

# Comparison of Perioperative Caudal Effectiveness of Addition of Clonidine to Bupivacaine in Pediatric Patients Undergoing Infraumbilical Surgery



## Medical Science

**KEYWORDS :** Bupivacaine, caudal, clonidine, post-operative analgesia, infraumbilical surgery, pediatrics

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### ABSTRACT

*Background:* Caudal block is a common technique for pediatric analgesia, but with the disadvantage of short duration of action after single injection of local anesthetics. Several adjuvants have been used to prolong the action of local anesthetics. We evaluated the efficacy of clonidine added to bupivacaine in prolonging the analgesia produced by caudal bupivacaine in children undergoing infraumbilical surgery.

*Materials and methods:* A study was conducted among 60 ASA I and II patients between age one to six years undergoing infraumbilical surgery were randomly allocated to one of two groups to receive a caudal injection of either 1 ml/kg of 0.25% bupivacaine in normal saline (Group 1) or 1 ml/kg of 0.25% bupivacaine with 2 µg/kg of clonidine in normal saline (Group 2). Haemodynamic parameters were observed before, during and after the surgical procedure. Post-operative pain was assessed for 24 hours using the Modified Hanallah pain score and side effects were noted.

*Results:* The mean duration of postop analgesia was significantly prolonged in Group 2 ( $p < 0.001$ ). Also, children in Group 2 had statistically significant lower pain scores. Clonidine in a dose of 2µg/kg added to 0.25% bupivacaine for caudal analgesia, during infraumbilical surgery, prolongs the duration of analgesia of bupivacaine without any side effects.

### INTRODUCTION

Caudal epidural analgesia is one of the most popular and commonly performed regional blocks in paediatric anaesthesia for infraumbilical surgeries as it is reliable and safe technique. Bupivacaine is the most widely used local anaesthetic in caudal block, only limitation being relatively short duration of postoperative analgesia. Even with the use of long acting amide local anaesthetics, like ropivacaine, maximum duration is 1-4 hours. So, to prolong the effect of postoperative analgesia various adjuvants like epinephrine, opioids like butorphanol, morphine and fentanyl needs to be added which themselves are associated with number of unpleasant side effects such as nausea, vomiting, pruritus and urinary retention, as well as, the risk of respiratory depression.<sup>[1]</sup>

Newer class of adjuvant, alpha 2 adrenergic agonist, like clonidine, offers significant analgesic benefits and also improves the quality and duration of caudally administered local anesthetics and reduce the need for additional analgesic requirement, decreases anaesthetic requirements and produces perioperative haemodynamic and sympathoadrenal stability. Alpha<sub>2</sub> receptors are also present in the spinal cord and hence modulates pain pathway resulting in analgesia.<sup>[2]</sup>

A study was conducted in our institute, in order to compare the efficacy of caudal bupivacaine with or without clonidine in equal volumes of 1ml/kg on pediatric patients undergoing infraumbilical surgery. We also studied the side effects and complications associated with it.

### AIMS

The study was designed to compare the duration of postop analgesia as primary outcome and secondary outcome being the caudal effectiveness and associated side effects.

### MATERIAL AND METHODS

After obtaining approval from hospital ethics committee and informed consent from parents or guardians, this prospective, randomised, double-blinded study was conducted on 60 patients of ASA grade I or II, in the age group 1 to 6 years who were undergoing infraumbilical surgery. Children with pre existing neurological disease, known hy-

persensitivity to local anaesthetics, bleeding diathesis or coagulation disorders, local sepsis, sacral deformity or tuberculosis of spine, on anticoagulants or CNS active drugs and with technical problems (persistent parasthesias, persistent bloody tap) were excluded from the study group. Patients were randomly allocated according to 60 coded slips in an opaque envelope into one of two groups of 30 patients each.

**Group I :** patients receiving bupivacaine 0.25% with normal saline (control group).

**Group II :** patients receiving bupivacaine 0.25% in combination with clonidine (2µg/kg).

Total Volume of drug solution was kept constant that is 1ml/kg.

Detailed preanaesthetic checkup of the patients was done a day prior to surgery and patient were kept fasting as per the standard guidelines depending upon age. On the day of surgery, premedication with syrup midazolam 0.5mg/kg body weight was given 30 minutes prior to surgery and in the operating room, precordial stethoscope and monitors were attached. General anaesthesia induced with halothane and nitrous oxide in oxygen via mask. Establishment of good intravenous line either before or after induction and anaesthesia was maintained via facemask with O<sub>2</sub> + Halothane + Nitrous oxide.

