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A Prospective Double Blind Study of Comparison of Postoperative Analgesic Efficacy of Caudal Ropivacaine Supplemented with Caudal or Intravenous Clonidine in Children Undergoing Subumblical Surgery.

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Abstract: *Caudal block is most popular regional anesthetic technique used in children. It provides excellent analgesia during surgery as well as in postoperative period in subumblical surgeries. In a randomised double blind study, 60 ASA I-II patients aged 2-8 years scheduled for Elective subumblical procedures were divided into two groups of 30 each patients. Group A received 1ml/kg of 0.2% ropivacaine in addition to 2 μg/kg of clonidine caudally and similar volume of normal saline intravenously and Group B received 1ml/kg of 0.2% ropivacaine and 2 μg/kg clonidine intravenously and simultaneously same volume of saline caudally. Hemodynamic parameters, duration of analgesia, pain scores using observational pain scoring (OPS), requirement of rescue analgesia, and various complications were recorded. The duration of analgesia in group B was 404 ± 196 minutes while in group A the duration was 428 ± 197 minutes. Maximum observational pain score (OPS) scores were comparable between the two groups. It was concluded that caudal or intravenous clonidine in the dose of 2μg/kg body weight as an additive to caudal block with ropivacaine (0.2% -1ml/kg) results in comparable analgesia and is safe and without any significant side effects.*

Keywords*: Caudal, Clonidine, Intravenous, Ropivacaine, Subumblical*

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I. Introduction

The provision of adequate analgesia is necessary after any surgery and it is all the more important in children [1]. There is a well defined pathway for the sensation of pain in the new-born infant. Nociception is associated with signs of distress even in new-born infants [2]. The density of nociceptive nerve endings in the skin of new-born infants is similar to or greater than that in adults [3, 4]. Under-treatment of postoperative pain even in the children and new-borns may trigger biochemical and physiologic stress response and cause impairments in pulmonary, cardiovascular, neuron-endocrine, gastrointestinal, immunological, and metabolic functions [1]. Pain after surgery is inevitable. Relieving pain has been the focus of continuing human effort. However, it has been recognized for some time that the management of acute pain, especially postoperative pain, has been consistently and systematically inadequate. If anything, the situation in children has been even worse, who have long been under medicated for acute pain [3]. Caudal block since its first description in 1933 for paediatric urological interventions has evolved to become the most popular regional anesthetic technique for use in children [5]. It provides excellent analgesia during surgery as well as during postoperative period in subumblical surgeries in children [6]. Ropivacaine hydrochloride is a member of the amide class of local anaesthetics and is supplied as the S-(-)-enantiomer. In vitro testing indicates that ropivacaine is comparable to (or slightly more potent than) bupivacaine in blocking sensory fibres and less active in blocking motor fibres. Clonidine produces analgesia without significant respiratory depression. The analgesic action of epidurally administered clonidine is due to stimulation of descending noradrenergic medullospinal pathways inhibiting the release of nociceptive neurotransmitters in the dorsal horn of spinal cord [7]. This randomised prospective controlled study was undertaken to compare the analgesic efficacy of caudal ropivacaine and caudal clonidine with caudal ropivacaine and intravenous clonidine for postoperative analgesia in children undergoing subumblical surgeries.

II. Material And Methods

This prospective, randomized, double blind study included 60 patients aged 2-8 years belonging to either ASA I or II class, undergoing elective below umbilical surgery. A proper approval from the institutional ethics committee was taken for the study. Preoperatively all the patients were clinically evaluated and investigated. The study protocol was explained to the parents and written informed consent was taken from them. All children had EMLA (prilocaine 2.5% and lidocaine 2.5%) applied to dorsum of both hands 1hr before

surgery. In the operation theatre after connecting the patient to the monitors, an intravenous line was established. Patients were induced with standard doses of thiopental (4 to 6mg/kg) + Atracurium (0.5mg/kg) to facilitate intubation and maintained on N2O in O2 plus 0.5-1% halothane as inhalational agent administered via LMA or ET tube. No intravenous or pre-rectal analgesic drugs were given to any patient intraoperatively. Patients were randomly allocated to one of the two groups of 30 patients each.

GROUP A: Received 1ml/kg of 0.2% ropivacaine hydrochloride in addition to 2µg/kg of clonidine caudally and similar volume of normal saline intravenously.

