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Comparative study of caudal bupivacaine and caudal bupivacaine-midazolam combination in paediatric patients for post-operative analgesia

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Abstract
Context: Single-shot caudal anaesthesia with local anaesthetics (bupivacaine) is the most commonly used regional technique for intraoperative and postoperative pain relief in children as it is safe, reliable and provides efficient analgesia but it has only a short duration of action. The present study has been carried out to evaluate the efficacy of caudal bupivacaine and caudal bupivacaine and midazolam for post operative analgesia in paediatric patients.
Aims and Objectives: To compare the effects of addition of midazolam to 0.25% bupivacaine on the duration of analgesia produced by caudal block and evaluate side effects if any.
Study Design: The study was a prospective, randomized, comparative study.
Materials and Methods: 50 patients with ASA grade 1, of age group 1 to 10 years, scheduled for elective unilateral inguinal herniotomy and urogenital surgeries are grouped into Group 1 that received caudal block with bupivacaine (0.25%) 1 ml/kg and Group 2 that received caudal block with bupivacaine (0.25%) 1 ml/kg with midazolam (50 microgram/kg) as additive.
Statistical analysis used: Data were analysed by analysis of variance with Fisher's exact test for nominal data. A value of $P<0.05$ was regarded as statistically significant.
Results: Onset of pain was faster in group 1. After eight postoperative hour observer pain score (OPS) showed statistically significant increase in values for Group 1 as compared to Group 2.
Conclusion: Addition of midazolam to caudal bupivacaine prolongs the duration of post operative analgesia and is remarkably safe.

Keywords: caudal block, midazolam, bupivacaine, observer pain score

Introduction
Single-shot caudal anaesthesia with local anaesthetics (bupivacaine) is the most commonly used regional technique for intraoperative and postoperative pain relief in children. The popularity of this technique is due to the safe, reliable and efficient analgesia. However the single-shot "kiddie caudal" may have only a short duration of action. Hence the present study was carried out to evaluate the efficacy of caudal bupivacaine and caudal bupivacaine with midazolam for post operative analgesia in paediatric patients.

Aims and Objectives
To compare the effects of addition of midazolam (50 microgram/kg) to 0.25% bupivacaine on the duration of analgesia produced by caudal block and evaluate side effects if any.

Material and Methods
After approval by the college ethics committee, written informed parental consent was obtained for each subject. We studied 50 patients, ASA physical status I, aged 1-10 yr, scheduled to undergo elective unilateral inguinal herniotomy and urogenital surgeries as inpatients. Exclusion criteria included contraindications to caudal block.
Premedication was done with inj. Glycopyrolate and all procedures were performed under general anaesthesia. Anaesthesia was induced with injection propofol 2-3mg/kg and oro-tracheal intubation was facilitated with inj. Suxamethonium Chloride 2mg/kg. Anaesthesia was maintained with 70% nitrous oxide in oxygen and isoflurane 0.2%-0.4%, with intermittent positive-pressure ventilation. After induction patients were allocated randomly to receive caudal block with injection Bupivacaine (0.25%) 1ml/kg (Group1) and injection Bupivacaine (0.25%) 1ml/kg with inj. Midazolam 50µg/kg as additive (Group 2) in left lateral position using a 23-guage short-bevel needle under aseptic conditions.
No intraoperative sedatives or opioids were administered.
The study design was randomized by using a random number table. A small Elastoplasts dressing was placed at the site of injection in all patients. The association of saline was not necessary because the methodology was based on a final caudal volume, which was similar in all groups. Surgical intervention started 10-15 min after the injection.
Heart rate (HR), Systolic Blood Pressure (SBP), and

peripheral oxygen saturation (SpO_2) were recorded before the anaesthesia induction and every 5 min after the placement of caudal anaesthesia.

During surgery, adequate analgesia was defined by hemodynamic stability, as indicated by the absence of an increase in SBP or HR by >15% of pre-incision baseline values; isoflurane concentration was maintained between 0.2% and 0.4%. An increase in HR or SBP within 15 min of skin incision indicated failure of caudal anaesthesia.

If the readings increased by >15%, the child received a rescue opioid (fentanyl; 2µg/kg initially and subsequently 0.5 µg/kg as dictated by hemodynamic variables), because analgesia was considered inadequate.

