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Comparison Between Caudal Bupivacaine and Caudal Midazolam for Post Operative Analgesia in Pediatric Patients of North India

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ABSTRACT
Pain is described as an unpleasant sensory and emotional experience linked to real or possible harm to body tissues or stated in relation to such harm. The current preference is to use a regional anaesthesia approach for surgery on the lower abdomen and limbs in paediatric patients. The appeal of this method is because to its simplicity and frequent effectiveness. Pain management after surgery should be a necessary and important aspect of the care provided to children. Effective pain management following outpatient surgery continues to be a significant obstacle. The use of midazolam in combination with caudal bupivacaine provides a longer period of pain relief and decreases the need for further pain medication in children having outpatient procedures below the belly button. The study was carried out in a forward-looking manner, with an open-label and randomised design involving 100 youngsters. Patients classified as ASA grade I/II, aged between 1 and 12 years, who were undergoing surgical procedures below the level of the umbilicus, were included in the study. A total of 100 patients were included in the current investigation and were randomly divided into two groups of 50 each. Both groups were similar in terms of age, sex, weight, duration of operation, and kind of surgery, with no significant difference. This study demonstrates that the inclusion of midazolam with caudal bupivacaine results in a prolonged period of pain relief and decreased need for additional pain medication in children who are having outpatient procedures below the belly button. No notable negative impact was seen when this investigation compared its use with bupivacaine alone. The length of pain relief was greater with Bupivacaine in comparison to Midazolam. Nevertheless, there was postoperative drowsiness with Midazolam, whereas Bupivacaine caused motor weakness.

INTRODUCTION

Pain is an uncomfortable personal feeling that can only be felt and not communicated, particularly in youngsters who depend entirely on their parents or carers for their health and safety. The idea of pain treatment after surgery and its use in children has greatly advanced in recent years. The local anaesthetic method greatly reduces the discomfort after surgery and the need for pain medication throughout the body. The caudal route is a straightforward and secure method in paediatric surgery that has a high percentage of success[1]. Effective pain management following outpatient surgery continues to be a significant obstacle. Midazolam used in combination with local anaesthetics for caudal epidural analgesia has been proven to be effective with little adverse effects. Managing acute pain is a crucial aspect of perioperative paediatric anaesthesia. Analgesic medications are typically given based on the principle of balanced pain relief, which entails using a variety of pain relievers that work together to enhance their effectiveness[2]. The method of using bupivacaine for caudal block gives pain relief during surgery that continues after the operation. The popularity of the method is because of its simplicity and high rate of success[3,4]. However, the pain-relieving benefit of a single injection of bupivacaine in the caudal area generally ends early after surgery, as the medication only lasts for 2-4 hrs[5]. Thus, over 60% of children who undergo orchidopexy or inguinal hernia repair using this method need additional pain relief after the surgery.6 Therefore, other substances such as adrenaline, morphine, tramadol, clonidine, ketamine, and midazolam have been used with caudal bupivacaine to prolong the duration of pain relief[7-9]. Postoperative pain continues to be a significant issue worldwide, even with notable progress in anaesthesia and surgery in recent times[10-12]. Pain has been recognised as the most frequent issue among children following outpatient surgery in Nigeria[13].

Caudal block is typically administered following the initiation of general anaesthesia and is utilised as a supplement for both intra-operative and postoperative pain relief in children undergoing surgical procedures below the umbilical level. A tail pain reliever could decrease the quantity of inhaled and intravenous anaesthesia given, change the body's response to surgery stress and help provide quick and seamless pain relief after the operation. To reduce the amount of pain medication needed during and after surgery, researchers have studied various medications for caudal anaesthesia. For example, neostigmine, bupivacaine, midazolam, ketamine, ropivacaine and dexmedetomidine[14].

MATERIALS AND METHODS

This was a possible, unblinded, randomised trial conducted among 100 youngsters.

Inclusion criteria: Patients classified as ASA grade I/II, aged between 1 and 12 years, who were undergoing surgical procedures below the umbilicus, were included in the study.

Exclusion criteria: Participants were not included if they had an allergy to the research medication, a tendency to bleed excessively, an infection on their back, a pre-existing neurological condition, congenital abnormalities in their lower back. Patients who had received painkillers before the surgery were also excluded.

Pre-operative evaluation: Age, body weight and baseline vital signs were documented for all the children before the operation. A record was made of the patient's medical history, including any past anaesthesia, surgeries, serious medical illnesses, drugs, and allergies. A comprehensive physical examination and assessment of the airway were performed. Haemoglobin level, blood glucose, urea, serum creatinine and urine analysis were conducted to exclude any pathological condition.

