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Comparative Study Of Caudal Bupivacaine and Bupivacaine With Clonidine In Infra Umbilical Surgeries In Children

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Abstract
Background*: Caudal epidural analgesia is one of the most commonly performed regional blocks in paediatric anaesthesia for intra and post-operative analgesia. However, the mean duration of analgesia provided by local anaesthetics alone is limited.* ***Methods****: This study was conducted in Nmch, Patna. Department of Anaesthesiology, among 60 children in the age group of 5 – 10 years coming for various elective infraumbilical surgical procedures. They were divided into two groups of 30 each. Group A received caudal 0.25% bupivacaine (1ml/kg) and group B received caudal 0.25% bupivacaine (1ml/kg) with clonidine (1.5µg/kg). The various parameters studied were hemodynamic changes, duration of analgesia and incidence of side effects.* ***Results****: The groups were similar in age, sex and weight. The hemodynamic parameters like heart rate, blood pressure, respiratory rate were also similar between the two groups after administering caudal block. The mean duration of analgesia in group B (433.5 ± 60 min) was significantly longer (p< 0.05) than group A (250.33 ±41 min).****Conclusion****: This study showed that the addition of clonidine in the dose of 1.5µg/kg to 0.25% bupivacaine (1ml/kg) improved the analgesic duration and efficacy after a single shot caudal block with minimal side effects in children.*

Keywords*: Caudal, bupivacaine, clonidine;,children*

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I. Introduction

The International Association for the Study of Pain defines *pain* as "an unpleasant sensory and emotional experience associated with actual or potential tissuedamage, or described in terms of such damage"[1]. In children, even the definition of pain has been debated.[2] Pain is a complex constellation of unpleasant sensory, perceptual, and emotional experiences and certain associated autonomic, psychological, emotional, and behavioral responses. In many newborns or infants, aswell as others who have mental retardation, pain cannot be described in such self- report terms. In fact, pain experienced by infants and children often goes unrecognized, even neglected, because of the operational definition of *pain* that requires self-report .Pain management is an essential component of care provided by paediatric anaesthesiologists. Most obvious, of course, is the integration of a pain management plan into the overall peri-operative plan. For many years, it has been recognized that paediatric patients are more likely to have pain treated less aggressively than their adult counterparts. Unfortunately, one can argue that this has led to a considerableamount of unnecessary suffering on the part of these patients. Pain perception does begin before birth, and potent analgesics alter the stress response to surgery, even in premature infants. The landmark article published by Anand and Hickey in 1987 clearly addressed the issue that newborns and infants do in fact experience pain. It is important to understand that pain due to surgical procedures not only results in an immediate nociceptive response but also results in changes in the nociceptive activation pathways that lead to hypersensitivity, hyperalgesia, and allodynia The use of regional anaesthetic techniques in infants and children has become increasingly accepted as standard of care during final decades of twentieth century. Regional anaesthetic techniques reduce the overall intra-operative requirement of both inhaled and intravenous anaesthetic agents and allow more rapidreturn of the conscious pre-operative state while providing effective post-operative pain relief with minimal sedation.[8]Caudal analgesia is one of the most popular regional anaesthetic techniqueemployed in children. It is a relatively simple technique with a predictable level of blockade, and is by far the most common regional technique used in paediatric surgery for lower abdominal, urological, and lower limb operations. Gradual offset usually provides analgesia beyond the duration of surgery, with a smooth recovery period and good postoperative pain control. This benefit is especially

important in ambulatory and same-day surgery patients because it reduces analgesic requirements and facilitates early discharge.[9] However, the mean duration of surgical analgesia provided by single shot caudal procedure is limited by the duration of action of local anaesthetics. Since then various methods have been devised to prolong the duration of action of single shot caudal block. 1:200,000 epinephrine added to local anaesthetic prolongs the analgesiceffects of lignocaine, but it seems to have little effect on the longer-acting bupivacaine.[9] The addition of opioids also prolongs analgesia but carries with it the risk of respiratory depression.[11] Ketamine produces analgesia after epidural administration and improves the duration and quality of analgesia provided by bupivacaine in caudal blocks (E&9); however, the potential for neurotoxic effects after inadvertent intrathecal administration limits its application. Clonidine, an alpha 2-adrenergic agonist, produces analgesia without significant respiratory depression after systemic, epidural, or intrathecal administration. Analgesic effect of clonidine is more pronounced after neuraxial injection, which suggests a spinal site of action and makes this route of administrationpreferable. The addition of clonidine also prolongs the duration of action of bupivacaine after intrathecal and epidural administration in adults. In children, a mixture of 1 ml/kg 0.25% bupivacaine and l-2 mcg/kg clonidine improves the duration and quality of analgesia provided by caudal block, although results differ widely, ranging from 16.4 hours for 1 mcg/kg to 5.8 and 9.8 hours for 2 mcg/kg.

