

## COMPARISON OF TWO DIFFERENT DOSES OF DEXMEDETOMIDINE WITH BUPIVACAINE IN PAEDIATRIC CAUDAL ANESTHESIA FOR INFRAUMBILICAL SURGERIES: A RANDOMIZED DOUBLE BLIND CLINICAL STUDY

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### ABSTRACT

**Objectives:** Caudal epidural analgesia is one of the most commonly performed regional techniques in paediatric anaesthesia for intra and post-operative analgesia. Various adjuvant like  $\alpha$ -2 agonists, ketamine, opioids etc. have been used to prolong the caudal analgesia. With favourable results dexmedetomidine, has been popularly used. Here we intend to study two different doses, 1 $\mu$ g/kg which has been proved to increase analgesia duration in comparison with 0.5 $\mu$ g/kg dexmedetomidine as an adjuvant.

**Methods:** Sixty children (aged 6 months- 6 years) posted for infraumbilical surgeries were randomly assigned in two groups. Group A (30) received caudal block 1ml/kg of 0.25% bupivacaine with 1  $\mu$ g/kg dexmedetomidine and Group B (30) received caudal block 1ml/kg of 0.25% bupivacaine with 0.5 $\mu$ g/kg dexmedetomidine. After giving premedication with 0.8 mg / kg of oral midazolam 30 minutes prior to surgery, patients were induced with propofol 2mg/kg and infusion 100 $\mu$ g/kg/hr started. Caudal block was performed and appropriate dosage of drug given depending on group. Patient's heart rate, oxygen saturation and blood pressure were recorded every 5 minutes intra-operatively and postoperatively every 15 minutes for next 2 hours and then every 30 minutes until the requirement of first rescue analgesia. Total duration of analgesia and mean pain score were noted.

**Results:** Intra-operatively there was no statistical significant difference in the heart rate, systolic, diastolic and mean arterial blood pressure between the two groups at any time interval. The total mean duration of analgesia in group A was significantly more compared to group B. Mean pain scores in the postoperative period were comparable till 660 min but later, the mean pain scores were higher in group B in comparison to group A from 660 min to the time of rescue analgesia, which was statistically significant. Other side effects were comparable in both the groups.

**Conclusion:** Caudal dexmedetomidine (1 $\mu$ g/kg) with 0.25% bupivacaine for paediatric infraumbilical surgeries achieved significant post-operative pain relief compared to caudal dexmedetomidine (0.5 $\mu$ g/kg) with 0.25% bupivacaine. However, 0.5 $\mu$ g/kg dexmedetomidine had lesser side effects in comparison to 1 $\mu$ g/kg dexmedetomidine.

**Author Affiliations:**<sup>1,2&3</sup>Dept of Anaesthesiology, S N Medical college, Navanagar, Bagalkot.**Keywords:** Caudal block, bupivacaine, dexmedetomidine, paediatric**\*Corresponding Author:**Vinod Hosalli, Associate Professor, Dept of Anaesthesiology, S N Medical college, Navanagar, Bagalkot. Mobile: 9886440240, Email: [drvinodhosalli@yahoo.co.in](mailto:drvinodhosalli@yahoo.co.in)**INTRODUCTION**

Pain is perhaps the most feared symptom of disease, which a man is always trying to alleviate and conquer since ages. Popular dogma had suggested that the human child does not feel pain, and that it is dangerous to give him powerful analgesia because of the risk of addiction. <sup>[1]</sup> Post-operative pain even in the children and newborns may trigger biochemical and physiologic stress response and cause impairments in pulmonary, cardiovascular, neuroendocrinal, gastrointestinal, immunological, and metabolic functions. <sup>[2]</sup> Caudal epidural block is one of the most common regional techniques in paediatric anaesthesia <sup>[3]</sup> is safe and found to be very effective in children, especially in infra-umbilical surgeries when combined with general anaesthesia. It allows rapid recovery from anaesthesia with good post-operative analgesia <sup>[4]</sup>. In spite of using long acting local anaesthetics, the main disadvantage of caudal analgesia remains the relatively short

duration of action<sup>[5]</sup>. Hence different additives have been used in order to improve the duration of action as well as the quality of analgesia of the local anesthetic used in the single shot caudal block technique such as opioids, epinephrine, clonidine, ketamine and neostigmine<sup>[6]</sup>.

