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A Comparative Study Of Caudal Epidural Bupivacaine And Midazolam-Bupivacaine Mixture For Post-Operative Analgesia In Children Repairing Congenital Inguinal Hernia

Md. Ataur Rahman[1], Md. Abul Kalam Azad[2]
[1]*Department Of Anesthesiology, Islami Bank Medical College, Airport Road, Nawdapara, Rajshahi*
[2]*Department Of Anesthesiology, Barind Medical College, Choto Bongram, Padma Abashik, Chandrima, Rajshahi*

Abstract:
Background: *Managing postoperative pain in pediatric anesthesia is challenging, with caudal epidural anesthesia being a preferred technique for its safety and efficacy. Enhancing analgesia duration through adjuvants like midazolam may improve outcomes.*
Objective: *This study compares the effectiveness of caudal epidural bupivacaine alone versus a bupivacaine-midazolam mixture in children undergoing repair of congenital inguinal hernia, circumcision, and hypospadias repair, focusing on postoperative analgesia duration and side effects.*
Materials and Methods: *A double-blind randomized controlled trial was conducted at Islami Bank Medical College Hospital from October 2023 to March 2024, involving 50 children aged 2-8 years, divided into two groups: Group A (bupivacaine-midazolam) and Group B (bupivacaine alone). Pain was assessed using the FLACC scale at specified intervals up to 24 hours post-surgery.*
Results: *Group A experienced significantly longer postoperative analgesia (10.72 ± 4.07 hours) compared to Group B (6.13 ± 1.98 hours). Mild pain was more common in Group A (72.7%) than Group B (87.5%), while moderate pain was higher in Group A (27.3%) than Group B (12.5%). Side effects were minimal, with Group A having no side effects and Group B experiencing 8% nausea and vomiting and 4% other side effects.*
Conclusion: *The addition of midazolam to caudal bupivacaine significantly prolongs postoperative analgesia and reduces the need for rescue analgesia in children, with minimal side effects.*
Keyword: *Postoperative analgesia, Caudal epidural anesthesia, Congenital inguinal hernia.*

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I. Introduction

Pediatric anesthesia is demanding but grafting sub-specialty of anesthesiology. The world wide acceptance and use of caudal anesthesia for lower abdominal surgeries has made pediatric anesthesia is a major part of most anesthetic practices. The common indications for younger are repair of congenital inguinal hernia, circumcision, hypospadias repair etc. Caudal block is one of the most commonly used pediatric regional anesthetic techniques for postoperative analgesia.[1] Caudal block is easy to perform; extensively safe if used in children, resulting in low pain scores; and when combined with general anesthesia, it reduces the requirement for volatile agents and opioids.**[1]** Caudal epidural anesthesia is the most popular regional anesthesia technique used in children. With advanced age, only the relative difficulty in localizing the sacral hiatus limits its use. However, in adults this technique has been widely used to control chronic pain by adjuvant use of fluoroscopy. Thus, the ability to locate the hiatus and define anatomical variations is the main determinant of the success and safety of caudal epidural anesthesia.**[2]**Ensuring adequate analgesia in the post-operative period is an indispensable part of a balanced anesthesia technique with increasing scope of day care surgery and emphasis on early discharge. In children undergoing infra-umbilical and lower limb surgeries, caudal block is a reliable and safe technique that can be used with general anesthesia for intra and post-operative analgesia.**[3]** Caudal epidural for such operations become the preferred technique because general anesthesia has become associated with higher rates of respiratory difficulties, more over a number of drugs using in general anesthesia obviously hazardous for children. Furthermore, caudal anesthesia decreases the risks of pulmonary aspiration. Isobaric bupivacaine is most common local anesthetic used in caudal anesthesia for pediatric surgery. Although a combination of bupivacaine & lidocaine can also be used. Single shot of plain bupivacaine the most popular local anesthetic being used in these cases. In order to extend the duration of analgesia there are many agents

which are used as adjunct such as Ketamine, Clonidine, Morphine, Fentanyl, Pethidine, Neostigmine, Sodium-bi-carbonate, Adrenaline, & Midazolam. Although a variety of ways are using to improve the quality of analgesia of caudal epidural local anesthetics, bupivacaine - midazolam mixture proof one of the safest combinations.

Magnitude of the problem

There is extensive use of opioids such as pethidine to relieve post-operative pain in children after recovery where there are no monitors and few nurses that they could not catch all post-operative patients, so it is a big challenge in our country.

Justification

To reduce the utilization of opioids in the post-operative period among children underwent surgery. Also by doing such procedure, the study will improve the skills among anesthesia providers and make them familiar with caudal anesthesia. The aims of this study is to prolong the post-operative analgesia among children undergoing repair of congenital inguinal hernia, circumcision, hypospadias repair in Islami Bank Medical College Hospitalby adding midazolam 50 µg/kg with bupivacaine 0.5ml/kg of 0.25% and at the same time to reduce the utilization of opioids post-operatively.