After stabilization of vitals for 5 minutes which were considered as baseline parameters, child was placed in lateral decubitus position. Under all aseptic precautions caudal block was performed with 24G intravenous needle, space was confirmed using 'whoosh test' and after confirming no cerebrospinal fluid or blood coming through needle, coded drug solution was injected.

Patient was placed in supine position and surgery was allowed after achieving caudal efficacy which was defined as the absence of gross movements or significant (>20%) change in heart rate and/or respiratory rate on application of forceps at the site of incision 5 minutes after placement of caudal anaesthesia and every 2 minutes thereafter upto

15 minutes. Quality of intraoperative anaesthesia was assessed using caudal effectiveness score. Continuous intraoperative monitoring was done and parameters heart rate, NIBP, SpO<sub>2</sub>, respiratory rate were recorded after every 5 minutes. Postoperatively patients were assessed for pain relief by using Modified Hanallah pain scale<sup>[3]</sup> and sedation score to assess the level of sedation which is graded as 1-asleep, not arousable by verbal contact; 2-asleep, arousable by verbal contact; 3-drowsy not sleeping; 4-alert/aware. Motor block duration was assessed by noting the time when children started moving their legs. Also, the total requirement of additional analgesia in first 24 hours after operation was noted. The drugs were given in coded manner.

After the completion of the study, decoding was done, results were compiled and statistically analyzed using ANOVA, Student's paired t test and Posthoc tests for parametric data and Chi square test for non parametric data. p value < 0.05 was considered significant.

**Observations and Discussion**

The demographic profile of the patients in both group I and group II was comparable with regards to age, weight, male female ratio and duration of surgery and no significant statistical difference was found. Table 1.

	Group 1	Group 2	Statistical analysis
Age	2.06±1.22	1.95±.74	NS
Weight (kg)	12.50±3.36	13.25±3.79	NS
Duration of surgery (in minutes)	36.50±7.45	34.75±7.51	NS

**Table 1:** Data are Mean±SD, HS:Statistically highly significant(p<0.001),S:Statistically significant(p<0.05), NS: Statistically not significant.

No statistical significant difference between the two groups (P>0.05) in terms of various vital parameters(Table 2) of the patients of both the groups.

Group	Group 1	Group 2	Statistical analysis
Mean HR beats/min	117.00±7.93	115.25±6.95	NS
Mean SBP mmHg	98.20±10.66	99.80±11.45	NS
Mean DBP mmHg	51.60±7.25	52.70±8.36	NS
Mean RR breaths/min	30.00±6.74	31.30±4.26	NS
Mean SpO <sub>2</sub>	99.50±.68	99.35±.74	NS

**Table 2, Data are Mean±SD, HS:Statistically highly significant(p<0.001),S:Statistically significant(p<0.05), NS: Statistically not significant.**

**Caudal efficacy**

It can be elucidated from table 3, that time taken to achieve caudal efficacy was shorten to 11.80±1.19 when clonidine was added to bupivacaine which was statistically significant(Table3).

	Group 1	Group 2	Statistical analysis
Time(CES)	12.5±1.59	11.80±1.19	S

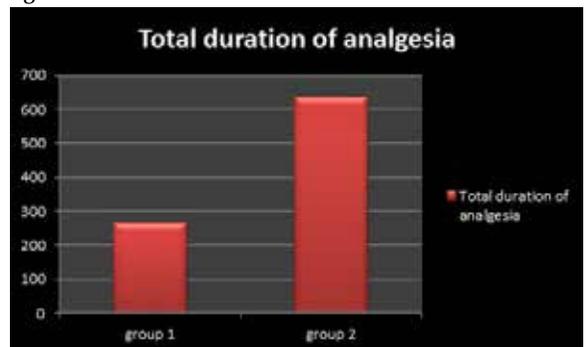
**Table 3;Data are Mean±SD, HS:Statistically highly significant(p<0.001),S:Statistically significant(p<0.05), NS: Statistically not significant.**

Our study results closely correspond with Ivani et al who found significant change in the mean time to onset of caudal block using 0.25% bupivacaine (12 mins.) and using 0.20% ropivacaine (9 mins.).<sup>[4]</sup>

**Intraoperative vitals**

No significant hypotension or bradycardia was observed in any patient. SpO<sub>2</sub> (>97%) was always within the clinically acceptable range in both the groups throughout the procedure (P > 0.05).Despite the addition of clonidine to bupivacaine, no significant difference was observed in the mean heart rate and blood pressure in both the groups throughout intraoperative period and none of the patient in any of the groups required intravenous atropine for correction of heart rate.