GROUP B: Received 1ml/kg of 0.2% ropivacaine hydrochloride and 2 µm/kg clonidine intravenously and simultaneously same volume of saline caudally.

A nurse not involved in study prepared the study medication. One syringe contained the diluted clonidine [15µg/ml] to give a dose of 2µg/k and the other contained same volume of normal saline. The caudal block was performed with the child positioned in left lateral position using an aseptic technique and a 22 gauge needle. After negative aspiration of blood and cerebrospinal fluid, ropivacaine 0.2 percent, 1ml/kg was injected. Simultaneously, the content of second syringe, containing the same volume of either study medication or saline was administered intravenously. The anaesthetist and all nursing staff involved in the care of child during the study period were blinded to the contents of the two syringes. An intra operative decrease in baseline arterial pressure or heart rate of greater than 15 percent from preoperative values were defined as hypotension or bradycardia respectively and were treated with rapid infusion of normal saline 10-20ml/kg or i/v atropine 10µg/kg. An intra-operative increase in baseline arterial blood pressure or heart rate of greater than 10 percent were defined as insufficient analgesia and were treated with additional doses of intravenous fentanyl 1µ gm/kg as needed. After surgery the children were transferred to the recovery room where heart rate, SPO_2 and blood pressure were monitored every 30 minutes until the child was awake and cooperative. During the study period pain was recorded by experienced nurses blinded to the treatment groups, every 1 hour after surgery using a scale of observational pain score. The indication for administering first paracetamol dose [intravenous] and subsequent doses was at a pain score greater than 4. In post-operative ward the children were under constant supervision by experienced nurses, and hence any pains experienced by children were treated if and when it occurs. The duration of post operative analgesia was defined as the time between administering the study drug [caudally or i/v] and the first intravenous paracetamol dose administered. The statistical analysis of the data was done by using test statistic student's't'-test for difference of means and chi-square test for nominal data. These tests were two sided and were referred for p-values for their significance. Any $p < 0.05$ was considered statistically significant . The analysis of the data was performed by using comprehensive statistical package, Statistical Package for Social Sciences (SPSS, Version 14.0), Chicago, U.S.A. for Windows.

III. Results

Sixty patients selected for this study were randomly divided into two groups of 30 patients each. The two groups were matched with regard to their age, gender, body weight and duration of surgery (TABLE 1)

TABLE 1: Demographic characteristics and Duration of Surgery of studied patients

		Group A(n=30)		Group B(n=30)		P value	Remarks
Age(Years) (Mean± SD)		**4.48 ± 2.27**		**3.87 ± 1.75**		**0.24**	**NS**
Gender (%)	**M**	**29**	**96.6%**	**28**	**93.3%**	**0.55**	**NS**
	F	**1**	**3.4%**	**2**	**6.7%**		
Weight(Kgs) (Mean±SD)		**18.9 ± 5.6**		**16.8 ± 6.0**		**0.17**	**NS**
Duration of surgery (mins) (Mean± SD)		**52 ± 32.5**		**49 ± 27.0**		**0.32**	**NS**

In the study, hemodynamic effects with regards to heart rate, systolic blood pressure, diastolic blood pressure as well as oxygen saturation showed a benign profile and no clinically relevant change were observed in these variables at various stages. Fig 1&2

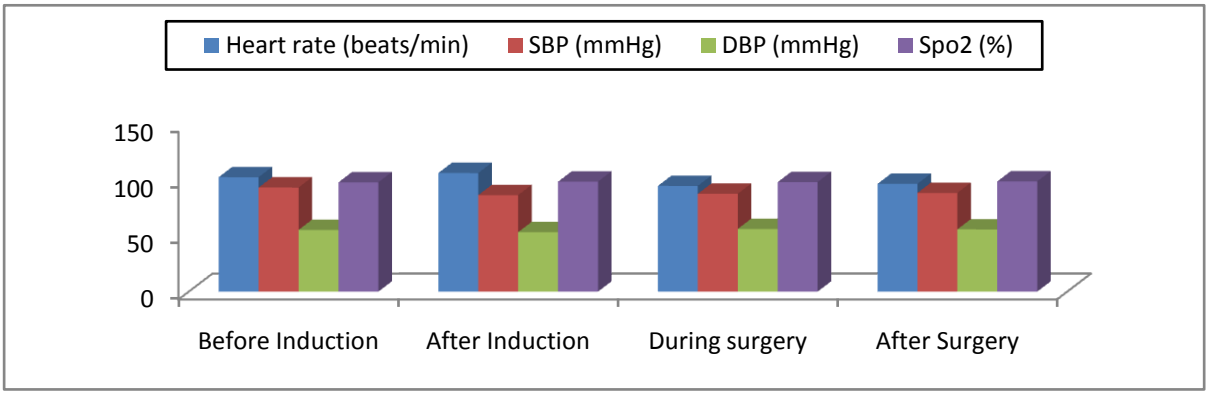

Fig 1: Bar chart depicting mean heart rate, blood pressure (systolic and diastolic), and oxygen saturation at various stages in Group A

