

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

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Abstract

Introduction: Caudal epidural block is the most commonly used regional technique for post-operative analgesia in children. Because of the side effects of bupivacaine which include motor weakness, urinary retention and cardiovascular and central nervous system toxicity, this study was conducted to evaluate the use of epidural midazolam as an alternative analgesic to bupivacaine for children undergoing inguinal herniotomy

Methods: After prior permission from the Institutional Ethical Committee, 60 boys, aged 1-10 years, posted for unilateral inguinal herniotomy were selected. The patients were allocated randomly into two groups (n=25) to receive caudal injection of either 0.25% Bupivacaine 1 ml/kg (group B) or Midazolam 50 microg/kg with normal saline 1 ml/kg (group M). In the post operative period heart rate, blood pressure, pain score, recovery to first analgesic time, total number of analgesics required in 24 hours and side effects if any were noted and analysed.

Results: There were no significant differences in quality of pain relief, postoperative behaviour or analgesic requirements between the Midazolam group and the Bupivacaine group. Recovery to first analgesic time though was longer in the Bupivacaine group (9.65 hr) than Midazolam group (7.32 hr); it was statistically not significant (P= 0.9). Any of the side effects such as motor weakness, urinary retention, and respiratory depression were not observed in both the groups. However in both the groups, few of the patients had post-operative vomiting.

Conclusion: We conclude that caudal Midazolam in a dose of 50 microg/kg provides equivalent analgesia to Bupivacaine 0.25%, when administered in a volume of 1 ml/kg for children undergoing unilateral inguinal herniotomy for hernia or high ligation of processus vaginalis for hydrocoele.

Keywords: Caudal Analgesia, Herniotomy, Midazolam, Bupivacaine

1. Introduction

The post-operative pain has equal importance as that of operative analgesia, but till 1960, the subject of post-operative pain relief in children had always been under treated. It was misbelieved that children do not suffer from pain as they don't feel it. They tolerate discomfort well, they don't respond to pain as the adults do.

Herniotomy a procedure to correct congenital hernias is associated with considerable post-operative pain which may result in restlessness, agitation, bleeding and psychological stress in children. In order to maximize post-operative analgesia, a number of agents have been tried by epidural and spinal route. Epidural and spinal opioids have been used but the associated major side effects like sedation; itching, urinary retention, nausea, vomiting, respiratory depression and tolerance have limited widespread use.

Caudal epidural block being prescribed by many as the "Wonder Technique" for analgesia has a definitive place in the post-operative pain relief protocols in many hospitals. The discovery of benzodiazepine receptors in the central nervous system was soon followed by use of epidural and intrathecal administration of water soluble benzodiazepines, midazolam, for pain relief in human beings.

Caudal epidural block is the most commonly used regional technique for post-operative analgesia in children. Because of the side effects of bupivacaine which include motor weakness, urinary retention and cardiovascular and central nervous system toxicity, this study was conducted to evaluate the use of epidural midazolam as an alternative analgesic to bupivacaine for children undergoing inguinal herniotomy and to study the efficiency of one drug over the

other i.e. of midazolam and bupivacaine, as an analgesic for children undergoing inguinal herniotomy.

2. Material and methods

After prior permission from the Institutional Ethical Committee, 60 boys, aged 1-10 years, posted for unilateral inguinal herniotomy were selected for this study. Patients with history of upper respiratory tract infections, cardio-respiratory diseases, systemic problems, coagulopathy, sepsis at the site of block, meningocele and myelocele and patients without consent (parental refusal) were excluded.

After routine pre-anesthetic check and written informed consent from parents, the children were kept NPO for 4 hours. All the patients were randomly allocated into two groups (Group M & B), using ‘slips of paper in a box’ technique.

The patients were premedicated with intramuscular ketamine, 5 mg/kg along with atropine 0.02mg/kg and after adequate sedation they were brought inside the operation theatre from premedication room and intravenous line was secured. Vital parameters like pulse rate, blood pressure and respiratory rate were monitored.

