ORIGINAL ARTICLE

COMPARISON BETWEEN CAUDAL BUPIVACAINE AND CAUDAL MIDAZOLAM FOR POST OPERATIVE ANALGESIA IN PEDIATRIC PATIENTS

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ABSTRACT

Objective: To evaluate the efficacy and side effect of caudal Bupivacaine as compared to caudal Midazolam for providing post operative analgesia in children.
Material and method: It was a prospective, open label, randomized study on 50 patients aged between 1-12 yrs of American society of anesthesiologist (ASA) grade I and II posted for below umbilical surgery under standardized general anesthesia. After induction, patients were allocated randomly into two groups. Gropup-1 received caudal block with inj. Bupivacaine (0.25%) 1ml/kg and Group-2 received caudal block with inj. Midazolam 50 μg/kg+ saline 1ml/kg. Children were continuously observed in recovery room for 20 minutes after which they were shifted to general ward. In ward OPS (observer pain scale) score was recorded at 0.5,2,4,8,12 and 24 hours after surgery.
Result: Pain score was comparable for initial half an hour postoperatively for both the groups but at 2, 4, and 8 hrs postoperatively Group-1 had low OPS compare to Group-2. The overall need for rescue analgesic was lower in Group-1 compare to Group-2.
Conclusion: We concluded that analgesic effect was longer and lesser need for rescue analgesic in the postoperative period in Bupivacaine group compare to Midazolam group.

KEY WORDS: Bupivacaine, Midazolam, caudal analgesia, anesthesia

INTRODUCTION

Pain is an unpleasant subjective sensation which can only be experienced and not expressed, especially in children who rely completely on their parents or care givers for their well being. The concept of post operative pain relief and its utilization in the pediatric age group has improved dramatically over the recent years. Till date various methods have been evaluated for providing post operative pain relief in pediatric population, nonetheless having some side effects which prohibit their use in children. For e.g. narcotics could cause respiratory depression and fear of needle stick injury in the case of parentral analgesics.

The regional anesthetic technique significantly decreases the post operative pain and systemic analgesic requirements. Caudal route is one of the simplest and safest way in pediatric surgery with a high success rate[1] Caudal block is usually placed after the induction of general anesthesia and is used as an adjuvant to both intra operative and post operative analgesia in children undergoing surgical procedure below the level of umbilicus. Caudal analgesic could reduce the amount of inhaled and intravenous anesthetic administration, alter the stress response to surgery and facilitate a rapid and smooth postoperative analgesia. In order to decrease intra and post operative analgesic requirements several drugs have been investigated for caudal anaesthesia. For e.g neostigmine, Bupivacaine, Midazolam, Ketamine, Ropivacaine and Dexmedetomidine.[2] Bupivacaine, a long acting local anesthetic agent has been used for pediatric caudal anesthesia. It provides prolong pain relief compare to Lignocaine and Ketamine. Midazolam an Imidazabenzodiazepine derivative causes antinociceptive effect by GABA mediation (GABA has been shown to have analgesic property) when injected intrathecally or epidurally. Highest density of binding sites was found within lamina of dorsal horn region.

The objective of this study was to compare the effect of Bupivacaine along with Midazolam to provide

postoperative analgesia when used for caudal analgesia in children undergoing lower abdominal surgeries.

MATERIALS AND METHODS

This was a prospective, open label, randomized study conducted among fifty children.

Inclusion criteria:
ASA grade I/II patients between ages 1-12 years undergoing surgical procedure below the level of umbilicus were included in the study.

Exclusion criteria:
Subjects were excluded if they had allergy to study drug, bleeding diathesis, infection on back, pre existing neurological disease and congenital anomalies of lower back. Patients received opioids preoperatively were also excluded.

Pre-operative evaluation:
Age, body weight and base line vital parameters were recorded for all the children preoperatively. History regarding previous anaesthesia, surgery, any significant medical illness, medications and allergy was recorded. Complete physical examination and airway assessment were done. Hemoglobin percentage, blood sugar, urea, serum creatinine and urine analysis were done to rule out any pathological condition.