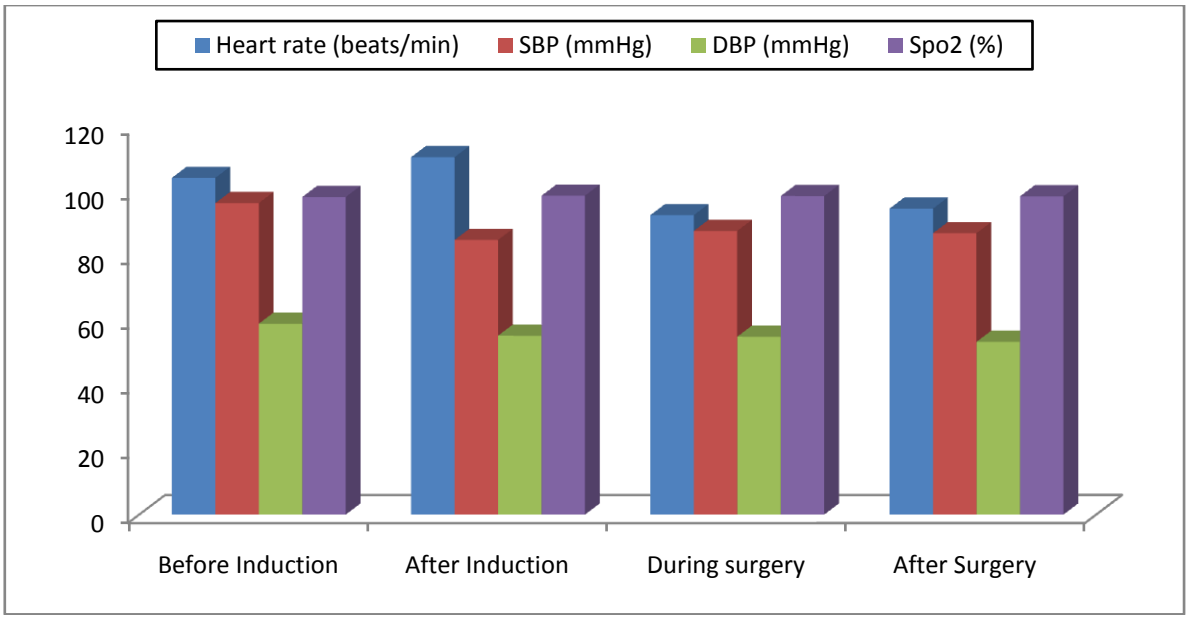

Fig 2: Bar chart depicting main heart rate, blood pressure (systolic and diastolic) and oxygen saturation at various stages in Group B

The mean pain scores were comparable between two groups at all stages post operatively till 12 hours **TABLE 3.**

Table 3:- Comparison of pain score (Mean ± SD) at various intervals of time between two groups

	Group A	Group B		
Time	Mean ± S.D	Mean ± S.D	t-value	p-value
30 min.	3.066 ± 0.253	3.033 ± 0.182	0.58	0.56
1 hr	3.066 ± 0.235	3.233 ± 0.430	1.22	0.23
2 hr	3.200 ± 0.305	3.66 ±0.556	1.93	0.08
3 hr	3.43 ± 0.727	3.60 ± 0.770	0.87	0.45
4 hr	3.012 ± 0.266	3.033 ± 0.182	0.35	0.68
6 hr	3.063 ± 0.238	3.233 ± 0.430	1.85	0.08
8 hr	3.102± 0.315	3.33 ±0.356	1.87	0.08
10 hr	3.34 ± 0.767	3.42 ± 0.720	0.91	0.42
12 hr	3.006 ± 0.2151	3.34 ± 0.675	1.55	0.10

Comparable number of patients in the two groups required rescue analgesia and the difference was found to be statistically non significant. (P >0.05) TABLE 4

Table 4: Comparison of post operative rescue analgesic dose in 12 hours in two groups.

