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COMPARATIVE STUDY OF DIFFERENT DOSAGE OF CLONIDINE WITH ROPIVACAINE IN CAUDAL BLOCK FOR POST OPERATIVE ANALGESIA IN PAEDIATRIC PATIENTS

Anaesthesiology

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ABSTRACT

Background And Aims: Pain perception in children, often goes undetected and undertreated. Caudal anaesthesia is the most commonly performed epidural technique in children. Single dose injection in caudal space is effective and most prevalent form of regional block especially in paediatrics, but addition of adjuncts might help in prolonging its action. The study was designed to evaluate and compare different doses of clonidine used as an adjunct to ropivacaine in caudal block **Materials and Methods:** The study design was prospective, randomized and double blind. Ninety patients were selected using total enumeration sampling technique and was randomized into three groups each containing thirty patients. **Results:** The mean duration of analgesia in group A, B and C were 7.72±1.8, 11.2±2.6 and 13.9±3.7 hours respectively. **Conclusion**: The addition of clonidine as an adjunct to 0.25% ropivacaine in caudal block significantly prolong the duration of postoperative analgesia. Furthermore, the clonidine when given at 2 µg/kg further prolongs its duration when compared to that is given at 1 µg/kg body weight as an adjunct to caudal anaesthesia.

KEYWORDS

Caudal block, ropivacaine, clonidine, duration of analgesia

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 [1]. Because of complexity of post-operative pain perception in children, coupled with fear and anxiety, it often goes undetected and undertreated. 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[2-4].

Recent advances have enabled the anaesthesiologists to manage 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.[5,6,7,8]

Caudal anaesthesia is the most commonly performed epidural technique in children[9]. Single dose injection in caudal space is effective and most prevalent form of regional block especially in children[10] weighing less than 20 kg, with low incidence of reported complications[11].

The main disadvantage of caudal block is its limited duration of action. However use of various adjuvants prolong caudal analgesia. Adrenaline prolongs the analgesic effects of lidocaine, but not of other long acting local anaesthetics. Opioids, as an adjunct carries with it a number of unpleasant side.effects, including that of late respiratory depression. The use of caudal opioids seems to have been superseded by clonidine and dexmedetomidine.

Clonidine is an imidazoline derivative with α_2 agonistic activity which after administration into the subarachnoid or epidural space, 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.

Thus, keeping these facts in mind, the present study was undertaken to evaluate and compare the efficacy of different dosage of clonidine with ropivacaine in caudal block for postoperative analgesia in paediatric patients

MATERIALS AND METHODS

A prospective, randomized and double blind study was conducted on paediatric patients of age group 1-6 years of either sex scheduled for elective infra-umbilical surgeries, during the period of (July 2015 to June2016) after obtaining approval from the hospital ethics committee. The objective of the study was

Objectives:

1. To compare the duration of analgesia among different groups.
2. To evaluate the efficacy of different dosage of clonidine (1µg/kg and2µg/kg B.W.) with ropivacaine (0.25%) in caudal block for post-operative analgesia in paediatric patients.

Inclusion Criteria

1. Patients of 1-6yrs of either sex scheduled for elective infra-umbilical surgeries under general anaesthesia.
2. ASA grade I and II.

Exclusion Criteria:

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.

Sample selection:

Ninety paediatric patients were selected by total enumeration sampling technique and randomly allocated into three groups, each containing thirty patients, by computer generated randomization table. Patients were blinded by sealed envelope technique and neither the anaesthesiologist nor the observer was kept aware of which drug was injected to which patient avoiding observer bias. Depending upon the drug dosage given for the caudal block, the three groups were defined as:

Group A (control group) (n=30)	0.25%ropivacaine hydrochloride(1ml/kg)
Group B (n=30)	0.25% ropivacaine hydrochloride (1ml/kg)+inj.clonidine hydrochloride 1µg/kg
Group C (n=30)	0.25%ropivacaine hydrochloride (1ml/kg) + inj. Clonidine hydrochloride 2µg/kg

Procedure:

After obtaining clearance from institutional ethics committee, a preoperative written informed consent was taken from the parents of the patients selected for the study**.** Before shifting the patient to operating room, inj. ondansetron 0.01mg/kg, inj. midazolam 0.05 mg/kg and inj. glycopyrrolate 0.01mg/kg, intravenously was administered as pre-medication to all the children.