Fluid therapy was standardized during and after surgery. During surgery, children received lactated Ringer's solution 6 ml. $kg^{-1.}$ h^{-1}, whereas 5% dextrose in 0.45% NaCl was infused at 4 ml· $kg^{-1.}h^{-1}$ in the postoperative period. An intraoperative decrease of SBP or HR by >30% was defined as hypotension or bradycardia, respectively, and was treated by fluid bolus, ephedrine or atropine, as necessary.

Each patient was observed for 2 hours in the recovery room before being transferred to the ward. HR and SpO2 were monitored continuously, and SBP was monitored every 5 min. When the child was awake in the recovery room, pain and sedation scores, respiratory rate, SBP, and HR were assessed. Assessments were repeated at 2, 4,8,12, and 24 h after recovery from anaesthesia.

Postoperative pain was assessed with a 5-point observer pain score: 1=asleep or awake and laughing; 2=awake, but no pain; 3 = mild pain (irritable/restless); 4 = moderate pain (crying, grimacing restless but consolable) and 5 = severe pain (crying /screaming /inconsolable).

The duration of absolute analgesia was defined as the time from caudal injection until the pain score was ≤ 2. Rescue analgesic was given for a pain score ≤ 4 in the form of Paracetamol suppository (20mg/kg) as necessary.

Sedation scores (0= eyes open spontaneously, 1=eyes open in response to physical stimulation and 3=unarousable) were measured along with pain.

Motor block was assessed on awakening by using a modified bromage scale that consisted of 4 points: 0 = full motor strength (flexion of knees and feet), 1=flexion of knees, 2=little movement of feet only, 3=no movement knees or feet. However younger children who could not move their legs on command were stimulated on the legs and feet.

The incidence of adverse effects such as nausea vomiting, dizziness, and purities was evaluated by a yes /no survey. Respiratory depression was defined as a respiratory rate of <10 breaths /min. All evaluations were performed along with assessments of pain and sedation.

Only elective urogenital surgeries were included in our study to avoid the type, nature and duration of pain associated with different types of surgery. Moreover, all cases were performed by the same surgical team to minimize the differences in tissue handling

Statistical analysis used

Data were analysed by analysis of variance with Fisher's exact test for nominal data. A value of $P<0.05$ was regarded as statistically significant.

Results

Patient's demographics were similar and fairly comparable in both groups and differences were statistically not significant (table-1, 2, 3).

In table 4 duration of analgesia using mean Observer Pain Score (OPS) was plotted and it revealed that the mean OPS is quite similar for the two groups during the first 4 hours but after the 8th post-operative hour there is a statistically significant increase in the values of OPS for group 1 (3.12) as compared to group 2(2.24).

In table 5 we see that 4 patients in group 1 have already had a OPS of > 4 by 8th post-operative hour requiring rescue analgesia while none of the patient in group 2 have OPS>4. This is a statistically significant difference.

Discussion

Pain is defined as an "unpleasant sensory and emotional experience associated with actual or potential tissue damage". The current trend is to prefer a regional anaesthetic technique for lower abdominal as well as limb surgery in paediatric patients. Post-operative pain management should be an essential and integral part of the care given to the paediatric patients.

If analgesia is given intraoperatively before the onset of pain, then all the responses due to pain can be suppressed and the child will be more comfortable during recovery.

In this study we have demonstrated the efficacy and the duration of analgesia of Injection bupivacaine and mixture of Inj. Bupivacaine and midazolam. The efficacy of analgesia is equal in both groups but the duration of analgesia is significantly longer when mixture of bupivacaine and midazolam is used in caudal block.

As per table 4, we can see that the mean OPS is quite similar for the two groups during the first 4 post op hours but after the 8th post-operative hour, there is a statistically significant ($P< 0.05$) increase in the values of OPS for group bupivacaine (3.12) compared to the group bupivacaine+ midazolam (2.24). This statistically significant increase in the OPS score is continued up to the 12th post-operative hour. After the 12th post-operative hour, the OPS score for the two groups start becoming similar reaching a value of 5 for Group bupivacaine and 4.84 for group bupivacaine+ midazolam. This reading suggests that the mixture of bupivacaine and midazolam provides a longer duration of post-operative analgesia compared to plain bupivacaine alone.