II. Objectives

This study has been done to compare bupivacaine 0.25% (1ml/kg) and bupivacaine 0.25% (1ml/kg) with clonidine (1.5 µg/kg) as a single shot caudal blockin infra-umbilical surgeries in children (5-10 years)

III. Review of Literature

In review of the caudal additives in children, it was suggested that the duration of analgesia by local anaesthetics alone was of short duration and prolongation of caudal analgesia can be achieved by addition of adjuvants like opioids, clonidine, ketamine and midazolam to local anaesthetics. Neuraxial administration of adjuvants results in excellent and long lasting analgesia due to its synergisitc effect with the local anaesthetics. This allows more dilute solution of localanaesthetics to be used and thereby decreasing its toxicity.[9]Seyedhazi M et al evaluated one hundred children aged 2-7 years, scheduled for elective lower abdominal surgery, in a randomized, double blind and placebo controlled clinical trial. They were divided into 2 equal groups to receive 0.25% bupivacaine (1 ml/kg) combined with either clonidine 2 mcg/kg or 1 ml normal saline.6% in group 1 and 42% in group 2 required supplementary analgesia after operation ($p<0.001$). According to p value, there were significant differences between the two groups in the heart rate, mean systolic and diastolic blood pressure. It was concludedthat addition of clonidine to bupivacaine improves the efficacy and duration of caudalanalgesia in children. Tripi PA et al evaluated a total of 35 children, aged 1 to 10 years, scheduled to undergo ureteroneocystostomy. They were randomized to receive a pre-incision caudal block consisting of either 1 ml/kg 0.125% bupivacaine (controls) or 1 ml/kg 0.125% bupivacaine with 1µg/kg clonidine (treatment group). Intravenous morphinerequirements for rescue therapy in the PACU were 0.02 mg/kg in treatment group and 0.05 mg/kg in the control group. The morphine requirements on 1st post-operative daywere 0.1 mg/kg in treatment group and 0.2 mg/kg for controls. Mean duration of analgesia for treatment group was 8 hours compared to 3.9 hours in the control group.It was concluded that addition of clonidine to bupivacaine significantly increases the duration of caudal analgesia without any hemodynamic instability, respiratory depression or sedation. Upadhyay KK et al randomly divided 50 children, aged 6 months to 6 years, undergoing elective lower abdominal and lower limb surgeries, into 2 groups. Group B, which received 0.75ml/kg of 0.25% plain bupivacaine by caudal route, achieved 5.59 hours of mean duration of analgesia. Group BC, that received additional 1 mcg/kg of caudal clonidine, achieved 10.33 hours of analgesia. Hence it was concluded that clonidine significantly prolongs the duration of post operative analgesia when added to bupivacaine without any fall in heart rate, blood pressure, respiratory rate and oxygen saturation .Constant I et al conducted a study among 64 children, aged 6 months to 9 years, scheduled to undergo bilateral correction of vesicoureteric reflux, which was expected to last more than 30 minutes. Addition of clonidine and fentanyl to bupivacaine, separately and together, was compared. Single shot caudal block was sufficient in only 57% of children in bupivacaine only group, 93% of children who received clonidine or fentanyl and 86% of children who received both. It was concluded that though both prolonged the duration of surgical analgesia, clonidine had some advantages over fentanyl as it did not produce clinically significant side effects. Klimscha W et al studied the analgesic efficacy, hemodynamic and respiratory safety of clonidine when added to bupivacaine for caudal blocks in 58 children, mean age of 3 years, scheduled for hernia repair. Motsch J et al studied 40 ASA I and II children of 4-8 years of age undergoing minor paediatric surgical procedures. They were divided into two groups.Caudal anaesthesia was performed with either 1 ml/kg of 0.175% bupivacaine in group I or 1 ml/kg of 0.175% bupivacaine with 5µg/kg of clonidine in group II. Meanduration of analgesia was 49±21 min in group I and 240 min in group II; the quality ofanalgesia was significantly better in group II. Koul A et al divided 40 children undergoing inguinal hernia repair into 2 groups. One group was given caudal injection of 0.75ml/kg of 0.25% bupivacaine alone and the

other group was given clonidine 2µg/kg along with 0.75ml/kg of 0.25%bupivacaine. Vetter RT et al evenly and randomly enrolled patients aged 6 mo to 6 yr in adouble-blind manner. Patients received a single caudal dose of either 2 mcg/kg of clonidine, or 10 mcg/kg of hydromorphone, or 50 mcg/kg of morphine, combined with 1.0 ml/kg of 0.2% ropivacaine with epinephrine. Caudal clonidine resulted in less postoperative nausea and vomiting (P = 0.01) and pruritus (P = 0.007) than did caudal hydromorphone or caudal morphine. Pain is perhaps the most feared symptom of a disease, which a man is always trying to alleviate and conquer since ages. Pain is defined, by International Association for the study of Pain, as "an unpleasant sensory and emotional experienceassociated with actual or potential tissue damage or described in terms of such damage