Once the child was brought to the operation theatre table, baseline value of heart rate, blood pressure, electrocardiogram and spo_2 were recorded before induction.

Induction of anaesthesia was achieved intravenously with inj. Ketamine 2 mg/kg and inj. succinylcholine 1mg/kg along with 1-2% sevoflurane with oxygen using Jackson Rees circuit. Patient were intubated with an appropriate sized endotracheal tube, bilateral air entry checked and tube was secured. Anaesthesia was maintained with oxygen, nitrous oxide, Sevoflurane and intermittent intravenous dosage of inj. Atracurium besylate.

The patient was placed in lateral decubitus position with both hip flexed, and the sacral hiatus was palpated. Under all aseptic preparation, a 25G needle was advanced at a 45^0 angle cephalad until pop was felt as the needle pierces the sacrococcygeal ligament. The angle of the needle was then flattened and advanced.

Aspiration for blood and CSF was performed, and after confirmation of negative aspiration, anaesthetic drug was injected slowly. After completion of block the child was returned back to the supine position and ventilation continued. All the vitals parameter were recorded again and thereafter at 15 minutes interval

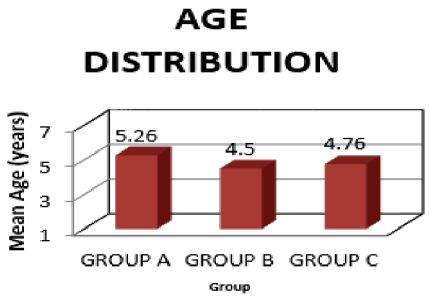
Effectiveness of the block was assessed by haemodynamic stability. No other narcotics, analgesics or sedatives were used intra-operatively.

- 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, reversal of neuromuscular block was done with intravenous combination of inj. neostigmine 0.08mg/kg and inj. glycopyrrolate 0.01mg/kg. 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. In absence of any post-operative complications, the child was shifted to the ward.
- Post-operative analgesia was assessed by using the paediatric observational FLACC, which was first put forward by Merkelet al[12] (1997), at 2 hours interval. The duration of caudal anaesthesia was defined as the interval between times of arrival in the post anaesthesia care unit to the recording of FLACC score of > 4.
- In the ward, 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.

Statistical analysis.

Data was analyzed by using descriptive and inferential statistics (Mean, SD, frequency percentage and independent 't' test), with the help of Graph Pad Prism. Results were represented using tables and graphs.

RESULTS:



n=90

Figure 1: Age distribution among three groups

Figure 1 shows that the mean age in Group A, Group B and Group C were 5.26 years, 4.5 years and 4.76 years respectively.

Table 1: Distribution of sex among three groups

n=90

Gender	Group A	Group B	Group C
	f (%)	f (%)	f (%)
Male	20 (66.7)	22 (73.3)	23 (76.7)
Female	10 (33.3)	8 (26.7)	7 (23.3)

Data represented in Table 1 shows that frequency distribution of male in Group A, group B and group C were 66.7%, 73.3% and 76.7% respectively whereas that for female in group a , Group B and Group C were 33.3%, 26.7% and 23.3 % respectively

Table 2: Mean duration of surgery in different groups

n=90

Parameter	Group A	Group B	Group C	P Value
	(Mean±SD)	(Mean±SD)	(Mean±SD)	
Duration of Surgery (min)	38.16±6.628	38.833±6.90	37.166±5.200	0.589

Data represented in Table 2 shows that the mean duration of surgery in Group A, Group B and Group C were 38.16±6.62 min, 38.83±6.90 min and 37.16±5.20 min respectively and was comparable among all the three groups.