General objective

To compare the post –operative analgesia of caudal midazolam plus bupivacaine with bupivacaine alone for children undergoing repair of congenital inguinal hernia, circumcision, hypospadias repair.

Specific objectives

1. To estimate the duration of post-operative analgesia after uses of caudal midazolam –bupivacaine mixture.
2. To estimate the duration of post-operative analgesia after uses of caudal bupivacaine alone.
3. To evaluate the side effects of using caudal midazolam –bupivacaine and bupivacaine alone.

Pain scale

FLACC: The FLACC assessment tool was developed in an attempt to provide a consistent method of pain assessment in non-verbal or preverbal children. This tools incorporates 5 categories of behavior that have been used in other behavioral scales. The acronym FLACC (Face, Legs, Activates, Cry and CONSOL ability) facilitates recall of the categories, each of which is scored from 0-2 with total scores ranging 0-10 similar to other clinical assessment tools.

Table: The criteria for FLACC behavior pain scale

Behavior	0	1	2
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested	Frequent to constant quivering, chin, clenched jaw
Legs	Normal position or relaxed	Uneasy, restless, tense, tense	Kicking or legs drawn up
Activity	Lying quietly, normal position, moves easily	Squirming, shifting, back and forth	Arched, rigid or jerking
Cry	No cry (awake or asleep)	Moans or whimpers; occasional complaint	Crying steadily, screams, sobs, frequent complaints
Consolably	Content, relaxed	Reassured by touching, hugging or being talked to, distractible	Difficult to console or comfort

Score	Severity of pain
0	Relaxed and comfortable
1-3	Mild discomfort
4-6	Moderate pain
7-10	Severe discomfort/pain

II. Methods

Double blind randomized controlled trials were conducted in Islami Bank Medical College Hospital in the period from October 2023 –March 2024. The target population was all children of age between 2-8 years' old who planned to undergo genitourinary surgery. Total 78 patients were selected for operative procedure although 57 were met the inclusion criteria. Neither the participants nor the observers know about the experiment. The primary outcome measure was the duration of post-operative analgesia, while the secondary outcome measures were the requirement of rescue analgesia post-operatively and the complications of the interventions.

Inclusion criteria

1. Patients ASA class I & II
2. Age 2-8 years.
3. Patients planned for repair of congenital inguinal hernia, circumcision& repair of hypospadias under general anesthesia.

Exclusion criteria

1. Parents refusal
2. Patient ASA class III or IV
3. Age below 2 year or more than 8 years.
4. Infection at the site of injection
5. Patient with coagulopathy
6. Patient with neurological deficit

After fulfilling the inclusion criteria, fifty children were assigned randomly into two groups, Group A (the study group, n= 25) received caudal midazolam 50 µg/kg plus bupivacaine 0.5 ml/kg of 0.25%, while Group B (the control group, n=25) received caudal bupivacaine alone 0.5 ml/kg of 0.25%.

$n = \frac{Nz^2}{(N-1)xd^2+z^2pq}$

n= sample size

N= the total number of patient per year from the waiting list

p= the prevalence of desired operation (50%)

q= (1-p)

d= maximum allowable error (5%)

n= $\frac{57\times1.96^2\times0.5\times0.5}{(56-1)\times(0.05)^2+1.96^2\times0.5\times0.5}$=50.

Procedure

After admission of the patient to the operating room, an intravenous line was secured and the monitor was attached. Then induction of general anesthesia (GA) was performed to all patients. After induction of GA and secured the airway the patient turned to the left side, the lower part of back was scrubbed and draped. Then the sacral hiatus was identified and a 22-24 G needle introduced to penetrate the sacro-ccosygeal ligament then withdraw the needle few millimeters, reduced the angle of the needle to 10-15 degree and advance it more caudal. After then gentle aspiration was done to exclude inadvertent intravascular or intrathecal needle placement, then a calculated dose and volume according to the patient weight was injected in the caudal space. Then the patient put into supine position. The heart rate, respiratory rate, blood pressure, pain score (FLACC) were recorded hourly in the first four hours and then every three hours for the rest of 24 hours. Also the requirements of supplementary analgesia were recorded in the first 24 hours after surgery. The study observed the side effects which have appeared in both groups.

Data analysis

Descriptive study was included frequency; minimum, maximum mean, standard deviation (SD) and percentage were used. Independent t-test was used for association whenever a variable has P-value < 0.05, it was considered significant.