The patients were preoxygenated with 100% on mask. Then the induction was done with IV ketamine, 1-2mg/kg and IV succinylcholine 1.5 mg/kg. Induced with Oxygen+ N₂O+ Halothane if required. The laryngoscopy was done and patient was intubated with proper size endotracheal tube. Anaesthesia was maintained with O₂+N₂O+Halothane through Jackson-Rees pediatric circuit with controlled ventilation. The muscle relaxant used was IV Atracurium.

Then the child was placed in the lateral position with the hips and knees flexed and caudal block was performed. The sacral region was prepared with betadine and spirit solution and following identification of sacral cornua, a 23G needle was inserted into the skin overlying the sacral hiatus. The needle was positioned at an angle of 65°-70° in an upward direction with level towards the abdomen. The epidural space was identified by the loss of resistance when the needle pierced the sacrococcygeal ligament. The needle was made parallel to the back and inserted into the canal 2-3 mm more. After the negative aspiration for blood or CSF, the drug was injected.

In Group B, Bupivacaine 0.25%, volume 1ml/kg was injected slowly in the epidural space.

In Group M, Midazolam 50 ug/kg, volume 1ml/kg diluted with normal saline was injected slowly in epidural space.

After the block (any of the two), the patient was turned to supine position and the surgery was carried out.

Intraoperatively continuous monitoring of blood pressure, heart rate, oxygen saturation with pulse oximetry was done.

Intraoperatively all children received calculated intravenous fluid.

At the end of surgery the patient was reversed with IV neostigmine 0.05mg/kg and IV atropine 0.02mg/kg. Thorough oropharyngeal and endotracheal suction was done and patient was extubated after return of reflexes.

Post-operatively following observations were made-

- 1) The post-operative pain was assessed by using “Pain-discomfort scale”(see proforma) at ½ hour, 1hour, 2hour, 6 hours, 12 hours and 24 hours after the surgery, by personal visit to the recovery ward. The score is taken as no pain, the score 1-4 as mild or insignificant pain and score≥5 as significant pain.
- 2) The time for first analgesic i.e. syrup ibuprofen 5ml/kg was noted when pain score≥5.
- 3) The total doses requirement in 24 hrs was recorded.
- 4) The motor weakness in lower limb was assessed and to unaided standing was noted.
- 5) The first micturation time was recorded by the parents and staff nurse.
- 6) The duration of pain relief was recorded as the time interval from the end of the surgery till the first analgesic dose was given.
- 7) The complications like nausea, vomiting, hematoma formation, infections, fever were looked for and were recorded.

2.1 Statistical analysis

The statistical analysis of the data in this study is done by using (paired) two tailed p value and Fiser’s exact test, where appropriate taking p < 0.05 as significant.

3. Observations and Results

The present study includes 60 children from age 1 to 10 years, undergoing unilateral inguinal herniotomy for congenital hernia, out of which 30 children constituted caudal Bupivacaine group(Group B) and 30 children were included in caudal Midazolam group(Group M). Data was collected in both groups for following parameters and observations of the analyzed data are tabulated as follows-

Table 1: Demographic characteristics of the patients

Character	B Group	M Group	P Value
Age (years) Mean (SD) Range	3.733 (±1.7) (1-10 years)	4.133 (± 2.161) (1-10 years)	0.3916
Weight (Kg) Mean (SD) Range	10.6 (± 3.165) (6-18 Kg)	12.366 (± 3.232) (6-20 Kg)	0.0395

(Paired) two tailed p value: p<0.05, significant

The average age in Group B was 3.733 (± 1.7) years and that in Group M was 4.133(±2.161) years. It ranged between 1 to 10 years in both the groups. Both the groups were comparable with respect to age. The weight of patients ranged between 6-18 kg in Group B and 6-20 kg in Group M. both the groups were comparable in this respect.

Table 2: Total duration of surgery

Character	B Group	M Group	P Value
Duration of surgery [Mean (± SD) minutes]	54.833 (± 9.048)	58.5 (± 10.18)	0.1458 (NS)

(Paired) two tailed p value. NS - Not significant

Mean total duration of surgery was more or less same in both the groups.

The haemodynamic parameters i.e. pulse rate and blood pressure were recorded after intramuscular ketamine, but before placement of block. The comparative analysis between pre operative and intra-operative values of these parameters is as follows.