IV. Material And Methods

This study was conducted at Nalanda medical college and Hospital, Patna. Bihar. This study included 60 children, of either sex, coming for various elective infra-umbilical surgical procedures such as herniotomies, circumcision,orchidopexy, perineal surgeries and minor lower extremity procedures.

Inclusion criteria:

Age group of 5-10 yrsASA grade I and II

Patients coming for elective infraumbilical surgeries

Exclusion criteria:

ASA grade III and IV Infection at the site of injectionCoagulopathy or anticoagulation, Congenital abnormalities of lower spine and meningesActive disease of the CNS

History of allergy to local anaesthetics

This study was approved by the Ethics and Standards committee of thisinstitution. Informed consent was obtained from the parent before including the children in the study.

Equipment:

23G needle (hypodermic),5 cc syringe (for whoosh test),Sterile swabs, bowl, sponge holding forceps, sterile hole towel and spirit.Drugs – Bupivacaine 0.5% vial, Clonidine 150 µg ampoule, Boyle's apparatus with halothane vaporizer, Jackson Reis circuit. All patients were visited on the pre-operative day and a detailed general physical examination, systemic examination including airway and spine examination was done. Baseline parameters like heart rate, blood pressure and respiratory rates were noted. Laboratory investigations like routine blood and urine examinations, bleeding time and clotting time, chest x-ray if required, HIV and HBsAg were done in all patients. Informed consent was obtained from the parent. Patient is now gently placed in the left lateral Sim's position, the vitals were checked again including adequacy of spontaneous breathing. Under strict aseptic conditions, sacral hiatus was identified by running the thumb up from coccyx towardsthe sacrum.

V. Results

A total number of 60 children in the age group of 5 – 10 years belonging toASA grade I and II were enrolled in this study. They were divided into two groups of30 each.

Children in group A received caudal bupivacaine 0.25% (1ml/kg)Children in group B received caudal bupivacaine 0.25% (1ml/kg) withclonidine (1.5µg/kg).

MEAN AGE OF PATIENTS

Group	No of patients	Mean age (yrs) ± SD	Mean difference	p value
Group A	30	7.1 ± 1.58		0.94
Group B	30	6.86 ± 1.6	0.24	(NS)

The mean age in group A was 7.1 ± 1.58 years and in group was6 .86 ± 1.6 years. The two groups did not differ significantly (p = 0.94) with respectto their age, which is depicted in graph 1.

SEX WISE DISTRIBUTION

Gender	**Group A n (%)**	**Group B n (%)**
Male	26 (87)	28 (93)
Female	4 (13)	2 (7)
Total	30	30

p = 0.39, NS

In group A there were 26 (87%) males and 4 (13%) females. Group B had 28(93%) males and 2 (7%) females. The groups were comparable with respect to sex.

MEAN WEIGHT OF THE PATIENTS

Weight (kg)	Group A	Group B	Mean difference	p value
Mean Weight ± SD	16.3 ± 2.9	15.7 ± 3.4	0.6	0.46 (NS)
Range	12 - 22	10 - 23		

The weight of the children in group A ranged from 12 to 22 kg with a mean weight of 16.3 ± 2.9 kg. In group B the weight ranged from 10 to 23 kg with a mean of 15.7 ± 3.4 kg. The two groups did not differ significantly with respect to weight (p= 0.46).The different surgical procedures performed during the study in the two groups are shown in table 6 and graph 4. In our study, herniotomy accounted for around 50% of cases, 13 (43%) in group A and 14(46%) in group B. Circumcision was done in 6(20%) and 8(26%) cases in group A and B respectively, while orchidopexy accounted for 2(7%) cases in both the groups. Anorectal surgeries like rectal biopsy, polyp excision, proctoplasty and fistula repair were done in 5(16%) and 4(14%) in group A and B respectively.