Parents were asked for written agreement from all children before the operation. All children were instructed not to eat or drink anything for a period of 4-6 hrs. An intravenous line was established and an infusion of isolyte-p was initiated. In the operating room, typical monitors such as an ECG and pulse oximeter were positioned. All patients received an injection of Glycopyrrolate at a dose of 4µg kg^{-1} as a premedication. Anaesthesia was initiated using an injection of Thiopental sodium at a dose of 5-7 mg kg^{-1} administered intravenously. Orotracheal intubation was aided by administering an injection of Suxamethonium chloride at a dose of 2 mg kg^{-1} intravenously. Following induction, patients were randomly assigned to Group-1 and Group-2. Group-1 was administered a caudal block with an injection of bupivacaine (0.25%) at a dose of 1ml kg^{-1} , while Group-2 received an injection of Midazolam at a dose of 50 µg kg along with saline at a dose of 1ml kg^{-1} .

Anaesthesia was sustained using a mixture of oxygen and nitrous oxide in equal proportions, along with isoflurane and vacuronium bromide at a dose of 80-100 µg kg^{-1} . Regulated ventilation was upheld during the procedure. No opioids or other medicines that influence central pain processing were administered during the operation. Throughout the entire process, the heart rate, oxygen saturation (SPO2) and ECG were continuously measured. The residual neuromuscular block was reversed by

intravenous injections of glycopyrrolate at a dose of 8 micrograms per kg^{-1} and neostigmine at a dose of 50 micrograms per kilogramme following the surgery. Children were consistently monitored in the recovery room for a duration of 20 mins. Following this, patients were transferred to regular hospital rooms where their OPS score was measured at 0.5, 2, 4, 8, 12 and 24 hrs post-surgery. Whenever a child had an OPS score >5, they were given a rescue dose of an analgesic called syrup Paracetamol, at a dosage of 15mg per kg^{-1}, delivered orally. The length of pain relief was determined by measuring the time from the end of the procedure to the administration of the first dose of additional pain medication. <Any adverse effects or complications that occurred either locally or throughout the body during the trial were documented.

RESULTS

A total of 100 participants were included in the current study and were randomly assigned to two groups, with 50 participants in each group. Both groups were similar in terms of age, sex, weight, duration of operation, and kind of surgery, with no significant difference seen (Table 1).

The analgesic impact was assessed using the OPS score in group 1 and group 2 at 0.5, 2, 4, 8, 12 and 24 hrs following the surgery (Table 2).

- Assessment of pain after 0.5 hrs of surgery: Both groups of patients experienced effective pain relief within the first 30 mins after waking up, with an average pain score of approximately 2 as reported by observers. No patients in either group needed additional pain medication.
- Assessment of pain 2 hours after surgery revealed that the average pain scores for groups 1 and 2 were 3.02 (0.58) and 3.8 (0.80) correspondingly. Two patients in group 2 needed further pain relief in the form of a rescue analgesic (paracetamol syrup, 15mg kg^{-1}). None of the patients in group -1 needed additional pain medication.
- Assessment of pain after 4 hours of surgery: The patients in group 1 had an average observer pain score of 4.12 (0.58) at 4 hours after waking up, while patients in group 2 had an average observer pain score of 5 (0.86). Three additional patients in group 2 needed a rescue analgesic, specifically syrup Paracetamol at a dosage of 15mg per kilo gramme. No patients in group 1 needed additional pain medication.
- Assessment of pain after 8 hours of surgery: The patients in group 1 showed an average pain level of 4.24 (0.52) as observed by the evaluator, while patients in group 2 showed an average pain score of 4.86 (0.52) as observed by the evaluator. An additional twelve patients in group 2 needed additional pain relief medication (liquid Paracetamol 15mg kg^{-1}). Among the patients in group -1, just five individuals needed additional pain relief medication.
- Assessment of pain 12 hours post-surgery: Patients in group 1 had an average pain score of 4.98 (±0.48), whereas patients in group 2 had an average pain score of 4.99 (±0.4).Seven additional patients in group 2 needed additional pain relief medication (syrup Paracetamol 15mg kg^{-1}), while in group 1, sixteen patients needed additional pain relief medication.
- Assessment of pain 24 hours post-surgery revealed that patients in both group-1 and group-2 had an average observer pain score of 5.0 (±0.0), which was similar. The remaining patients in both groups needed further pain relief.

The need for additional pain relief after 8 hours was observed in 20% of individuals in group 1, compared to 68% of patients in group 2. Likewise, 84% of patients in group -1 needed rescue analgesia after 12 hours, compared to 96% in group- 2. The decreased occurrence of the requirement for additional pain relief at the end of 8 hours after surgery was statistically significant, with a p-value of less than 0.05, in group-1.

