Comparision of Plain Bupivacaine And Bupivacaine With Dexmedetoidine for Caudal Block in Children

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ABSTRACT
Background & Objectiv
Caudal epidural analgesia is one of the most commonly performed regional techniques in paediatric anaesthesia for intra and post-operative analgesia. However, the duration of analgesia is limited by the duration of action of local anaesthetics. Addition of opioids like morphine, fentanyl is associated with side effects like respiratory depression, urinary retention and pruritus. Dexmedetomidine a α2 agonist is known for its analgesic effects with lesser side effects. Hence, this study was conducted to know the efficacy and safety of addition of dexmedetomidine to bupivacaine in a single shot caudal block in children.

Methods: This study was conducted among 60 children in the age group of 1 – 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 dexmedetomidine 1 μg/kg. The various parameters studied were intraoperative hemodynamic changes, duration of post operative analgesia, post operative analgesic requirement and incidence of side-effects. Pain assessment was done at the 0, 1st, 2nd, 3rd, 4th, 8th, 12th, 16th, 20th and 24th hour after the surgery.

Results: The groups were similar in age, sex and weight. The mean duration of analgesia in group B (598.17 ± 78.33 min) was significantly longer (p< 0.001) than in group A (298 ± 44.6 min).

The pain score in the two groups were similar up to 2 hours after surgery but was higher in group A at the end of 3rd and 4th hour compared with group B. Incidence of bradycardia, hypotension vomiting was comparable in both the groups

Conclusion: This study showed that the addition of dexmedetomidine in the dose of 1μg/kg to 0.25% bupivacaine 1ml/kg prolonged the duration of analgesia with less post operative analgesic requirement after a single shot caudal block with minimal side effects in children.

INTRODUCTION
The International Association for the Study of Pain defines pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage”1. In children, even the definition of pain has been debated1. Pain is a complex constellation of unpleasant sensory, perceptual, and emotional experiences and certain associated autonomic, psychological, emotional, and behavioral responses.

The use of regional anaesthetic techniques in infants and children has become increasingly accepted as 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 sedation2.

Caudal analgesia is one of the most popular regional anaesthetic technique employed 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 discharge3.

Dexmedetomidine (DEX) is a highly selective α2 agonist with sedative and analgesic properties. It has an α2/α1 selectivity ratio of 1600 : 1, which is eight times more potent than clonidine (200 : 1), thus reducing the unwanted side effects involving α-1 receptors.

This clinical study is therefore undertaken to compare caudal bupivacaine with dexmedetomidine and bupivacaine alone with regards to hemodynamic changes, analgesic potency and side effects in children.

MATERIALS AND METHODS
This study included 60 children, of either sex, coming for various elective infra-umbilical surgical procedures such as herniotomies circumsicion, orchidopexy, perineal surgeries and minor procedures in lower extremities.

Inclusion criteria:
Age group of 1-6 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 therapy
Congenital abnormalities of lower spine and meninges
History of developmental delay or mental retardation
History of allergy to local anaesthetics.

A thorough preanaesthetic assessment was done. Solid foods were restricted for 6 hours, milk for 4-5 hours and clear fluids for 2-3 hours prior to surgery.

PREMEDICATION: IV canula was secured and Inj. Atropine 0.01 mg/kg IV given.

PROCEDURE: After shifting to the operation theatre each patient was induced with Sevoflurane (4-8%) and depolarizing muscle relaxant (Inj. succinylcholine 2 mg/kg) was used to facilitate intubation. The airway was secured by using appropriate sized endotracheal tube. Jackson-Rees circuit was used for controlled ventilation. No other analgesics or sedatives were used.

CAUDAL BLOCK: The anaesthetized patient was placed in left lateral decubitus position with legs flexed. After identifying the sacral hiatus, a 23G hypodermic needle with its bevel facing anteriorly was inserted at an angle of 45° to the skin till the sacro-Coccygeal membrane was pierced, when a distinct “pop” was felt. The needle was now lowered to an angle of 15° and advanced 1-2 cm to make sure that the entire bevel was inside the space. Confirmation of the needle point being in the epidural space was done with the “whoosh” test and the lack of resistance encountered by injection of 2-3 ml of air. Aspiration was done to exclude dural puncture or vessel puncture and the drug was injected.

Drug and dosage: The patients were randomly divided into 2 groups of 30 each.

Group A received 0.25% of Bupivacaine 1 ml/kg + 1ml normal saline

Group B received 0.25% of Bupivacaine 1 ml/kg + Dexmedetomidine 1µg/kg in normal saline 1ml.

After injection was complete, the needle was removed and the patient was placed in supine position. General anaesthesia was maintained by using Oxygen, Sevoflurane and NDMR (Inj. Atracurium 0.5 mg/kg).

MONITORING: Intra operatively hear rate, blood pressure and oxygen saturation were closely monitored.

RECOVERY: Anaesthetic agents were withdrawn at the beginning of skin closure. 100% Oxygen was administrated. Reversal agent Inj. Neostigmine (0.05mg/kg) with Inj. Glycopyrrolate (0.02 mg/kg) was given.