Mohammed Naguib *et al*. in 1995 conducted 45 cases using caudal midazolam 50ug/kg with 0.25% bupivacaine for inguinal herniotomy, dividing the patients into three groups with group A receiving caudal bupivacaine, group B receiving caudal bupivacaine+ midazolam and group C receiving plain caudal midazolam [1].

They found that there was no statistically significant change in heart rate, systolic blood pressure and respiratory rate which is similar to our study. They also observed that vomiting occurred post operatively in two (13.3%) patients who received caudal bupivacaine and in one (6.6%) patient who received caudal bupivacaine and midazolam. No patients in midazolam group had any sequelae. 4 patients (26.7%) in both bupivacaine and bupivacaine-midazolam groups were unable

to stand at 6 hours post operatively. In contrast none of the patients in caudal midazolam group had no signs of motor weakness. Results of our study differed from Mohammed Naguibs study as none of the patients in either group had any incidence of side effects.

Gulec *et al*. in 1998 conducted 60 cases with caudal 0.25% bupivacaine (Group A), 0.25% Bupivacaine-Midazolam 50ug/kg (Group B) and 0.25% Bupivacaine-Morphine 0.05mg/kg (Group C) and found the duration of analgesia (OPS<4) was 12.15+/-1.2 hours in Group B, 14.40+/-1.6 hours in Group C and 8.15 +/-1.3 hours in Group A [2].

In our study group, the duration of analgesia was 7.6±1.2 hrs in Group 1 and 11.8± 0.9 hrs in Group 2, which is similar to the study conducted by Gulec *et al*.

In 1999 Nishiyama *et al*. while studying post-operative analgesia with epidural Midazolam and Bupivacaine observed that epidural midazolam together with Bupivacaine adds to the central analgesia, sedative and amnesic effects [3]. In our study no sedation was seen with caudal midazolam.

Mahajan *et al*. in 2001 observed that lower pain score was seen with the addition of Midazolam 50ug/kg to caudal Bupivacaine 0.25% 0.5ml/kg. In the bupivacaine-midazolam group, the duration of analgesia was longer ($p<0.001$) (11+/-0.5 hours) as compared to the plain bupivacaine group (7.4+/-2.1 hours) [4]. Fewer children (26.6%) in group bupivacaine-midazolam required additional analgesia during the first 24 post-operative hours where as in Group Bupivacaine 60% of children received analgesia supplement within 6 hours of surgery ($p<0.05$). This study is similar to our study where group 1 had duration of analgesia of 7.6+/-1.2 hours and Group 2 had duration of 11.8+/- 0.9 hours.

J.J. Lee and A.D. Rubin *et al*. associated the clinical value of Bupivacaine (Group A) and Bupivacaine-clonidine (Group B) in children. The mean duration of caudal analgesia for Group A and B were 5.2+/-1.2 hours and9.8+/-2.1 hours respectively ($p<0.001$) and Group B required significantly supplemental analgesia after operation [5]. There was no significant difference in the incidence of side effects between the two groups. The longer duration of sedation in group B resulted partly from the sedative effect of clonidine and partly from the longer duration of analgesia provided by clonidine. They concluded that when added to Bupivacaine, clonidine improves the efficacy of caudal analgesia in children. According to our study group, the duration of analgesia in Bupivacaine-Midazolam group is longer than the study group of J.J. Lee and also the side effects of clonidine are not seen.

In 1998, Nishiyama *et al*. studied the effect of diluent volume on post-operative analgesia and sedation produced by epidurally administered Midazolam. They concluded that 5 to 10 ml saline is the optimum volume for epidural injection when using Midazolam 50ug/kg for post-operative analgesia following upper abdominal surgery [6]. In our study, the diluent volume used for Midazolam group was 1ml/kg and dose used was 50ug/kg having optimal analgesia without sedation, amnesia and urinary retention.

In 1992, Nishiyama *et al*. evaluated 4 dosed (25, 50, 75 and 100ug/kg) of epidural midazolam mixed with saline in patients undergoing upper abdominal surgery [7]. They concluded that Midazolam 50ug/kg was the optimal dose for post-operative analgesia. Higher doses were associated with increased sedation score. This study correlates with our study.

Conclusion

Addition of midazolam (50 microgram/kg) to caudal bupivacaine prolongs the duration of post operative analgesia and is remarkably safe.

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