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A COMPARATIVE STUDY OF CAUDAL BLOCK WITH BUPIVACAINE AND BUPIVACAINE WITH CLONIDINE IN INFRAUMBILICAL SURGERIES IN CHILDREN

Anaesthesiology

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ABSTRACT

INTRODUCTION:- Pain management is an essential component of care provided by paediatric anaesthesiologists. The use of regional anaesthetic techniques in infants and children has become increasingly accepted as standard of care during final decades of twentieth century. Caudal analgesia is one of the most popular regional anaesthetic technique employed in paediatric surgery for lower abdominal, urological, and lower limb operations. Single dose caudal analgesia with bupivacaine is very safe and has been effectively used in pediatric surgical procedures for provision of postoperative analgesia**.** Nowadays clonidine, an alpha 2 agonist has been extensively used in neuraxial blocks and peripheral nerve blocks to prolong the action of bupivacaine. It is one of the most commonly used additives with bupivacaine for caudal analgesia in children. So this clinical study is planned to compare caudal bupivacaine with clonidine and bupivacaine alone with regards to hemodynamic changes, analgesic potency and side effects in children.

MATERIAL AND METHODS:- This study was conducted at Govt Medical College and Associate group of Hospitals, Kota from jan.2018 to dec.2018. This study included 60 children, of either sex, coming for various elective infra-umbilical surgical procedures. Standard procedure was followed for caudal block. The patients were randomly divided into 2 groups of 30 each. **Group B** received 0.25% of bupivacaine 1 ml/kg. **Group BC** received 0.25% of bupivacaine 1 ml/kg with clonidine 1.0µg/kg. All data were collected and analysed with the help of suitable statistical parameters.

RESULTS:- The mean duration of analgesia was 250.33 ± 41.4 min in group B with a range of 180 to 355 min. In group BC, 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 ($p<0.001$).

KEYWORDS

Bupivacaine, Clonidine, Caudal analgesia, Infraumbilical surgeries

INTRODUCTION

Pain is perhaps the most feared symptoms of disease, which a human being is always trying to alleviate and conquer since ages. Children are special in this regard because in them, it is a very complex phenomenon. It is very difficult to differentiate restlessness or crying due to pain from that of hunger or fear in children.[1]

Pain management is an essential component of care provided by paediatric anaesthesiologists. 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**.**[2]

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 rapid return of the conscious pre-operative state while providing effective post-operative pain relief with minimal sedation.[3] Caudal analgesia is one of the most popular regional anaesthetic technique employed in children. It is the most common regional technique used in paediatric surgery for lower abdominal, urological, and lower limb operations.[4] The ease of performing the block and the extensive safety record of its use in children are the reasons for the popularity of caudal analgesia. They can be combined with general anesthesia to reduce the requirement for volatile agents and opioids, allowing rapid, pain-free recovery with minimal post-operative vomiting and an early resumption of oral intake. Depending on the volume, dose or concentration of local anesthetic, caudal epidural blocks results in sympathetic block, sensory analgesia and motor block. Complications are rare. Single dose caudal analgesia with bupivacaine is very safe and has been effectively used in pediatric surgical procedures for provision of postoperative analgesia**.**[5] 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.[4] The major drawback is the relatively limited duration of post-operative analgesia with bupivacaine alone.

Several adjuncts such as opioids, ketamine, midazolam, clonidine and neostigmine have been used with bupivacaine to prolong its action , and to prolong the duration of post-operative analgesia provided by the 'single shot' caudal technique.[6]

Nowadays clonidine, an alpha 2 agonist has been extensively used in neuraxial blocks and peripheral nerve blocks to prolong the action of bupivacaine. It is one of the most commonly used additives with bupivacaine for caudal analgesia in children.[7] However, the role of clonidine in improving and prolonging the analgesia produced by caudal bupivacaine is highly variable in different published studies. Also, the duration of post-operative analgesia using caudal clonidine bupivacaine mixtures is also highly variable.[6] Clonidine, 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 administration preferable. The addition of clonidine also prolongs the duration of action of bupivacaine after intrathecal and epidural administration in adults.[8] 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.[4]

So this clinical study is planned to compare caudal bupivacaine with clonidine and bupivacaine alone with regards to hemodynamic changes, analgesic potency and side effects in children.

MATERIAL AND METHOD

This study was conducted at Govt Medical College and Associate group of Hospitals, Kota from jan.2018 to dec.2018.