Table 3: Mean pre-operative pulse rate and blood pressure-and their intraoperative changes in both the groups

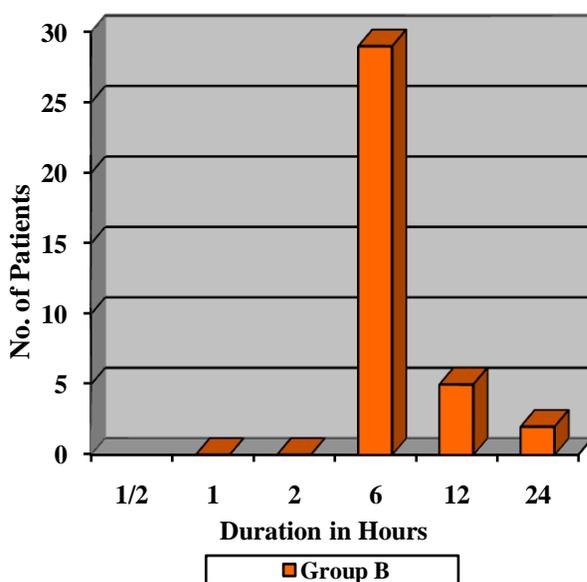
Parameter	Group B	Group M
Pulse Rate (per min)		
Mean preoperative	111.66 (± 8.155)	111.8 (± 8.04)
Mean intraoperative	119.6 (± 8.492)	121 (± 9.002)
Blood pressure (mm Hg systolic)		
Mean preoperative	108.8 (± 4.715)	110.6 (± 3.936)
Mean intraoperative	100.33 (± 4.003)	100.6 (± 4.039)

Post-operatively, the pain was assessed at the intervals of hour, 1 hour, 2 hours, 6 hours, 12 hours and 24 hours, using modified pain discomfort score [1]. We have taken: Score 0 - No pain; Score 1 to 4 - Mild! Insignificant pain discomfort; Score 5 - Significant pain

Table 4: Post-operative pain-discomfort scoring

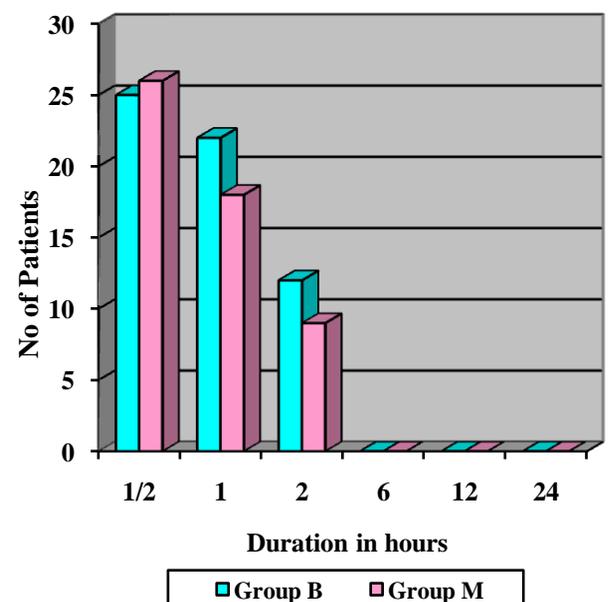
Score	Group B n (%)						Group M n (%)					
	Time (Hours)						Time (Hours)					
	1/2	1	2	6	12	24	1/2	1	2	6	12	24
0	25 (83.33)	22 (73.33)	12 (40)	0 (0)	0 (0)	0 (0)	26 (86.66)	18 (60)	9 (30)	0 (0)	0 (0)	0 (0)
1	5 (16.66)	7 (23.33)	14 (46.66)	3 (10)	0 (0)	0 (0)	3 (10)	11 (36.66)	6 (20)	0 (0)	0 (0)	0 (0)
2	0 (0)	1 (3.33)	3 (10)	5 (16.66)	0 (0)	0 (0)	1 (3.33)	1 (3.33)	15 (50)	1 (3.33)	0 (0)	0 (0)
3	0 (0)	0 (0)	1 (3.33)	17 (56.66)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	7 (23.33)	0 (0)	0 (0)
4	0 (0)	0 (0)	0 (0)	4 (13.33)	5 (16.66)	2 (6.66)	0 (0)	0 (0)	0 (0)	17 (56.66)	1 (3.33)	0 (0)
≥5	0 (0)	0 (0)	0 (0)	1 (3.33)	25 (83.33)	28 (93.33)	0 (0)	0 (0)	0 (0)	5 (16.66)	29 (96.66)	30 (100)