Later the subject was shifted to post anaesthesia care unit (PACU) and monitored for the next 24 hours i.e., every 4, 8, 12, 16, 20, and 24th hour for:

- FLACC pain scale
- Hypotension
- Bradycardia
- PONV
- Urinary retention.

OBSERVATION & RESULTS

Children in group B received caudal bupivacaine 0.25% (1ml/kg) with dexmedetomidine (1µg/kg) in 1ml normal saline.

The Paediatric observational FLACC Pain Score was below 4 at the end of first and second hour in both the groups and did not require any analgesia.

At the end of third and fourth hour, 3 (10%) and 10 (33.33%) of the patients in group A had a pain score of ≥ 4 respectively and required rescue analgesics whereas none of the patients had a score of ≥ 4 in group B. The difference was statistically highly significant.

At the end of 12th hour, group A had 20 (66.67%) patients with pain score of ≥ 4 while group B had 1 (3.3%) patient with similar pain score. The difference was statistically highly significant.

At the end of 16th hour group A had 2 (6.67%) patients with pain score of ≥ 4 while group B had 1 (3.33%) patient with similar pain score. The difference was statistically not significant.

At the end of 24th hour, group A had 15 (50%) patients with pain score of ≥ 4 and group B had 8 (26.67%) patients with similar pain score respectively, the difference being statistically significant.

Duration of post operative Analgesia

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean duration of Analgesia (Min)</th>
<th>SD</th>
<th>Range (Min)</th>
<th>p value</th>
<th>Statistical Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>298.17</td>
<td>± 44.58</td>
<td>230 – 405</td>
<td>0.001</td>
<td>HS</td>
</tr>
<tr>
<td>Group B</td>
<td>598.17</td>
<td>± 78.33</td>
<td>485 – 755</td>
<td></td>
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</table>

The total duration of post-operative analgesia in group A was 298.17 ± 44.58 minutes with a range of 230 – 405 minutes, while in group B, it was 598.17 ± 78.33 minutes with a range of 485 – 755 minutes. This difference between the two groups was highly significant and was shown in the graph.

The total number of rescue analgesics used in the form of paracetamol suppository whenever FLACC pain score was ≥ 4. In group A, 14 (46.7%) children required two doses and 16 (53.3%) required three doses of rescue analgesics. In group B, 3 (10%) children required only single dose, 26 (86.7%) children required two doses and only one child re-
Effects like respiratory depression, pruritus, urinary retention and nausea/vomiting. Hence other drugs like α2 agonists have been used to improve analgesia in the post-operative period while avoiding the side-effects associated with usage of opioids.

Among the α2 agonists, clonidine and dexmedetomidine are commonly used. Clonidine has been extensively used in all types of regional anaesthetic techniques. Dexmedetomidine is a highly selective α2 agonist especially for the 2A subtype with sedative and analgesic properties and minimal respiratory depression. It has a α2/α1 selectivity ratio of (1600:1) which is eight times more potent than clonidine (200:1). It is short acting drug than clonidine with a distribution half life of 30 minutes and elimination half life of 2 hours. Dexmedetomidine is a preservative-free solution and contains no additives or stabilizers. Epidural dexmedetomidine has been used in the range of 0.5–2 μg/kg without any incidence of neurological deficits.

This study, using caudal epidural block with bupivacaine alone and bupivacaine with dexmedetomidine combination was conducted in 60 children in the age group of 5 to 6 years, of ASA status I and II coming for various elective infra-umbilical surgeries. Epidural dexmedetomidine has been used in the range 1 μg/kg without any incidence of neurological deficits.

In this study, using caudal epidural block with bupivacaine alone and bupivacaine with dexmedetomidine combination was conducted in 60 children in the age group of 5 to 6 years, of ASA status I and II coming for various elective infra-umbilical surgeries. Epidural dexmedetomidine has been used in the range 1 μg/kg without any incidence of neurological deficits.

Incidence of complications

The incidence of bradycardia was seen in 1 (3.3%) child in group A compared to 2 (6.6%) in group B. Hypotension was observed in 1 (3.3%) child in group A while none in group B. Nausea and vomiting was present in 2 (6.7%) children in group A compared to 1 (3.3%) in group B. These differences were statistically not significant. Pruritis was not noted in both the groups.

DRUGS AND DOSAGE

In our study we have used a single dose of 0.25% bupivacaine 1ml/kg.

Armitage has recommended 0.25% bupivacaine in a dose of 0.5 ml/kg for lumbo-sacral, 1 ml/kg for thoraco-lumbar, 1.25 ml/kg for mid-thoracic level of block and the plasma bupivacaine levels were always below 1.2μg/ml, which was below the toxic levels. Gunter et al have reported that 0.175% bupivacaine offered the best combination of effectiveness, rapid recovery and discharge for paediatric surgical outpatients.

