Scholars Journal of Applied Medical Sciences
Abbreviated Key Title: Sch J App Med Sci
ISSN 2347-954X (Print) | ISSN 2320-6691 (Online)
Journal homepage: https://saspublishers.com

OPEN ACCESS

Anesthesiology

"Comparative Evaluation of Caudal Tramadol and Adjuvant to Bupivacaine in Paediatric Age Group"

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DOI: 10.36347/sjams.2022.v10i03.019 | **Received:** 21.02.2022 | **Accepted:** 27.03.2022 | **Published:** 30.03.2022

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Abstract **Original Research Article**

Background: Caudal anaesthesia is a type of regional anaesthesia in which local anesthetic is injected into epidural space. It is most popular regional anaesthesia with a predictable level of blockade used in paediatric surgeries. Adjuvants can be added to local anaesthetics for prolonging the duration of analgesia. ***Objective:*** To find out the duration of analgesia of caudal Bupivacaine in combination with Tramadol. ***Methods:*** This prospective, randomised, double-blind, comparative study was done in Department of Anesthesiology, Sher-e-bangla Medical College Hospital, Barishal, Bangladesh from June to December 2020. Total of 50 patients, aged between 2 to 9 years undergoing elective lower abdominal, urological and lower extremity surgeries. The patients were randomized to group A (n=25) receiving 1 ml/kg of 0.25% bupivacaine and group B (n=25) receiving 1 ml/kg of 0.25% bupivacaine plus 1mg/kg of tramadol caudally. Duration of analgesia, hemodynamic responses and adverse effects were noted and analysed. ***Results:*** Thirty patients in both groups were comparable with regard to demographic data and hemodynamic response and were statistically non-significant (P>0.05). It was observed that the mean duration of analgesia was significantly longer in group B (468.5±164.5 min versus 241.5±69.4 min, P<0.001). One patient in each group had postoperative vomiting. ***Conclusion:*** This study concludes that Tramadol 1 mg/kg can be added to 0.25% Bupivacaine for caudal analgesia with total volume of 1 ml/kg to prolong the duration of postoperative analgesia in children undergoing lower abdominal, urological, lower extremity surgery without an increase of adverse effects.

Keywords: Bupivacaine, Caudal Analgesia, Tramadol.

INTRODUCTION

Caudal anaesthesia is a type of regional anaesthesia in which local anesthetic is injected into epidural space. It is most popular regional anaesthesia with a predictable level of blockade used in pediatric surgeries. The main drawback of caudal analgesia is the short duration of action with a local anaesthetic agent in a single injection. To overcome this problem, various drugs can be added to local anaesthetics as an adjuvant to prolong the duration of analgesia. Caudal epidural block with bupivacaine is a common local anaesthetic technique in paediatric anaesthesia. However, a single caudal injection of bupivacaine provides analgesia for only 2–4 h. The administration of opioids into the epidural space significantly prolongs the duration of caudal analgesia but is associated with a number of unpleasant side-effects including the potentially serious risk of respiratory depression [1]. Various regional anaesthetic procedures have gained popularity for postoperative analgesia because in addition to provide analgesia, they also reduce the need of general anaesthetic intra-operatively without significant adverse effects and maintain a smooth intraoperative as well as postoperative period. In children, caudal anaesthesia is typically combined with general anaesthesia for intraoperative supplementation and postoperative analgesia. It is commonly used for surgical procedures below the diaphragm like urogenital, rectal, inguinal, and lower extremity [2]. Tramadol is one of those various adjuvants and is a centrally acting synthetic opioid analgesic equipotent to pethidine with a striking lack of respiratory depressant effect. In addition, biotransformation of Tramadol in the liver results in many metabolites of which O-desmethyl tramadol is the major metabolite exerting modest analgesic effect [3].We commonly practice intravenous Tramadol for analgesia but the practice of administering Tramadol epidurally is not commonly practised in our set up. Similarly, there are a lot of studies done by administering Tramadol epidurally as an adjuvant to

Bupivacaine in different parts of the world but there is the lack of sufficient adequately powered studies from our set up. From those studies, it has been shown that epidural Tramadol prolongs the duration of analgesia.