Figure 1a: Number of patients with duration of post-operative analgesia



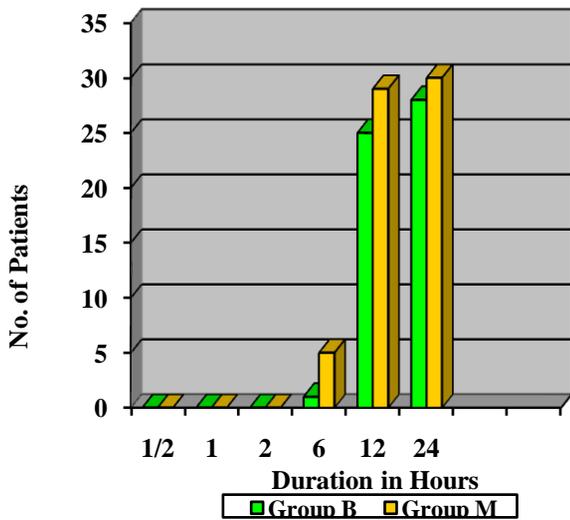
Patients with no pain (score 0) at various intervals

Figure 1b: Number of patients with duration of post-operative analgesia



Patients with significant pain (score >5) at various intervals

Figure 1c: Number of patients with duration of post-operative analgesia



Patients with insignificant pain (score ≤ 4) at various intervals

Figure 1d: Number of patients with duration of post-operative analgesia

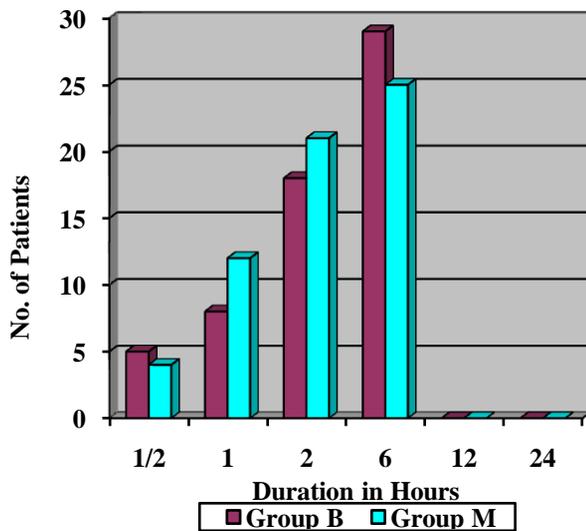


Figure 2: Mean pain score in various post operative intervals in the two groups

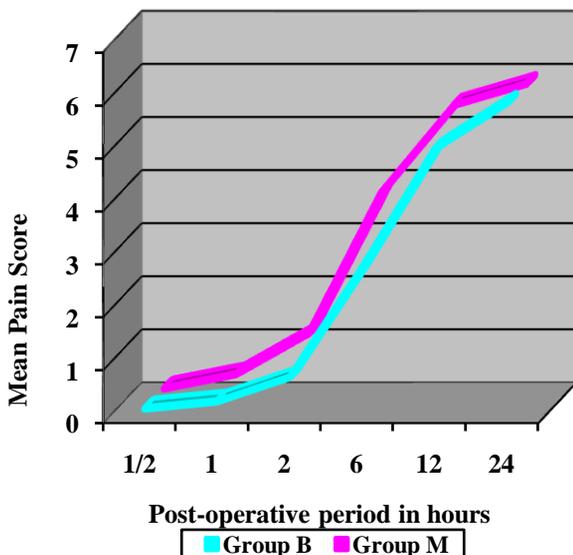


Table 5: Mean pain score in the post-operative period in the two groups

Duration	Group B Mean (Sd)	Group M Mean (Sd)	P Value
Half	0.166 (± 0.379)	0.16 (± 0.4611)	> 0.9999 (NS)
1 Hour	0.3 (± 0.5350)	0.43 (± 0.5683)	0.3533 (NS)
2 Hours	0.76 (± 0.77)	1.2 (± 0.8867)	0.048 (S)
6 Hours	2.83 (± 0.9129)	3.86 (± 0.7303)	0.0001(S)
12 Hours	5.06 (± 0.6397)	5.5 (± 0.5724)	0.0076 (S)
24 Hours	5.93 (± 0.7397)	5.9 (± 0.7120)	0.8595 (NS)