Dexmedetomidine is more selective  $\alpha_2$ -agonist especially for the 2A subtype receptor, it is 8 times more selective than clonidine and its lipophilic ratio is 3.5 times greater than clonidine which makes it much more effective sedative and analgesic agent, without undesirable cardiovascular effects from alpha-1 receptor activation<sup>[7,8]</sup>.

The aim of this randomized, double-blinded, study was to compare the duration of post-operative analgesia, sedation, hemodynamic changes and any adverse effects with two different doses caudal dexmedetomidine in combination with bupivacaine, in paediatric patients undergoing various elective infra-umbilical surgical procedures.

## MATERIALS AND METHODS

This study was approved by the local clinical research ethics committee and written informed consent was obtained from the parents of patients before the surgery. Sixty children of both genders of American Society of Anesthesiologists (ASA) physical status I–II, aged 6 months–6 years, scheduled for various elective infra-umbilical surgical procedures such as herniotomy, orchidopexy, circumcision etc. were enrolled for the study.

Exclusion criteria included history of mental retardation or delayed development that may interfere with pain intensity assessment, known or suspected coagulopathy, any congenital anomalies of the sacrum, any infection at the site of injection, known or suspected allergy to any of the studied drugs, parents not willing to participate in the study, ASA grade 3, 4 and 5 or having congenital heart disease were excluded from the study.

The patients were randomized in a double blinded fashion using closed envelop method to get enrolled into 2 equal groups: Group A (n= 30) received caudal 1ml/kg of 0.25% bupivacaine with 1 µg/kg dexmedetomidine constituted to 1 ml, Group B (n=30) received caudal 1ml/kg of 0.25% bupivacaine with 0.5µg/ kg dexmedetomidine constituted to 1ml.

All patients were pre-medicated with syrup. midazolam 0.8mg/kg, 30 min prior to induction, patients were kept fasting according to the ASA guidelines. On arrival to the operating theatre, the standard monitors were applied. All patients were induced with Inj. propofol 2mg/kg and then intravenous infusion of 100µg/kg/min was started and maintained on spontaneous respiration. An infusion of Ringer Lactate was started and was administered according to the calculated requirements. Patient heart rate, oxygen saturation, and blood pressure were recorded every 5 minutes from starting to the end of the procedure.

Under strict aseptic precautions single dose caudal epidural injection was done using 25 G needle. Proper position of the needle was confirmed by the pop sensed during penetration of the sacro-coccygeal ligament, which was followed by the whoosh test done using 0.5 ml of air. After needle insertion and negative aspiration of blood or cerebrospinal fluid, the study drug was injected according to the group allocated. The block was deemed as successful if there is absence of gross movement of limbs to painful stimulus and when increases in heart rate or systolic arterial pressure in response to skin incision was  $\leq 20\%$  [9]. No analgesia was given by any

route intra-operatively. Failed caudal block cases were excluded from the study.

Towards the end of surgery propofol infusion was stopped and the duration of surgery and time of recovery from propofol was noted. Sedation score was assessed using Ramsay’s sedation scale (1= anxious and agitated, 2=cooperative, calm. 3= responsive to commands 4= brisk response to glabellar tap, 5 = light response to glabellar tap, 6 = unresponsive). [10] Bolus intravenous propofol 1mg/kg is given as and when required during intra-operative period to maintain Ramsay sedation score 4 or 5. Number of boluses required intra-operatively were noted.

Post operatively child was monitored for heart rate , non- invasive blood pressure, oxygen saturation and pain score using modification of the objective pain scale by Hannallah and colleagues every 15 minutes for first 2 hours and there after every 30 minutes until the requirement of first rescue analgesia, time of which was noted.

Duration of first rescue analgesia is defined as the time interval between the administration of caudal block and the first requirement of rescue analgesia postoperatively.

Pain scoring (modification of the objective pain scale by Hannallah and colleagues).<sup>[11]</sup>

OBSERVATION	CRITERIA	POINTS
Crying	No crying	0
	Crying but responds to TLC	1
	Crying and not responding to TLC	2
Movement	None	0
Restlessness	present	1
Thrashing	present	2
Agitation	Asleep/ calm	0
	Mild	1
Hysterical	present	2

**TLC- Tender Loving Care**

Pain defined by pain score >3 points

When the pain score was >3, rescue analgesia was given with fentanyl 1µg/kg, and duration was noted. Any episodes of hypotension or bradycardia and adverse effects like postoperative vomiting etc. in the postoperative period were noted.