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 1-5 yrs
- ASA grade I and II
- Patients coming for elective infraumbilical surgeries

- **Exclusion criteria:**
- ASA grade III and IV
- Infection at the site of injection
- Coagulopathy or anticoagulation
- Congenital abnormalities of lower spine and meninges
- Active disease of the CNS
- History of allergy to local anaesthetics

Ethics:
The study was approved by institutional ethical committee of Govt. Medical College and attached group of Hospitals Kota, Rajasthan, India.

METHODS:
Pre-anaesthetic assessment:
Standard protocol was followed for Pre-anaesthetic assessment of patients Informed consent was obtained from the parent before including the children in the study.

Pre-operative fasting :
Solid foods were restricted for 6 hours, milk for 4-5 hours and clear fluids for 2-3 hours prior to surgery.

Pre-medication :
All patients were pre-medicated with syrup Promethazine 1 mg/kg, once on the night before the surgery and another dose in the morning, 1 hour prior to surgery.

Procedure:
Patients were induced with oxygen, nitrous oxide (50:50) and halothane (in increasing concentration) using Jackson Reis circuit and intravenous line was secured. Injection atropine 0.02mg/kg was given intravenously after securing IV access. An infusion of Ringer Lactate was started and fluid was administered according to the calculated requirements.

Caudal block:
Standard procedure was followed. After injection was complete, the needle was removed and the child was placed in supine position. No analgesia was given by any route pre-operatively or intra-operatively. Anaesthesia was maintained with oxygen, nitrous oxide and halothane (0.5-2%) through a face mask with patient on spontaneous ventilation throughout the surgery.

Drug and dosage:
The patients were randomly divided into 2 groups of 30 each.
Group B received 0.25% of bupivacaine 1 ml/kg.

Group BC received 0.25% of bupivacaine 1 ml/kg with clonidine 1.0µg/kg.

Monitoring :
Monitoring included precordial stethoscope, pulse-oximetry, NIBP, respiratory rate and ECG. The time of caudal block and duration of surgery was noted.

Recovery :
Anaesthetic agents were discontinued at the beginning of skin closure. 100% oxygen through a face mask was administered for 3-5 minutes. Once the vitals were stable and the child was awake, the child was shifted and placed in semi-prone position in the recovery room. On arrival to the recovery room, the child was monitored for another 1 hour with SpO2, respiratory rate, NIBP and heart rate every 15 minutes. After that the child was shifted to the ward and monitored thereafter.

Parameters studied :
Hemodynamic parameters :
Patients were monitored for heart rate, respiratory rate and blood pressure after administration of caudal block at 0,5,15,30,45,60,120 and 180 minutes and the values were recorded.

Duration of action :
Duration of action of drug is defined as the time interval between the administration of caudal block and the first requirement of supplementary analgesia for the patient.

Post-operative analgesia :
Post-operative analgesia is assessed by Paediatric Objective Pain Scale. The assessment was done for a period of 24 hours after caudal block. If the pain score was more than 6 for 2 consecutive intervals of 10 minutes, then supplementary analgesia with rectal Paracetamol (15mg/kg) was given. These assessments were made at 1,2,3,4,8,12 and 24 hours after caudal block.

Statistical analysis:
The results of continuous variables are expressed as mean ± SD and proportion as percentage. The difference between the two groups was assessed by student's - t test and chi-square test. For all the tests a 'p' value of 0.05 and less was considered for statistical significance.

RESULTS:
Table: 1 Duration of analgesia

Duration of analgesia (min)	Group-B	Group-BC
Mean	250.3	433.5
SD	41.4	60.2
P-value	0.0001	
Remarks	Significant	

The mean duration of analgesia was 250.33 ± 41.4 min in group B with a range of 180 to 355 min. In group BC, 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 ($p<0.001$).

Figure: 1 pain score at various time intervals

Table: 2 Incidences of complications

Complications	Group B	Group BC
Hypotension	0	0
Vomiting	3 (9%)	2 (6%)
Dural puncture	0	0
Blood vessel puncture	0	0
Respiratory depression	0	0
Pruritis	0	0

The incidence of nausea and vomiting was among 3(9%) children in group B compared to 2(6%) in group BC. This was not statistically significant. There was no incidence of hypotension, bradycardia, dural or vessel puncture and respiratory depression in the two groups.