Table 3: Comparison of duration of analgesia among different groups

n=90

Parameter	GROUPS					
	A	B	C	A vs B	A vs C	B vs C
Duration of Analgesia (in hours)	(Mean± SD)	(Mean ± SD	(Mean± SD	P value	P value	P value
	7.73±1.8	11.2 ± 2.6	13.9±3.7	<0.0001	<0.0001	<0.0018

Data represented in table 3 shows that the mean duration of analgesia in Group A, Group B and Group C were 7.73±1.81 hour, 11.2±2.65 hour and 13.93±3.73 hour respectively. The P value of Group A vs B, A vs C and B vs C were all statistically significant.

Table 4: Comparison of FLACC score among different groups

FLACC SCORE at different interval	GROUPS					
	A	B	C	A vs B	A vs C	B vs C
	Mean± SD)	(Mean± SD	(Mean± SD	P value	P value	P value
In recovery room at 0 hour	0.16±0.37	0.1±0.30	0.06±0.25	0.49	0.22	0.58
In recovery room at 2 hour	0.4±0.85	0.2±0.40	0.13±0.34	0.25	0.11	0.47
4 hours after surgery	0.5±1.17	0.3±0.65	0.23±0.37	0.42	0.23	0.61
6 hours after surgery	1.8±1.18	1.4±0.79	1.2±0.49	0.13	<0.01	0.56
8 hours after surgery	4.4±1.21	1.6±1.19	1±1.17	<0.001	<0.001	0.05
10 hours after surgery	4.1±1.56	2.5±1.25	1.7±1.57	<0.001	<0.001	0.03
12 hours after surgery	4.2±1.33	4.3±1.19	2.86±1.22	0.76	<0.001	<0.001
14 hours after surgery	4.1±1.55	4.0±1.24	4.2±1.67	0.78	0.81	0.60

Data represented in table 4 shows that FLACC score between Group A vs B & A vs C became statistically significant after 8 hours of surgery, indicating the prolongation of analgesic effect due to addition of clonidine in both group B & C whereas P value between B vs C became statistically significant at 12 hours of surgery indicating the longer duration of action in group C when compared to group B,

DISCUSSION:

Postoperative pain in paediatric patients frequently goes undiagnosed and hence undertreated. The widespread presence of fear and separation anxiety frequently adds on to this phenomenon. All these significant yet undetected issues encouraged the author to investigate in this field.

The demographic profile and the duration of the surgery was comparable in all the three groups that were incorporated in the study.

Caudal epidural analgesia is one of the most popular and commonly performed regional blocks in paediatrics and 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. But, the main disadvantage of caudal block is the short duration of action after a single injection of local anaesthetic solution. In addition to this, the main interest of the study was to compare and evaluate the efficacy of different dosage of clonidine (1µg/kg and 2µg/kg.) with ropivacaine (0.25%) in caudal block for postoperative analgesia in paediatric patients. As evident in our study, where duration of analgesia in group A (7.7 hours) was significantly lower when

compared to that of group B (11.2 hours) or C (13.9 hours).

Our findings were similar to that of Sukhminder J Bajwaet al[13] (2010) who performed the caudal block using ropivacaine 0.25% (Group I) and ropivacaine 0.25% and clonidine 2 µg/kg (Group II) and found the prolonged duration of analgesia in group (II) 13.4 ± 3.4 hr and to that of Upadhyayet al[14](2005) who 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:

Our study firmly establish the fact that addition of clonidine as an adjunct to 0.25% ropivacaine in caudal block significantly prolong the duration of postoperative analgesia. Furthermore, the clonidine when given at 2 µg/kg further prolongs its duration when compared to that is given at 1 µg/kg body weight as an adjunct to caudal anaesthesia.

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