No of doses	Group A No. of patients (%)	Group B No. of patients (%)	P value	Remarks
0	4 (13.33)	4 (13.33)	0.854	Non-sig
1	14 (46.67)	16 (53.33)		
2	12 (40.00)	10 (33.33)		

The difference in incidence of complications in both the groups was statistically insignificant. (P>0.05) TABLE 5

Table 5: Comparison of post operative complications in the two groups.

Complications	Group A No. of Patients (%)	Group B No. of Patients (%)	P value	Remarks
Nil	24 (80.00)	23 (76.70)	0.750	NS
Vomiting	3 (10.00)	2 (6.7)		
Nausea	0	1 (3.30)		
Urinary retention	2 (6.70)	3 (10.00)		
Pruritis	1 (3.30)	1 (3.40)		

IV. Discussion

Pain after surgery is inevitable and the relief of acute pain, especially postoperative pain, has been consistently and systematically inadequate[3]. Caudal block is one of the common regional anesthetic technique used in paediatric age group undergoing infra umbilical surgery. It is generally considered a simple & safe procedure [7]but its main disadvantage is its relatively short duration of action, even with the use of long-acting local anesthetic agents such as ropivacaine [8]. In order to improve the duration of action and quality of analgesia of a caudal block with ropivacaine, various drugs have been used, e.g. opioids, epinephrine, midazolam, neostigmine, ketamine and clonidine [7]. Since the discovery that epidural clonidine, an alpha 2 receptor agonist, produces analgesia [9], the drug has been used increasingly in anesthetic practice [10]. Clonidine has been shown to produce analgesia without causing significant respiratory depression after systemic, epidural or spinal administration. Although epidural clonidine may also cause hypotension, bradycardia and sedation in higher doses, serious adverse effects are uncommon in the dose range (1-2 µg/kg body weight) normally used in children [11].

Both the groups were homogenous with reference to age, sex, weight and duration of anesthesia and surgery. Mean age of patients in group B was 3.87$\pm$1.75 years whereas in group A mean age was 4.48$\pm$2.27 years (p=0.24). Although males dominated in both groups, yet the difference in male female ratio between the groups was statistically insignificant (p= 0.554). Mean weight of patients in group B was 15.10 $\pm$ 5.25 kg as compared to 16.75$\pm$4.60 kg in group A(p=0.43).

No significant differences with respect to mean heart rate, blood pressure (systolic and diastolic) and oxygen saturation were noted during perioperative period between the groups. No patient required drug therapy to treat hypotension or bradycardia. No episode of oxygen saturation < 95% was recorded. Our results correlate with the study of Aynur Akin et al (2010)[12] who observed no significant differences in mean arterial pressure and heart rate with the administration of 2µg/kg of clonidine (caudal or intravenous) to patients undergoing subumblical surgeries.

In our study, the quality of analgesia postoperatively was assessed using observer pain scale at 30 minutes intervals while in recovery room and thereafter 2 hourly for 12 hours. We found patients in group A had comparable pain scores during 12 hour study period as compared to group B and the difference was statistically insignificant (P>0.05). The mean duration of analgesia in group B was 404 ± 196 minutes while in group A mean duration of analgesia was 428 ± 197 minutes. The duration of analgesia in group A and B was comparable and the difference was statistically insignificant (p=0.64). Our observation correlate with that of T.G Hansen et al (2004)[13],who in their study observed better and longer post operative analgesia with caudal or intravenous clonidine when added to caudal bupivacaine. This was confirmed by longer time of interval to first request of analgesic dose.

The difference in duration of analgesia in our study was not statistically significant. The rescue analgesic requirement was almost similar between the two groups. The study of T.G Hansen et al (2004)[13] found no difference in duration of analgesia duration between two groups of patients who received either caudal bupivacaine (0.125%) with an equal volume of either clonidine (2µg/kg) or saline, which contradicts our study. The incidence of nausea, vomiting, urinary retention and pruritis were comparable between the two groups in our study.

V. Conclusion

We conclude that using Caudal or intravenous clonidine in the dose of 2µg/kg body weight as an additive to caudal block with ropivacaine (0.2% -1ml/kg) in patients undergoing infra umbilical surgeries is safe, provides comparable analgesia without any significant side effects

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