(Paired) two tailed p value

S =Significant, NS= Not significant

As evident from Table 4 and 5

At ½ hour

25 (83.33%) patients in Group B and (86.66%) patients in Group M had no pain till ½ hour and 5 (16.66%) patients in Group B and 4 (13.33%) patients in Group M had mild or insignificant pain. The mean pain score was 0.166 (± 0.379) in Group B and 0.16 (± 0.4611) in Group M

At 1 hour

22 (73.33%) patients in Group B and 18 (60%) patients in Group M had no pain and 8 (26.66%) patients in Group B and 12 (39.99%) patients in Group M had mild pain till 1 hour after surgery. The mean pain score was 0.3 (0.5350) in Group B and 0.43 (± 0.5683) in Group M.

At 2 hours

12 (40%) patients in Group B and 9 (30%) patients in Group M had no pain. And 18 (60%) patients in Group B and 21 (70%) patients in Group M had mild pain.

The mean pain score was 0.76 (± 0.77) in Group B and 1; 2 (± 0.8867) in Group M.

At 6 hours

29 (96.66%) patients in Group B and 25 (83.33%) patients in Group M had mild pain. And 1 (3.33%) patient in Group B and 5 (16.66%) patients in Group M had significant pain and discomfort by the end of 6 hours.

The mean pain score at 6 hours was 2.83 (± 0.9129) in Group B and 3.86 (± 0.7303) in Group M.

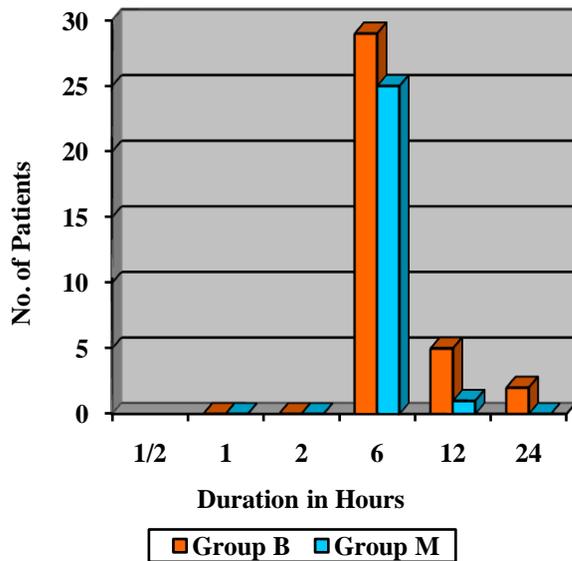
At 12 hours

5 (16.66%) patients in Group B and 1 (3.33%) patient in Group M had mild pain. 25 (83.33%) patients in Group B and 29 (96.66%) patients in Group M had significant pain and discomfort at end of 12 hours.

The mean pain score was 5.06 (± 0.6397) in Group B and 5.5 (± 0.5724) in Group M.

At 24 hours

2 (6.66%) patients in Group B and no patient in Group M had mild pain. And 28 (93.33%) patients in Group B and all 30 (100%) patients in Group M had significant pain.



The mean pain score was 5.93 (± 0.7397) in Group B and 5.9 (± 0.7120) in Group M.

The duration of adequate post-operative analgesia or pain free period was taken as time from completion of surgery till the pain discomfort score ≥ 5 was observed at which time rescue analgesic was given.

Table 6: Number of patients with duration of post-operative analgesia

Duration of Analgesia (Hours)	Group B N (%)	Group M N (%)
1	0 (0)	0 (0)
2	0 (0)	0 (0)
6	29 (96.66)	25 (83.33)
12	5 (16.66)	1 (3.33)
24	2 (6.66)	0 (0)

The above table shows that no patient in both the groups required analgesic at 2 hours after surgery.

29 (96.66%) patients in Group B and 25 (83.33%) patients in Group M had pain free period (post-operative analgesia) for 6 hours.

