hours after surgery	2.7±1.55	3.66±1.24	0.010
9	16 hours after surgery	1.9±1.44	3.26±1.17	0.0002
10	20 hours after surgery	1.56±0.85	2.96±0.18	<0.0001
11	24 hours after surgery	1.83±0.59	3.03±0.18	<0.0001

TABLE -5: COMPARISON OF SEDATION SCORES

S.No.	Time Interval of sedation Score	GROUP A	GROUP B	p-value
1	In recovery room at 0 hour	1.8±1.34	2.83±1.66	0.010
2	In recovery room at 1 hour	1.4±0.72	1.9±0.92	0.022
3	In recovery room at 2 hour	1.03±0.18	1.33±0.60	0.011
4	4 hours after surgery	1±0.0	1±0.0	-

5	6 hours after surgery	1±0.0	1±0.0	-
6	8 hours after surgery	1±0.0	1±0.0	-
7	10 hours after surgery	1±0.0	1±0.0	-
8	12 hours after surgery	1±0.0	1±0.0	-
9	16 hours after surgery	1±0.0	1±0.0	-
10	20 hours after surgery	1±0.0	1±0.0	-
11	24 hours after surgery	1±0.0	1±0.0	-

TABLE - 6: SIDE EFFECTS AND COMPLICATIONS

Complications	Group A		Group B	
	No.	%	No.	%
Nausea and vomiting	0	0	0	0
Hypotension	0	0	0	0
Bradycardia	0	0	0	0
Shivering	3	10	0	0
Dyspnoea	0	0	0	0
Respiratory depression	0	0	0	0

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. Ropivacaine has been shown to be suitable for caudal block in children. Its duration of action is similar to that of bupivacaine (in equivalent doses), but the motor block is slower in onset, less intense. Furthermore, Ropivacaine appears to cause less cardiac and central nervous system toxicity than bupivacaine. These newer agents seem promising prospects, particularly when extending the use of caudal analgesia into day-care surgery.¹⁹ Prolongation of caudal analgesia using a

'single-shot' technique has also been achieved by the addition of various adjuvants.

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

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. The statistical analysis of these result with the help of student 't' test revealed that there was a significant difference in the duration of analgesia between groups ($p < 0.0001$). Similar results were also observed by **Klimschaetal**⁸, **Sukhminder J Bajwa et al**⁹, **Manickam A et al**¹⁰ who studied the effectiveness of caudal clonidine in small children.

α2adrenoceptor agonists like clonidine, have been known to prolong the effects of local anaesthetics.

This has been explained by three possible mechanisms. First, clonidine blocks A δ and C fibres manifesting as an increase in K⁺ conductance in isolated neurons thus intensifying local anaesthetic conduction block. Secondly, clonidine may cause local vasoconstriction, thus decreasing local anaesthetic spread and removal around neural structures by action on post synaptic α_2 receptors. Thirdly, clonidine combined with spinal local anaesthetics or used in peripheral blocks intensifies and prolongs analgesia.¹¹

In our study, the mean sedation scores of all the three groups at the different time intervals of recovery room at 0,1,2,4, hours were 1.8 \pm 1.34, 1.4 \pm 0.72, 1.03 \pm 0.18, 1 \pm 0.0 in group A and 2.83 \pm 1.66, 1.9 \pm 0.92, 1.33 \pm 0.60, 1 \pm 0.0, in group B. More sedation score was found in group B, as compared to Group A which was statistically insignificant. Similar observation and result of sedation score was observed by LakM *et al*¹², Meghani Y *et al*¹³, Chatrath V *et al*¹⁴ have also found significant increase in the post-operative sedation scores.

Sedation may be beneficial in the paediatric population. Children who sleep in the immediate postoperative period are perceived as more comfortable by the families. Also it helps in better post-operative monitoring as such children are more cooperative and tolerate intravenous lines and monitors better.

In our study, the mean spo₂ (%) in all the groups before induction were 98.7 \pm 0.87 in group A and 98.66 \pm 0.95 in group B. Statistical analysis showed no variations in spo₂ with baseline in both the groups. Analysis of oxygen saturation values also showed no significant change, also there was no significant difference in HR, SBP, DBP between the groups.

Shivering was observed in three patients in group A while none of the patients in group B. Clonidine, probably acting through α_2 receptors, synchronously decreases the cold response threshold while slightly increasing the sweating threshold suggesting that it acts on the central thermoregulatory system rather than preventing shivering peripherally.

CONCLUSION

From the ongoing observations and discussion it can be concluded that Addition of clonidine 1 μ g/kg BW with Ropivacaine 0.25% for caudal block in children

significantly prolongs the duration of post operative analgesia 11-13 hrs, increase the time interval for the requirement of rescue analgesia.

clonidine 1 μ g/kg BW with Ropivacaine 0.25% also does not produce side effect and complication like respiratory depression, hypotension, bradycardia, nausea and vomiting, also an added advantage in the prevention of shivering when given as an adjuvant with local anaesthetics for caudal block

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