**Duration of analgesia: figure 1**



The duration of analgesia was defined as the time from caudal injection until pain score ≥4. As can be observed from figure 1, the addition of clonidine 2 µg/kg to 0.25% bupivacaine (group 2) statistically prolonged the duration of analgesia to 664.50±185.93mins (11.07±3.09 h) as compared to plain bupivacaine 243.50±79.73mins (4.05±1.32 h), in our study (p <0.001).

Similar to our study, Koul et al, Parmeshwari et al and El Hennawy et al found that duration of analgesia with clonidine added to local anaesthetics and without was 10.25 hours vs 4.55 hours; 593.4 ± 423.3 min vs 288.7 ± 259.1 min; and 12( 3 21) h vs 5(4–6) h. respectively.<sup>[5,6,7]</sup> Jamali et al, found mean duration of combination of clonidine and bupivacaine as 16.5h vs 7.6h with plain bupivacaine.<sup>[8]</sup> Moreover less number of children required further analgesia with clonidine than with plain bupivacaine. Our results were contrary to Sharpe et al and Cook et al who found that addition of clonidine to local anaesthetics caused much less increase the mean duration of analgesia to 382.0(200.6) min vs 280.7(171.6) min and 5.8 h vs 3.2 h respectively. The difference may be due to small volume of bupivacaine (0.5ml/kg) used by Sharpe et al and omission of premedication by Cook et al. However, study by Motsch et al has shown mean duration of postoperative analgesia to be 20.9 ±7.4 h in children receiving caudal clonidine, but the dose used was 5µg/kg in patients undergoing relatively minor surgery.<sup>[9,10]</sup>

The variation in the duration of analgesia achieved by the addition of clonidine to local anaesthetics is evident in the above mentioned studies. This could be due to factors like differences in study design, dose of clonidine used, volume and concentration of the injected local anaesthetic drug, calculation of analgesia time, method of pain scoring and difference in the type of surgeries performed, use of premedication and volatile anaesthetic used, indications for rescue analgesia and statistical analysis.

### Sedation:

In our study, the patients receiving clonidine in addition to bupivacaine (group 2), remained sedated for significantly longer time i.e. till 8 hours than those who received plain bupivacaine (group 1)  $\approx$  2 h. The prolonged sedation in these children coincided with the duration of postoperative analgesia in these groups. Hence, this sedation can be attributed to both sedative effect of clonidine. Sedation score was not more than 2 in any patient both in recovery room or ward and they were easily arousable.

The results of our study were in concordance with Lee et al who demonstrated a longer duration of postoperative sedation following caudal bupivacaine with clonidine 2  $\mu\text{g}/\text{kg}$  than with bupivacaine alone (mean 9.1 h vs 5.8 h).<sup>[11]</sup> The authors concluded that the increased duration of sedation reflected superior analgesia; similar to our study. Ivani et al and Klimscha et al also demonstrated increased sedation when caudal clonidine was used as part of the anaesthetic technique.<sup>[4,12]</sup>

### Complications

None of the children in the two groups had respiratory depression, hypotension, bradycardia or vomiting. Only one children from group 2, experienced urinary retention i.e. time to first micturition  $>6$  hours, which comes out to be statistically insignificant. Our study results echo the observations of Cook et al, Ivani et al and Klimscha et al who also did not notice any significant complications.<sup>[10,12]</sup> Sharpe et al, El Hennawy, Parmeswari et al, Koul et al studied the addition of clonidine to bupivacaine and ropivacaine and found that two patients in each group complained of nausea and vomiting but none of the patients had urinary retention or any other side effects.<sup>[9,7,6,5]</sup> Increased incidence of nausea and vomiting in the above mentioned study could be due to the difference in premedication; the dose of clonidine used.

### Conclusion

Hence, the results in our study conclude that bupivacaine is effective for caudal anaesthesia. The addition of clonidine in a dose of 2 $\mu\text{g}/\text{kg}$  to bupivacaine significantly prolongs the duration of postoperative analgesia without causing any significant side effects.

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