5 (16.66%) patients in Group B and 1 (3.33%) patient in Group M had post-operative analgesia for 12 hours. 2 (6.66%) patients in Group B and no patient in Group M had post-operative analgesia for 24 hours.

Table 7: Mean Total Duration of Analgesia in Two Groups

Character	Group B	Group M	P Value
Duration of Analgesia Mean (± SD)	491.66 (± 64.572) Minutes (8 hours 19 minutes)	456.83 (± 59.29) Minutes (7 hours 6 minutes)	< 0.0001 (S)

(Paired) two tailed p value; S - significant

The mean duration of post-operative pain relief (or pain free period) between the two groups was significant.

Total number of analgesic doses required in first 24 hours of surgery were recorded in all patients. The details are as shown in the table 8.

Table 8: Number of doses of post-operative analgesic required in 24 hours

Number of Doses	Group B n (%)	Group M n (%)	P Value
2	11 (36.66)	18 (60)	
3	19 (63.33)	12 (40)	
Average	2.633 (± 0.4901)	2.4 (± 0.4983)	0.072 (NS)

(Paired) two tailed p value. NS - Not significant

11 (36.66%) patients in Group B and 18 (60%) patients in Group M received 2 doses in first 24 hours.

19 (63.33%) patients in Group B and 12 (40%) in Group M received 3 analgesic doses in first 24 hours.

The mean total numbers of doses required in 24 hours were 2.633 (± 0.4901) in Group B against 2.4 (± 0.4983) in Group M.

Table 9: Time to first micturition

Character	Group B	Group M	P Value
Time to first micturition Mean (± SD)	286.83 (± 58.47) Minutes (4 hours 7 minutes)	276.16 (± 57.47) Minutes (4 hours 6 minutes)	0.47 (NS)

(Paired) two tailed p value. NS - Not significant

In Group B, patients had an average micturition time of 4 hours 7 minutes [286.83 (± 58.47) minute] and in Group M, patients had an average micturition time of 4 hours 6 minutes [276.16 (± 57.47) minutes].

Both the groups were almost similar in this respect, (p=0.47), as they had only minimum difference in the duration.

3 (10%) patients in Group B and Group M has post-operative voiding beyond 6 hours and none required any intervention. The longest time to void was 8 hours in 1 patient of Group B.

Table 10: Time for first unaided walking

Character	Group B	Group M	P Value
0-2 Hours	1 (3.33)	2 (6.66)	
2-6 Hours	29 (96.66)	28 (93.33)	
Mean (± SD)	3 Hours 56 mins (± 0.9072)	3 Hours 36 mins (± 1.003)	0.1824 (NS)

(Paired) two tailed p value. NS - Not significant

The above table shows that 1 (3.33%) patient in Group B and 2 (6.66%) patients in Group M could walk unaided within 2 hours of surgery.

29 (96.66%) patients in Group B and 28 (93.33%) patients in Group M started walking unaided between 2 to 6 hours duration.

The mean duration of motor loss was 3 hours 56 mins (± 0.9072) in Group B and 3 hours 36 minutes (± 1.003) in Group M.

Table 11: Incidence of adverse effects

Group	Number of Patients (%)		P Value
	Nausea Vomiting (+)	Nausea Vomiting (-)	
Group B	7 (23.33)	23 (66.66)	0.7480 (NS)
Group M	5 (16.66)	25 (83.33)	

Fisher's exact test: NS - Not significant; (+) Present; (-) Absent

Group	Number of Patients (%)		P Value
	Delayed Voiding (+)	Delayed Voiding (-)	
Group B	3 (10)	27 (90)	1.3293 (NS)
Group M	3 (10)	27 (90)	

Fisher's exact test: NS - Not significant; (+) Present; (-) Absent

In Group B, 7 (23.33%) patients have nausea and vomiting and 5 (16.66%) patients in Group M had nausea and vomiting.

3 (10%) patients in both the groups passed urine with delay i.e. after 6 hours. They required no active intervention.

No evidence of post-operative infection was seen in any of the groups.

No other complications were seen in either groups.