Written consent of all children was obtained from parents preoperatively. All children were kept nil by mouth for 4-6 hrs. Intravenous line was secured and injection isolyte-p was started. In operation theatre, standard monitor like ECG and pulse oxymeter were placed. All patients were given inj. Glycopyrolate 4μg/kg as a premedication. General anesthesia was induced with inj. Thiopental sodium 5-7 mg/kg by I.V route and orotracheal intubation was facilitated with inj. Suxamethonium chloride 2 mg/kg by I.V route. After induction patients were allocated randomlyin Group-1 and Group-2. Group-1 received caudal block with inj. bupivacaine (0.25%) 1ml/kg in group-1 and Group-2 received inj. Midazolam 50 μg/kg +saline 1ml/kg.

Anesthesia was maintained with O2:N2O (50:50), isofluorane and vacuronium bromide 80-100 μg/kg. Controlled ventilation was maintained throughout surgery. Intra operatively, no opioids or other drugs which affect the central pain processing were used. During entire procedure heart rate, oxygen saturation (SPO2) and ECG were continuously monitored. Residual neuro muscular block was reversed with inj. Glycopyrolate 8μg/kg and inj. Neostigmine 50 μg/kg I.V after surgery.

Children were continuously observed in recovery room for 20 mins. After which they were shifted to general wards where OPS score was recorded at 0.5,2,4,8,12 and 24 hrs after surgery. Whenever child had OPS score of > 5, rescue dose of analgesic (syrp. Paracetamol 15mg/kg) was administered orally. This duration of analgesia was calculated from end of the surgery to the first dose of rescue analgesic given. Any local or systemic complications throughout the study were recorded. The data was collected and analyzed using SPSS version 13.0 computer software.

Observer pain scale (OPS)

Item	Score
No Pain	
Laughing Euphoric	1
Happy Contented	2
Calm or Asleep	3
Mild-Moderate Pain	
Crying Grimacing, Restless Can distract with toy or parental presence	4
Severe Pain	
Crying Screaming, Inconsolable	5

RESULT

A total of 50 patients were enrolled in the present study and were randomized into two groups of 25 each. Both the groups were comparable with respect to age, sex, weight, duration of surgery and type of surgery with no statistical difference (Table 1).

Table 1: Demographic data of patients in two groups

	Group 1 (Bupivacaine) (n=25)	Group 2 (midazolam) (n=25)
Age (yrs)	3.4±1.52	3.4±1.52
Weight (kg)	11.92±3.37	11.92±3.09
Duration of surgery (min)	41±3.53	38.8±5.45
Sex		
Male	25	24
Female	-	1
Type of surgery		
Inguinal hernia	17 (68%)	16 (64%)
Circumcision	3 (12%)	5 (20%)
Hypospadias	4 (16%)	2 (8%)
Orchidopexy	0 (0%)	1 (4%)
Lt. Adductor tenotomy	1 (4%)	0 (0%)

Analgesic effect was evaluated by OPS score in group-1 and group-2 at 0.5,2,4,8,12 and 24 hrs after surgery (Table-2).

1) Evaluation of pain after 0.5 hours of surgery: Patients in both the groups had good analgesia in the first half an hour post awakening with an average observer pain score was around 2. None of the patients required rescue analgesic in both groups.

2) Evaluation of pain after 2 hours of surgery: The average pain scores in both the groups- 1 & 2 were 2.24(± 0.43) & 3.4(±0.70) respectively. Two patients in group- 2 required rescue analgesic (syrp. Paracetamol

15mg/kg). None of the patients in group -1 required rescue analgesic.

3) Evaluation of pain after 4 hours of surgery : The patients in group- 1 displayed a mean observer pain score of 3.16 (±0.47) at 4 hours post awakening while patients in group- 2 displayed a mean observer pain score of 4.0(±0.64) . Three more patients in group- 2 required rescue analgesic (syrp. Paracetamol15mg/kg). None of the patients in group -1 required rescue analgesic.

4) Evaluation of pain after 8 hours of surgery: The patients in group -1 demonstrated an average observer pain score of 4.16(±0.47) whereas patients in group- 2 demonstrated an average observer pain score of 4.68(±0.47). Another twelve patients in group- 2 required rescue analgesic (syrp. Paracetamol 15mg/kg). In group -1 only five patients required rescue analgesic.