DISCUSSION:
Caudal epidural analgesia is one of the most popular and commonly performed regional blocks in pediatrics anesthesia. It is a reliable and safe technique that can be used with general anesthesia for intra and post-operative analgesia in pediatric patients undergoing lower abdominal and limb surgeries. The awareness of pain relief in pediatric patients is increasing in both neonates and children. The past decade

has witnessed many advances in the understanding and treatment of pain in children. The use of adjuncts can effectively help in reduction of the dose and an increase in duration of the local anesthetic agents.[9] Our study was undertaken to assess the efficacy and safety of clonidine with bupivacaine in paediatric patients undergoing lower abdominal and lower limb surgeries under caudal analgesia.

The duration of analgesia was significantly prolonged in bupivacaine-clonidine group(433.5±60.2 min) compared to bupivacaine alone group (250.33±41.4 min) in our study**.(Table-1)** This is in agreement with a study by **J J Lee and colleagues,**[10] which found that addition of clonidine to local anaesthetic prolongs the duration of analgesia after a single shot caudal block. They reported an increase in the mean duration of analgesia (588 ± 120 min) after the addition of clonidine when compared to local anaesthetic alone (312 ± 60 min).

Jamali and colleagues[11], 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 of boys, 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). The duration of analgesia achieved by the addition of clonidine to bupivacaine varies widely in these studies (5.8 - 16.5 hours). This may be the result of a number of factors: dose of clonidine used; differences in premedication and volatile anaesthetics used; type of surgery; indications for rescue analgesia; assessment of pain and statistical analysis.

Bhatia et al[13] found duration of analgesia to be 4.54±1.17 hours for the plain bupivacaine group and 10±1.15 for the Bupivacaine + clonidine group respectively (p value< 0.0001 significant).

Pain assessment is the most important and critical component of pain management. Assessing pain in children is an ever challenging as well as a difficult task, mainly because so far no reliable, universal method of assessing and measuring child's pain is available. In our study, we have used Pediatric Objective Pain scale which is a valid, objective and reliable method of pain assessment in children between 5 to 10 years. Objective pain scale has been used to equate pain and discomfort in young children with changes in standardized behavioural and physiologic parameters. It does not require patient participation. If the pain score is more or equal to 6 at 2 consecutive intervals of 10 minutes, supplementary analgesic with rectal paracetamol (15 mg/kg) was given.

There was no incidence of pain score in group-B and group-BC was below 6 at the end of first and second hour and did not require any analgesia. At the end of third hour, 15(50%) of the patients in group-B had a pain score below 6 and 1 (3.33%) patients had pain score of 6. In group-BC all patients had pain score was below 6. At the end of fourth hour, 15(50%) of patients in group B had a pain score below 6 and 14 (46.7%) patients had pain score of 6 In group-BC 96.7% had pain score below 6 and 3.33 had pain score of 6. The differences were found statistically significant with p-value equal to 0.03. **(Figure-1)**

In our study, 3 of the children in group B and 2 of them in group BC had an episode of vomiting which was treated with Inj Metaclopramide (0.1 - 0.2 mg/kg) IV. The incidence of vomiting was comparable in both the groups, 9% and 6% in group B and BC respectively.(**Table-2**). The addition of clonidine to bupivacaine in our study, did not result in an increase in the incidence of side effects. The main side-effects of epidurally administered clonidine are bradycardia, hypotension and sedation. In our study, bradycardia or hypotension, warranting treatment, did not occur. Sedation correlated well with the duration of analgesia.

In our study, there is no significant hemodynamic differences between two groups. Similarly, **Joshi W et al**[14] 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. This could be due to small concentration of local anaesthetic used and the use of parental pain scores following discharge from the hospital.

CONCLUSION:

It is concluded that clonidine in a dose of 1 µg/kg, added to 0.25% bupivacaine for caudal analgesia and administered as a 1ml/kg mixture in children, for infraumbilical surgery, significantly prolongs the duration of post-operative analgesia when compared to 1ml/kg of 0.25% bupivacaine alone, without any side effects.

CONFLICT OF INTEREST: there is no conflict of interest between authors.

ABBREVIATION:

ASA	American Society of Anaesthesiologists
BC	Bupivacaine with clonidine
SD	Standard deviation
CNS	CENTRAL NERVOUS SYSTEM

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