4. Discussion

Post-operative pain is an acute pain, which starts with surgical trauma and usually ends with tissue healing. Post-operative analgesia has been neglected for a long time whereas post-operative pain has been considered an inevitable cost of operations. Post-operative pain, apart from causing discomfort and distress, has got deleterious effects on body mechanisms.

After discovery of benzodiazepine receptors in the CNS and spinal cord, it was thought that it could be used epidurally or intrathecally for relief of post-operative pain. Of the entire agent used, epidural midazolam seems to be promising drug because of absence of aforementioned side effects.

Several families of spinal receptors are known to modulate the processing of nociceptive stimuli. Among these are the GABA receptors.

Benzodiazepines alone lack GABA - mimetic effects. Acting through their own binding sites, they enhance the effects of GABA at many sites within CNS.

Midazolam has been shown to have antinociceptive properties in the animals, in the early 1980s, when given by epidural route as well as intrathecal route[2].

Further, use of epidural and caudal midazolam was studied in conjunction with local anaesthetics, for post-operative pain relief, in both adults Nishiyama [3] and children [4].

Later on it was demonstrated that adding midazolam to a continuous epidural infusion of bupivacaine resulted in better analgesia, greater amnesia and sedation than bupivacaine alone without any side effects in patients undergoing laparotomy [5].

The caudal block is most accepted method of analgesia in children undergoing inguino-genital operations, used for providing both surgical and postOperative analgesia. However there are few studies which have evaluated effect of caudal midazolam in children [6-8]. Thus we design a study to compare the effect caudal bupivacaine with caudal midazolam for post operative analgesia.

In the present study, we have compared caudal

bupivacaine with the caudal midazolam for post-operative analgesia in children undergoing unilateral inguinal herniotomy. The study includes 60 children, from age 1 to 10 years, posted for unilateral inguinal herniotomy.

The patients were divided randomly into two groups of 30 each.

Group B - Caudal 0.25% Bupivacaine 1ml/kg. (n=30)

Group M - Caudal Midazolam 50 µg/kg with normal saline 1 ml/kg. (n=30)

The mean age in Group B was 3.733 years and that of Group M was 4.133 years.

The mean weight in Group B was 10.6kg and that of Group M was 12.366kg.

Thus patients in both the groups were comparable in characteristics like age and weight.

The mean duration of surgery in Group B was 54.833 mins and that of Group M was 58.5 mins. Thus both the groups were also comparable in type of surgery they underwent and duration of surgery.

In the present study, we have used intramuscular ketamine 5 mg/kg mixed with 0.02 mg/kg of atropine to sedate the child.

It was our intention in designing the study to provide post-operative analgesia. All operations were carried out under general, anaesthesia. Anaesthesia was induced by IV ketamine 1-2 mg/kg and IV scoline 2 mg/kg. In all patients, anaesthesia was maintained with 70% nitrous oxide in oxygen and halothane delivered via Jackson-Rees circuit with controlled ventilation. The muscle relaxant used was IV Atracurium 0.5 mg/kg. No intraoperative sedatives or opioids were administered.

In the study, blocks are performed pre-emptively, with the aim to reduce the intraoperative anaesthetic requirements.

At the end of surgery, the patients were reversed with IV Neostigmine 0.05 mg/kg + IV Atropine 0.02 mg/kg. The patients were extubated after thorough oropharyngeal suction and return of reflexes,

Due to, paucity of literature, the effective dose of epidural midazolam for post-operative analgesia is not known till date. Dose of 50 µg/kg had been used for epidural administration in previous human studies [4][5].

Keeping in mind the safety and clinical efficacy of dose of midazolam epidurally from the previous studies, we decided to use midazolam in the dose of 50 µg/kg. The drug used was preservative free:

Changes in Intra operative cardiovascular parameters

Pulse rate and blood pressure were monitored intra-operative in all the patients. As shown in table no 3 (in observation chapter), pulse rate and blood pressure were maintained within normal range and mean pre-operative and post operative values did not differ significantly in both the groups. This also shows that vitals were well maintained in both the groups.