MATERIALS AND METHODS

This prospective, randomised, double-blind, comparative study was done in Department of Anesthesiology, Sher-e-bangla Medical College Hospital, Barishal, Bangladesh from June to December 2020. The sample size taken was 25 in each group. This study was conducted to determine the duration of analgesia of caudal Tramadol as an adjuvant to Bupivacaine as a primary outcome and compare the hemodynamic response and assess the adverse effects of study drugs as secondary outcomes. The ASA physical status I and II of both sexes of aged two to nine years scheduled for elective lower abdominal, urological and lower extremity surgeries were included in the study. The exclusion criteria included parents' refusal, neurological deficit, mental retardation, coagulopathy, allergy to study drugs, infection at the injection site and obvious spinal or skeletal deformity.

One day prior to the surgery, pre-anaesthetic evaluation of the patients was done with detailed history, physical examination and relevant laboratory investigations. Patients were kept nil per orally for at least six hours before the time of surgery but they were allowed to have milk till four hours before and water till two hours before the time of surgery.

In operation room, standard monitors were attached which included an electrocardiogram, non-invasive blood pressure, pulse oximeter and temperature. Induction was done either with intravenous anaesthetic (propofol or sodium thiopentone) after appropriate-sized intravenous cannulation or gaseous induction with halothane. The pulse rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, electrocardiogram, arterial oxygen saturation and temperature were monitored.

Patients enrolled into the study were randomised into two groups by lottery withdrawn by a trained staff from a sequentially numbered container. After a trained staff generated the random allocation sequence, an anesthesiologist enrolled participants and assigned them to interventions who were not involved in observing the outcome variables. The baseline hemodynamic parameters were noted before performing the caudal block. Trained staffs were asked to prepare the drugs, so that neither the investigator nor the subjects were aware of the study group.

Group a received 0.25% Bupivacaine. Group B received 0.25% Bupivacaine plus Tramadol 1 mg/kg. Tramadol was available as 2 ml ampoule containing injection Tramadol 50 mg/ml. Each 10ml of the prepared solution contained 0.25% Bupivacaine or 0.25% Bupivacaine with 10mg Tramadol. The volume of the drug to be injected was calculated according to Armitage recommends 1 ml/ kg for a lumbosacral block. The anesthesiologist and the staffs involved in measuring hemodynamic parameters, measuring the duration of analgesia, noting the adverse effects of study drugs and the patient remained unaware of the group allocations. Duration of analgesia (time of caudal administration of drugs to the first dose of rescue analgesia) was noted. The degree of analgesia was assessed using FLACC (Face Legs Activity Cry Consolability) scale. The assessment was done every 30 minutes for 2 hours, and then hourly till the patient received the first dose of rescue analgesia. At the same time, the adverse effects of the study drugs (nausea, vomiting, and arrhythmia) were also noted.

Interpreting the FLACC score
0 = relaxed and comfortable;
1 to 3 = mild discomfort;
4 to 6 = moderate pain;
7 to 10 = severe pain or discomfort or both.

Patients with a score of 4 or more than 4 received rescue analgesic. Inj. Pethidine 0.5 mg/kg intravascularly was injected as rescue analgesic.

Collected data were analysed by means of statistical software SPSS 21 and appropriate tests. Chi-square test was used for categories like sex and incidence of adverse effects. Student's t-test was used for continuous parametric data like age, weight, heart rate, blood pressure and duration of analgesia. The p-value of less than 0.05 was taken as statistically significant.

RESULTS

Table-1: Demographic Data (N=50)

Variables	Group A (n=25)	Group B (n=25)	P value
Age (months)	48.07±19.9	54.87±22.8	0.164
Sex (M/F)	20/5	16/9	0.26
Weight (kg)	14.73±4.1	16.08±4.5	0.235

Fifty patients were included in the study. Age Age (months) 48.07±19.9 of Group A and 54.87±22.8 of Group B. Heart rate and mean arterial pressure at different intervals of time were comparable between two groups.