Complication rates were slightly higher in group-1 patients than in group-2. 11 patients had motor weakness and 7 patients had vomiting in group-1 whereas 3 patients had vomiting in group-2. (Table 3-4)

DISCUSSIONS

Pain is characterised as an unpleasant sensory and emotional encounter linked to real or possible harm to tissues or stated in relation to such harm[15]. Nowadays, the use of postoperative pain relief administered

Table 1: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	4
With toy or parental presence	
Severe pain	
Crying screaming, inconsolable	5

Table 2: Demographic data of patients in two groups

	Group 1 (Bupivacaine) (n=50)	Group 2 (midazolam) (n=50)
Age (yrs)	4.2±1.86	4.2±1.98
Weight (kg^{-1})	12.82±4.12	12.82±3.98
Duration of surgery (min)	43±3.96	40.8±5.95
Sex		
Male	50	48
Female	-	2
Type of surgery		
Inguinal hernia	35 (70%)	33 (66%)
Circumcision	7 (14%)	11 (22%)
Hypospadias	9 (18%)	5 (10%)
Orchidopexy	0 (0%)	3 (6%)
Lt. Adductor tenotomy	2 (4%)	0 (0%)

Table 3: Post operative OPS score

Post-operative duration (hours)	Group-1 (Bupivacaine) (n=50) Mean (SD)	Group-2 (Midazolam) (n=50) Mean (SD)
0.5	2.16 (0.37)	2.72(0.79)
2	3.02(0.58)	3. 8 (0.80)
4	4.12 (0.58)	5(0.86)
8	4.24(0.52)	4.86(0.52)
12	4.98 (0.48)	4.99 (0.4)
24	5 (0.0)	5 (0.0)

Table 4: Post operative complications:

Complication	Group-1 (Bupivacaine) (n=50)	Group-2 (midazolam) (n=50)
Vomiting	7	3
Retention of urine	-	-
Motor weakness	3	-

through the caudal route is common in children who are undergoing urogenital procedures. Bupivacaine, a local anaesthetic with a prolonged duration of action, is utilised due to its extended period of effectiveness, which can last up to 6-12 hours. Lately, a number of substances are being added to bupivacaine to extend the length and enhance the effectiveness of pain relief in various surgical operations for children[16]. In our research, we found that caudal Bupivacaine and caudal Midazolam had the same level of effectiveness in managing pain after surgery in children within the initial 30 mins after the operation. However, children who received Bupivacaine saw considerably reduced pain levels at 2, 4 and 8 hours after the operation. The overall requirement for rescue pain medication was considerably lower in the Bupivacaine group. The data indicates that bupivacaine offers a longer period of pain relief after surgery when compared to Midazolam. At 12 and 24 hours, the OPS score of both groups was nearly the same. A comparable investigation was carried out in 1998 by Gulec *et al*.[17] using posterior 0.25% Bupivacaine (group-A), 0.25% bupivacaine-midazolam (group-B), 0.25% bupivacaine morphine 0.05mg kg^{-1} (group-C) The study demonstrated that the duration of pain relief was 8.15±1.3 hours in group A, which closely resembled our own study.

Pradhan *et al*.[18] in 2008 concluded that recovery to first analgesic time was longer in Bupivacaine group (9.65 hours) comapare to Midazolam group (7.32 hours). In 1998 Nishiyama *et al*.[19] The researchers determined that a volume of 5-10 ml of saline is the best amount for epidural injection when using Midazolam 50µg kg^{-1} for postoperative pain relief after upper abdominal surgery. However, in our study, we found that using Midazolam 50µg kg^{-1} with a volume of 1ml kg^{-1} provided optimal pain relief without causing sedation, amnesia, or urinary retention[20]. It may be determined that giving caudal midazolam at a dosage of 50µg kg^{-1} offers the same level of pain relief as bupivacaine 0.25% when given after surgery in a volume of 1ml kg^{-1} for children who have had unilateral inguinal herniotomy. A popular approach nowadays is to favour a local anaesthetic method for surgeries involving the lower abdomen and limbs in children. The appeal of this method is because to its simplicity and frequent effectiveness[21,22].

CONCLUSION

This study demonstrates that the inclusion of midazolam with caudal bupivacaine results in a prolonged period of pain relief and decreased need for additional pain medication in children who are having outpatient procedures below the belly button. No notable negative impact was seen when this investigation compared its use with bupivacaine alone. The length of pain relief was greater with Bupivacaine in comparison to Midazolam. Nevertheless, there was postoperative drowsiness with Midazolam, whereas motor weakening was observed with Bupivacaine. In children who are having groin procedures (herniotomy /orchidopexy), the combination of neostigmine 2 mg kg^{-1} 1 and bupivacaine delivered by the caudal channel provides better pain management after the surgery compared to using bupivacaine alone. This combination does not increase the occurrence of adverse effects. Administering extra tramadol through the caudal route provided longer and adequate pain relief after surgery compared to pure bupivacaine.

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