DURATION OF ANALGESIA

Duration of analgesia (min)	Group A	Group B
Mean duration ± SD	250.33 ± 41.4	433.5 ± 60.2
Range	180 - 355	265 – 530

$p < 0.01$, student's unpaired 't' test

The mean duration of analgesia was 250.33 ± 41.4 min in group A with a range of 180 to 355 min. In group B, the mean duration of analgesia was 433.5 ± 60.2 min with a range of 265 to 530 min. The difference in the mean duration of analgesia was statistically highly significant ($p<0.001$) The incidence of nausea and vomiting was among 3(9%) children in group A compared to 2(6%) in group B. This was not statistically significant. There was no incidence of hypotension, bradycardia, dural or vessel puncture and respiratory depression in the two groups.

VI. Discussion

The past decade has witnessed many advances in the understanding and treatment of pain in children. Caudal epidural blockade is one of the most popular regional block used in paediatric anaesthesia. This reliable and safe technique is used widely for many surgical procedures in combination with general anaesthesia. It allows rapid recovery from anaesthesia with effective post-operative analgesia. The main disadvantage of this technique is the short duration of action following single shot caudal using only local anaesthetic. To avoid extradural catheter placement, which carries the risk of infection, and yet prolong the duration of single-shot caudalanaesthesia, various additives to local anaesthetic solutions have been used. Hence, recently several studies have reported caudal use of opioids and other drugs in children to improve postoperative analgesia. Though the use of caudal opioids did prolong the duration of analgesia, it was associated with side-effects like respiratory depression, pruritis, urinary retention, nausea and vomiting. Hence, other drugs like clonidine have been administered to improve analgesia in the postoperative period while avoiding the side-effects associated with opioid use. In this study, caudal epidural block using bupivacaine alone and bupivacaine with clonidine combination was conducted in 60 children in the age group of 5 to 10 years of ASA grade I and II coming for various elective infra-umbilical surgeries. Age, sex and weight :In the present study, there was no significant difference in the two groups with regard to age, weight and sex. The mean age was 7.1 ± 1.6 years in group A and 6.86 ± 1.6 years in group B. The mean weight was 16.3 ± 2.9 kg in group A and 15.7 ± 3.4 kg in group B. In both the groups males were more (> 80%). herniotomy, orchidopexy and circumcision in our study. Cook et al[10] studied the effect of caudal analgesia in paediatric patients in the age group of 1-10 years, undergoing only orchidopexy, hence all the cases were male (100%).The patients were induced with oxygen- nitrous oxide (50% - 50%) and halothane (in increasing concentration) and caudal block was performed using the same technique and same type of needle in all the patients. Klimscha and colleagues[18] demonstrated that in small children (mean age 3 yrs) undergoing daycase hernia repair, the addition of clonidine 1 or 2 µg/kg to bupivacaine 0.25% (0.75ml/kg) significantly prolonged the mean duration of analgesia and reduced the post-operative analgesic requirement within the first 24 hours. The analgesic effects were similar in both the groups, although the relatively low level of pain associated with inguinal herniotomy may have made it difficult to separate the analgesic efficacy of the two doses. Motsch and colleagues found that clonidine 5µg/kg significantly prolonged caudal block with bupivacaine 0.175% (1ml/kg) in children aged 4 – 8 years undergoing minor surgery. In our study, we chose 0.25% bupivacaine which provides better quality of analgesia when compared to lower concentrations and clonidine 1.5µg/kg which prolongs the duration of analgesia significantly while avoiding the

side effects like excessive sedation and bradycardia associated with higher doses. Jamali and colleagues, in a study of children aged 1-7 years undergoing sub- umbilical surgery, found that the mean duration of post-operative analgesia was significantly increased on adding clonidine 1 µg/kg (990 ±570 min) to plain bupivacaine 0.25%(1 ml/kg) (460 ± 420 min). Cook B et al[12] confirmed the superiority of caudal clonidine 2 µg/kg over epinephrine 5 µg/ml added to bupivacaine 0.25% (1 ml/kg) in a double blind study ofboys, 1-10 years of age, undergoing orchidopexy. The mean duration was significantly longer in clonidine group (348 min) compared with those receiving epinephrine (192 min). However, Joshi W et al concluded that there was no significant demographic, hemodynamic, or pain score differences between the groups as well as there was no difference in analgesic duration. This study was conducted in 36 children undergoing elective surgery using bupivacaine 0.125% (1mg/kg) with equal volume of either clonidine 2µg/kg or saline.

VII. Conclusion

The present study demonstrated that caudal administration of bupivacaine 0.25% (1 ml/kg) with clonidine (1.5 µg/kg) resulted in superior analgesia with longer duration of action compared with 0.25% bupivacaine (1 ml/kg) alone, without any significantdifference in the hemodynamic parameters and the incidence of side-effects.

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