5) Evaluation of pain after 12 hours of surgery: The patients in group -1 had an average observer pain score of 4.84(±0.37) while as patients in group- 2 had an average observer pain score of 4.96(±0.2).Another seven patients in group- 2 required rescue analgesic (syrp. Paracetamol 15mg/kg) whereas in group -1 sixteen patients required rescue analgesic.

6) Evaluation of pain after 24 hours of surgery: Group -1 and group-2 patients had similar average observer pain score of 5.0 (±0.0). Rest of the patients in both the groups required rescue analgesic.

The requirement of rescue analgesic after 8 hours in group- 1 was noted in 20% of the patients while in group -2 this requirement was noted in 68% of the patients. Similarly, after 12 hours rescue analgesic was required in 84% of patients in group -1 whereas it was 96% in group- 2. The reduced incidence of need for rescue analgesic at the end of 8 hours post surgery was statistically significant i.e. ($p < 0.05$) in group- 1.

Table-2: Post operative OPS score

Post-operative duration (hrs)	Group-1 (Bupivacaine) (n=25) Mean (SD)	Group-2 (Midazolam) (n=25) Mean (SD)
0.5	2.16 (0.37)	2.72(0.79)
2	2.24(0.43)	3.4 (0.70)
4	3.16 (0.47)	4(0.64)
8	4.16(0.47)	4.68(0.47)
12	4.84 (0.37)	4.96 (0.2)
24	5 (0.0)	5 (0.0)

Complication rates were slightly higher in group-1 patients than in group-2. 5 patients had motor weakness and 3 patients had vomiting in group-1 whereas 1 patient had vomiting in group-2. (Table-3)

DISCUSSION

Pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.[3]

The current trend is to prefer a regional anaesthetic technique for lower abdominal as well as limb surgery in pediatric patients. The popularity of this technique is due to its simplicity and frequent success.[4,5] Post operative pain management should be an essential and integral part of the care given to the pediatric patients.

Table-3: Post operative complications:

Complication	Group-1 (Bupivacaine) (n=25)	Group-2 (midazolam) (n=25)
Vomiting	3	1
Retention of urine	-	-
Motor weakness	5	-

In our study, we observed that caudal Bupivacaine and caudal Midazolam were equally effective in controlling postoperative pain in children in the first half an hour of the postoperative period. However significantly lower pain scores were observed in children receiving Bupivacaine at 2, 4 and 8 hours post operatively. The overall need for rescue analgesic was significantly lower in the Bupivacaine group. It suggests that bupivacaine provides longer duration of postoperative analgesia compared to Midazolam. At 12 and 24 hrs, OPS score of both the groups were almost equal.

Similar study conducted in 1998 by Gulec et al.[6] with caudal 0.25% Bupivacaine (group-A), 0.25% bupivacaine-midazolam (gropu-B), 0.25% bupivacaine-morphine 0.05mg/kg (group-C) showed that duration of analgesia was 8.15±1.3 hrs in group-A which was almost similar with our study.

Pradhan B et al.[7] in 2008 concluded that recovery to first analgesic time was longer in Bupivacaine group (9.65 hrs) comapare to Midazolam group (7.32 hrs).

In 1998 Nishiyama et al.[8] concluded that 5-10 ml saline is the optimum volume for epidural injection when using Midazolam 50μg/kg for postoperative analgesia for upper abdominal surgery. While in our study, Midazolam 50μg/kg with 1ml/kg volume was optimal for analgesia without sedation, amnesia and urinary retention.

Mohamed Naguib et al.[9] conclude that caudal midazolam in a dose of 50μg/kg provides equivalent analgesia to bupivacain 0.25% when administered postoperatively in a volume of 1ml/kg for children following unilateral inguinal herniiotomy.

CONCLUSION

We concluded from our study that duration of analgesia was longer with Bupivacaine compared to Midazolam. However, post operative sedation was

present with Midazolam while motor weakness was seen with Bupivacaine.

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