Post-operative Pain Relief

This is the time from the end of the surgery to the commencement of pain i.e. to time of the first analgesic required. In the present study, modified pain discomfort score is used [1] and the score of ≥ 5 is taken as cut off point for termination of pain relief and indication analgesic administration. The children were observed at the intervals of ½ hour, 1 hour, 2 hours, 6 hours, 12 hours and 24 hours. In the present study mean duration of pain relief is 491.660 (± 64.572) minutes in Group B patients (8 hours 19 minutes) and 456.8:33 (± 59.29) minutes in Group M patients (7 hours 6 minutes).

The average numbers of doses required were 2.63 in Group B and 2.4 in Group M

Mohamed Naguib *et al* [4] found reduced amount of analgesic supplementation in caudal bupivacaine-midazolam group as compared to bupivacaine group and midazolam group.

Nishiyama *et al* [3] found reduced frequency of indomethacin suppository of 1.2(± 1.1) minutes in midazolam group as compared to 2 (± 1.1) minutes in the control group.

First micturition time

The mean micturition time in the present study is 286.83 (± 58.47) minutes i.e. 4 hours 7 minutes in Group B and 276.16 (± 57.47) minutes i.e. 4 hours 6 minutes in Group M ($p=0.47$). 3 (10%) patients in Group B and 3(10%) patients in Group M had micturition after 6 hours, but they required no active intervention for that. The longest duration for first micturition was 8 hours in Group B. The difference between the two groups regarding first micturition time was found to be statistically insignificant. Different authors have used varying concentrations and volumes of caudal bupivacaine and the literature regarding time to void have uniformly lacked reference to the state of hydration [9].

Motor Loss

It is well known that caudal block is associated with motor weakness.

The problems with motor weakness are it is distressing for the older children and in day care surgery, discharge time is delayed. The need to carry the older children by parents may be difficult.

In this study, parents were asked to note the time for first unaided walking. The residual sedation of anaesthetics used during the operation (Inj Ketamine and inhalational agents) kept the subjects restricted to their beds or sleeping in immediate post-operative period.

The mean duration of unaided walking was 3.933 hours (± 0.9072) in group B and 3.6(± 1.003) hours in group M. This was statistically insignificant.

Complications

In our study, we paid special attention to any potential side effects or complications during the perioperative period and it was found that incidence of side effect in both the groups was statistically insignificant.

The incidence of post-operative nausea and vomiting in this study was 23.33% in Group B and 16.66% in Group

Since we have not used opioid analgesics in our study, the incidences of nausea and vomiting may be explained on the basis of preoperative and post operative fasting status and use of ketamine and volatile anaesthetic agents.

Relatively more number of patients vomited in caudal bupivacaine group as compared to caudal midazolam group.

There were no instances of hypotension, bradycardia, sedation, respiratory depression, residual paralysis or toxic reactions in any of the patients, observed for 24 hours. We didn't encounter dural puncture during caudal block.

In our study, special attention was given to sensory and motor deficits for any neurological sequelae at the end of 24 hours. No such deficit was seen in the study.

Thus in the present study we found that -

- 1) The mean duration of post-operative pain relief in group B was 491-660 (± 64.572) minutes i.e. 8 hours 19 mins and in group M 456.833 (± 59.29). minutes i.e. 7 hours 6 mins.
- 2) The Group M patients micturated earlier and had early ambulation than group B patients.
- 3) The incidence of vomiting was 23.33% in Group B and 16.66% in Group M, which was statistically insignificant.

Both the drugs provided satisfactory post-operative analgesia. Although mean duration of post-operative analgesia was slightly longer in Group B [491.660 (± 64.572) minutes i.e. 8 hours 19 minutes] than that observed in Group M [456.833 (± 59.29) minutes i.e. 7 hours 6 minutes] The difference is statistically significant ($p < 0.001$).

From the above observations, it can be stated that caudal epidural block with midazolam compared to caudal epidural block with bupivacaine has shown similar degree of post-operative analgesia in children of unilateral inguinal herniotomy; with benefits of

- No post-operative motor weakness resulting in early ambulation.
- No urinary retention.
- Less vomiting.
- Less potential for serious complications.

4. Conclusion

Thus, we conclude that the caudal administration of midazolam in dose of 50 $\mu\text{g}/\text{kg}$ provides equivalent analgesia to bupivacaine 0.25%, when administered pre-operatively in a volume of 1 ml/kg to children undergoing unilateral inguinal herniotomy, without any significant adverse effects.

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