However, Jamali et al and Cook et al used 0.25% bupivacaine 1ml/kg for paediatric herniotomy and orchidopexy respectively, as a single shot caudal block. Higher concentration can produce motor blockade in the immediate post-operative period and delay the discharge. Since all our patients were monitored for 24 hours post-operatively in the hospital, as 0.25% bupivacaine 1ml/kg was used as single shot caudal block which gives a better quality of analgesia.

El-Hennawy et al compared bupivacaine 0.25% 1ml/kg alone and dexmedetomidine 2μg/kg or clonidine 2 μg/kg with bupivacaine 0.25%, 1ml/kg caudally. They concluded that the addition of dexmedetomidine or clonidine to caudal bupivacaine significantly promoted analgesia time (16–18) and (12–21) hours respectively than the use of bupivacaine alone [5 (4–6) hours with a p < 0.001 i.e., Highly significant.

Saadawy et al showed that the duration of analgesia was significantly longer with dexmedetomidine administration 1μg/kg with bupivacaine 0.25% 1ml/kg (18.5 h) than plain bupivacaine 0.25% 1ml/kg (6.2 h) (p<0.001) and the incidence of agitation following sevoflurane anaesthesia was significantly lower with dexmedetomidine (p<0.05).

Neogi et al compared ropivacaine 0.25% 1ml/kg alone and dexmedetomidine 1μg/kg or clonidine 1 μg/kg with ropivacaine 0.25% 1ml/kg caudally. The mean duration of analgesia was 6.32±0.46 hours in the ropivacaine group, 13.17±0.68 hours in the clonidine group and 15.26±0.86 hours in the dexmedetomidine group. They concluded that addition of clonidine or dexmedetomidine to ropivacaine administered caudally significantly increases the duration of analgesia.

In the present study also there is a prolongation in the duration of post-operative analgesia in the dexmedetomidine group (598.17 ± 78.33 minutes) compared to the bupivacaine group (298.17 ± 44.58 minutes). This difference between the two groups is highly significant, both clinically and statistically.

DURATION OF POST-OPERATIVE ANALGESIA:

In this study, the FLACC Pain Scale was chosen to assess post operative pain. Previous studies of paediatric postoperative caudal analgesia have used the Children’s Hospital of Eastern Ontario Pain Scale, the Children and Infants Postoperative Pain Scale, or the Objective Pain Scale. However, several of these studies observed no significant difference in postoperative observational pain score. The FLACC Pain Scale, being an observational and behaviour pain measurement score, was reliable and validated for children aged 2 months – 7 years.
The time to first analgesic requirement or total duration of post-operative analgesia in bupivacaine group was 4.96 ± 0.74 hours with a range of 3.83 - 6.75 h, while in dexmedetomidine group; it was 9.96 ± 1.33 h with a range of 8.08 – 12.58 h. This difference between the two groups was highly significant.

El –Hennawy et al11 showed that the addition of dexmedetomidine or clonidine to caudal bupivacaine promoted the analgesia time 16(14-18)h and 12(3-21)h respectively than the use of bupivacaine alone 5(4-6)h with P<0.001 i.e, highly significant.

Saadawy et al16 showed that the addition of dexmedetomidine to caudal bupivacaine significantly prolongs the analgesia 18.5±2.8h than the use of bupivacaine alone 6.2±2.8h with p<0.001 i.e, highly significant.

The FLACC pain score never reached ≥ 4 during the first two hours in both the groups. At the end of third and fourth hour, 3 (10%) and 10 (30%) patients in group A had a pain score of ≥4 and required rescue analgesic whereas none of the patients had a score of ≥ 4 in group B. This difference between the two groups was highly significant. During the remaining time interval except at the end of 8th and 20th hour group A patients achieved higher FLACC score than group B.

COMPLICATIONS:
In our study one (3.3%) child in bupivacaine group and 2 (6.7%) children in dexmedetomidine group had bradycardia, which was treated with injection atropine 0.01mg/kg iv. Hypotension was observed in 1 (3.3%) child in group A which was treated with fluid bolus, while none in group B. Nausea and vomiting was present in 2 (6.7%) children in group A compared to 1(3.3%) in group B and was treated with injection ondansetron 0.08 mg/kg. These differences were not statistically significant.

Saadawy et al16 showed the incidence of vomiting, time for first micturition and spontaneous leg movements were not significant among caudal bupivacaine-dexmedetomidine and bupivacaine alone groups only one child in bupivacaine group required urinary catheterization.

El Hennawy et al11 showed no significant differences in the incidence of pruritis, PONV, mean time to first micturition on addition of clonidine or dexmedetomidine to caudal bupivacaine.

CONCLUSION
The present study demonstrated that caudal administration of bupivacaine 0.25% (1ml/kg) with dexmedetomidine (1 μg/kg) resulted in reduced anaesthetic requirement, prolongation of the duration of analgesia and less post operative analgesic requirement compared with 0.25% bupivacaine (1ml/kg) alone, without any significant difference in the hemodynamic parameters or increase in the incidence of side-effects in children undergoing infra umbilical surgeries. Hence low dose dexmedetomidine safely prolongs the duration of post-operative analgesia when it is added to bupivacaine for caudal block for infra umbilical paediatric surgeries.