**Statistical Analysis:**

Statistical analysis was done using SPSS software version 11.0. All the values are expressed as mean±SD. Unpaired t- test was applied to know the difference between 2 groups in quantitative data. Chi- square test was applied for proportions and qualitative

data.  $P < 0.05$  was considered as statistically significant.

**RESULTS**

A total of 60 subjects of ASA grade 1 and 2 , aged 6 months to 6 yrs were enrolled in this study. Age, weight and duration of anaesthesia and surgery were similar between the caudal groups.

Intra-operatively there was no statistical significant difference in the heart rate, systolic, diastolic and mean arterial blood pressure between the two groups at any time interval.

Postoperatively there was increase in heart rate in group B and was not statistically significant (figure-1). There was no statistical significant change in the mean systolic, diastolic and mean arterial blood pressure when compared in group A and group B, except at the time of requirement of rescue analgesia in group B (Figure-2).

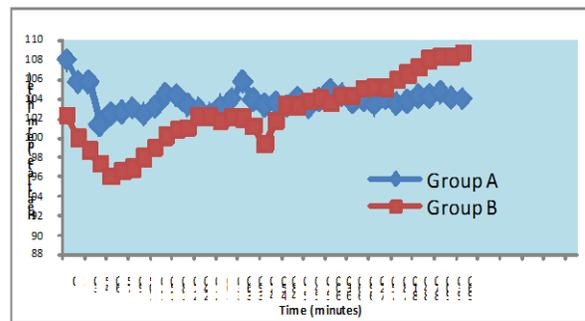
There was no statistically significant difference in the requirement of propofol boluses among both groups.

Duration of recovery from anaesthesia following discontinuing propofol infusion was  $10.50 \pm 3.83$  minutes in group A and  $9.33 \pm 3.99$  minutes in group B, which was statistically not significant.

The total mean duration of analgesia in group A was significantly more compared to group B (Figure-3).

Mean pain scores in the postoperative period were comparable till 660 min but later, the mean pain scores were higher in group B in comparison to group A from 660 min to the time of rescue analgesia (when score  $> 3$ ), which was statistically significant(Figure-4).

Figure 1: Comparison of changes in



postoperative heart rate.

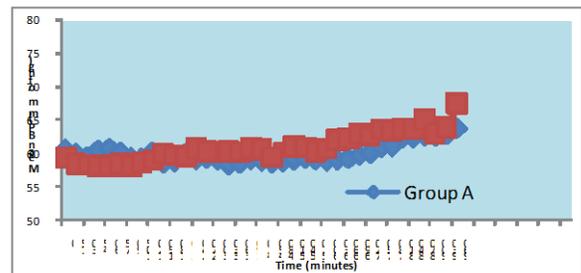


Figure 2: Comparison of changes in postoperative mean arterial blood pressure

In the postoperative period 3(10%) patients in group A had hypotension but no case had hypotension in group B and it was statistically not significant.

Postoperative vomiting was seen among 6 (20%) patients in group A and 1 (3.33%) patient in group B, which was statistically significant. Postoperatively none of the patients had bradycardia, pruritis or any other complications in both the groups.

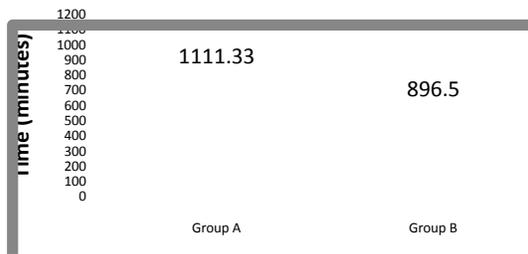


Figure 3: Comparison of mean duration of analgesia

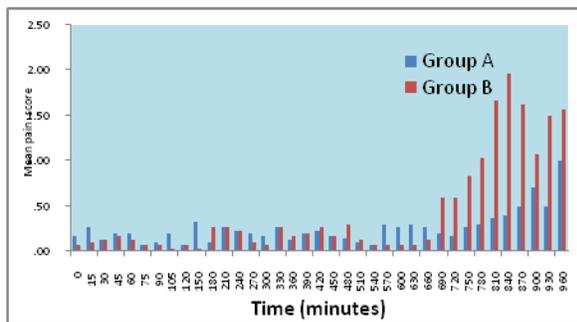


Figure 4: Comparison of mean pain scores

**DISCUSSION:**

Caudal epidural analgesia is a widely used technique for providing regional anaesthesia and analgesia in children undergoing infra umbilical and lower limb surgeries and to prolong its effect wide range of additives have been used in combination with local anaesthetics to promote analgesia.<sup>[12]</sup>