III. Results

Fifty patients were enrolled in this study; they were assigned randomly into two groups. *Group A* the study group (n=25) received caudal midazolam 50 µg/kg plus bupivacaine 0.5ml/kg of 0.25% while *Group B* the control group (n=25) received caudal bupivacaine alone 0.5ml/kg of 0.25%.

Demographic characteristics among the groups

Table I: Demographic characteristics among two groups

	A (n=25)				B (n=25)			
	Min	max	mean	SD	Min	Max	Mean	SD
Age	2	8	6.94	3.07	2	8	5.4	2.44
Weight	10	34	20.11	6.93	9	42	17.92	7.29

The mean age was found 6.94±3.07 years in group A and 5.4±2.44 years in group B. The mean weight was found 20.11±6.93 kg in group A and 17.92±7.29 kg in group B (Table I).

Table II: the severity of pain and rescue analgesia among two groups

Pain			A			B
	N	%	Rescue analgesia	N	%	Rescue analgesia
Mild	8	72.7	Paracetamol/ Ibuprofen	7	87.5	Paracetamol/ Ibuprofen
Moderate	3	27.3	Diclofenac injection	1	12.5	Diclofenac injection
Total	11	100		8	100	

Mild pain was found 8(72.7%) in group A and 7(87.5%) in group B. Moderate pain was 3(27.3%) in group A and 1(12.5%) in group B (Table II).

Table III: The side effects among two groups

	A		B	
	Yes	No	Yes	No
Nausea & vomiting	0	25 (100%)	2 (8%)	23 (92%)
Pruritus	0	25 (100%)	0	25 (100%)
Respiratory depression	0	25 (100%)	0	25 (100%)
Others	0	25 (100%)	1 (4%)	24 (96%)

There were no side effects occurred in group A but only 2(8.0%) patients had nausea & vomiting and 1(4.0%) other side effect in group B. (Table III)

IV. Discussion

The study used for combination of caudal midazolam and bupivacaine mixture in comparison with bupivacaine alone. *Group A,* the study group (n=25) received caudal midazolam 50 µg/kg plus bupivacaine 0.5ml/kg of 0.25% while *Group B,* the control group (n=25) received caudal bupivacaine alone 0.5ml/kg of 0.25%. In this study it was observed that the mean age was found 6.94±3.07 years in group A and 5.4±2.44 years in group B. The mean weight was found 20.11±6.93 kg in group A and 17.92±7.29 kg in group B (Table I). Mogahed and Salama[3] study showed that the mean age was 3.57±1.16 years in group I and 4.18±1.25 years in group II. Mean weight was 14.7±3.22 years and 15.5±2.87 years in group I and group II respectively. Chatrath et al.[4] study also observed that the age group we selected was 1-8 years old pediatric patients, and the dosage of ropivacaine we used in our study was 1 ml/kg of 0.2% ropivacaine. This dosage has been documented to be safe in this age group by the study done by Wulf et al.[5] who evaluated the pharmacokinetics of ropivacaine 0.2% in children after caudal epidural injection. Hansen et al.[6] study revealed that the mean age was found 60 months in intravenous group and 61 months in caudal group. Mean weight was 20 kg intravenous group and 21 kg in caudal group.

In present study observed that mild pain was found 8(72.7%) in group A and 7(87.5%) in group B. Moderate pain was 3(27.3%) in group A and 1(12.5%) in group B (Table II). In study Chatrath et al.[5]concluded that the post-operative pain score at 6th and 24th h post-surgerywere significantly lower in dexamethasone group. Soujanya et al.[8] study observed that also pain scores were lower in Bupivacaine group.

In current study revealed that there were no side effects occurred in group A but only 2(8.0%) patients had nausea & vomiting and 1(4.0%) other side effect in group B. Mogahed and Salama[4] study observed that several adjuvants have been used to prolong the duration of analgesia with bupivacaine for caudal analgesia in children. Opioids, ketamine and midazolam are some of the commonly used drugs. The use of opioids is associated with an increased incidence of pruritus and post-operative nausea and vomiting.**[9-10]** The advantage of ketamine is that it prolongs the duration of analgesia without an increase in the incidence of respiratory depression, pruritus and urinary retention which are commonly seen with opioids. Chatrath et al.**[5]** study found that vomiting and retching was noticed in one patient in Group R. No other side effects were noticed. In study of Soujanya et al.[8]showed postoperative complications like nausea, vomiting, and respiratory depressions were not seen among all 3 groups.

V. Conclusion

In conclusion this study demonstrates that adding midazolam 50µg/kg to caudal bupivacaine 0.5ml/kg of 0.25% significantly resulted in prolongation of post – operative analgesia duration from 6.13 ± 1.98 hours to 10.72 ± 4.07 hours.

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Conflict of interest

The authors declared that they have no conflict of interest.

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