Dexmedetomidine, potentiates the action of local anesthetics without increasing the incidence of side-effects and compared to clonidine it’s a highly selective  $\alpha_2$  adrenergic receptor agonist, and this facilitates its use in larger doses for analgesia and sedation without the fear of inadvertent effects on the hemodynamics.<sup>[13]</sup>

Epidural dexmedetomidine has been used in the range of 1.5–2  $\mu\text{g}/\text{kg}$  without any incidence of neurological deficits. Saadawy et al have adopted a study design by using a low dose of dexmedetomidine of 1 $\mu\text{g}/\text{kg}$  which was based on previous reports in adults.<sup>[14]</sup> So, we conducted this study to compare the duration of analgesia by decreasing the dose i.e with 0.5 $\mu\text{g}/\text{kg}$  of dexmedetomidine and 1 $\mu\text{g}/\text{kg}$  of dexmedetomidine added to 0.25% bupivacaine caudally in patients undergoing infra umbilical surgeries.

Supporting the results of the present study was the results of El-Hennawy et al, who compared the use of single dose caudal epidural injection of dexmedetomidine or clonidine or placebo (normal saline) added to bupivacaine, and proved that the duration of analgesia was found to be significantly prolonged with dexmedetomidine, and to a lesser extent with clonidine than with plain bupivacaine, without any increase in the incidence of side-effects.<sup>[15]</sup>

Bharti N et al compared patients of one group receiving 0.2% plain ropivacaine 0.75 ml/kg and group 2, 3, and 4 receiving dexmedetomidine 0.5, 1.0, and 1.5 µg/kg, respectively. They concluded that postoperative analgesia was significantly prolonged in all dexmedetomidine groups compared to plain ropivacaine.<sup>[16]</sup>

In another study by Bhaskar et al on patients receiving ropivacaine with dexmedetomidine 2µg/kg and another group with fentanyl 2µg/kg under general anaesthesia and concluded that dexmedetomidine in comparison to fentanyl offers longer postoperative analgesia.<sup>[17]</sup>

Results of duration of analgesia in this study were similar to the study by Neogiet al, who compared dexmedetomidine(1µg/kg) and clonidine(1µg/kg) and concluded that addition of both clonidine and dexmedetomidine to ropivacaine administered caudally significantly increases the duration of analgesia.<sup>[18]</sup>

Our experience with dexmedetomidine for caudal blockade is consistent with the results obtained studies by Manjunath et al adjuvant effect of fentanyl or clonidine to ropivacaine 0.2% for paediatric caudal analgesia for lower abdominal surgeries, concluded that fentanyl or clonidine when added to

ropivacaine prolongs the duration and quality of analgesia.<sup>[19]</sup>

In our study when the mean pain scores (assessed by objective pain scale modified Hanallah pain scale) between the 2 groups were compared in postoperative period, mean pain scores were higher in group B in compared to group A from the time of rescue analgesia (when score >3), which was statistically significant.

There was no statistically significant difference in the hemodynamic parameters between the groups at any point of time, Similar hemodynamic stability with respect to heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure was seen in previous studies conducted by El-Hennawy et al<sup>[15]</sup>, Saadawy et al<sup>[14]</sup> and El shamaa HA et al<sup>[20]</sup>.

In our study intra-operative hypotension and bradycardia were recorded in both groups, which were statistically not significant. Similar results were seen in study conducted by Anand VG et al<sup>[10]</sup>, Neogi et al<sup>[18]</sup> and Lee JJ et al.<sup>[21]</sup>

We used Ramsay sedation score for assessment of sedation intra-operatively. Bolus propofol was given to maintain the

score of 4 or 5 and our study is supported by results of Anand et al<sup>[10]</sup> and Thakker et al<sup>[22]</sup>

### CONCLUSION:

To conclude,caudal dexmedetomidine (1µg/kg) with 0.25% bupivacaine for pediatric infraumbilical surgeries achieved significant post-operative pain relief compared to caudal dexmedetomidine (0.5µg/kg) with 0.25% bupivacaine without any significant difference in hemodynamic parameters. However incidence of side effects was less with 0.5 µg/kg dexmedetomidine compared to 1µg/kg dexmedetomidine group.

**CONFLICT OF INTEREST** -None

**ETHICAL CLEARANCE FROM INSTITUTION** - Obtained

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