Table-2: Heart rate at different intervals of time (N=50)

Heart rate (beats per minute)	Group A		Group B		P value
	Mean	SD	Mean	SD	
Baseline	108.9	14.6	110.0	14.9	0.807
Just after administration of study drug	108.9	14.6	109.8	14.9	0.972
3 min after administration of study drug	108.3	14.3	109.6	14.7	0.846
5 min after administration of study drug	111.4	12.8	108.4	15.6	0.596
10 min after administration of study drug	110.8	13.2	110.5	13.6	0.916

Table-3: Mean arterial pressure at different intervals of time (N=50)

Mean arterial pressure (mm of Hg)	Group A		Group B		P value
	Mean	SD	Mean	SD	
Baseline	62.6	7.8	66.4	7.6	0.062
Just after administration of study drug	58.4	7.7	62.8	9.7	0.06
3 min after administration of study drug	58.6	7.5	64.1	9.7	0.052
5 min after administration of study drug	58.9	8.3	64.3	8.7	0.051
10 min after administration of study drug	62.2	7.3	64.3	7.8	0.118

The mean duration of analgesia in group A was (241.5±69.4) minutes whereas in group B it was (468.5±164.5) minutes with the P<0.001. The incidence of vomiting was equal in both the groups (3.3% in each group). No other adverse effects like arrhythmia, hypotension, bradycardia, seizure, respiratory depression or urinary retention were seen.

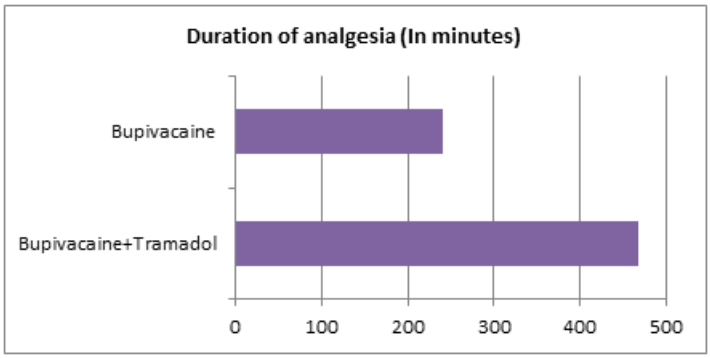

Fig-1: Duration of analgesia.

DISCUSSION

The most important symptom which brings a patient to a doctor is pain, so effective management of pain is most important and justifies the existence of all anesthesiologists as analgesia is important component of anaesthesia. Uncontrolled postoperative pain can lead to various unwanted effects like delayed recovery from surgery, restriction of mobility, the risk of thromboembolism, and increased level of blood glucose. These effects cause poor wound healing, immune dysfunction and paralytic ileus. Patients with inadequate analgesia cannot breathe deeply; have an ineffective cough, which leads to various postoperative pulmonary complications. Regional anaesthetic techniques are used effectively to manage acute pain after a variety of surgeries. The benefits of regional anaesthetic techniques include avoidance of perioperative opioids and their adverse effects, early ambulation, and excellent analgesia. Caudal anaesthesia is the most popular regional anaesthesia technique with a predictable level of blockade for children. Various drugs can be added to local anesthetics as an adjuvant to prolong the duration of caudal analgesia provided by a single injection. Tramadol is one of them used along with Bupivacaine in the caudal block which is an opioid analgesic equipotent to Pethidine with the striking lack of respiratory depressant effect and cost effective also that can be used in our set up for the benefit of the patients undergoing different surgeries. Meena Doda *et al*. [4] did a study in children to compare the quality and duration of pain relief after a single shot caudal block with 0.5 ml/kg of 0.25% Bupivacaine alone and 0.25% Bupivacaine plus Tramadol 2 mg/kg. It was found that the mean duration of the time interval between the caudal block and the first dose of analgesic was significantly longer when the combination of Bupivacaine and Tramadol was used. It was found in this study that Tramadol 1 mg/kg can be used as an adjunct to 0.25%. Bupivacaine for caudal analgesia in children with total volume of 1 ml/kg for increasing the duration of postoperative analgesia without an increase of adverse effects. Similar results were reported by Md. Shafiqul Islam *et al.* [5] in a study of children undergoing sub umbilical surgeries with the caudally

administered mixture of Tramadol and Bupivacaine. They found that mean duration of pain relief was significantly longer (P<0.001) when the mixture of Tramadol and Bupivacaine was used compared to Bupivacaine alone. The dose of Tramadol used by them is greater and the total volume is smaller, however, the concentration of Bupivacaine is similar as compared to our study. A similar result was found by Laiq N *et al*. [6] in a study done in children undergoing hypospadias surgery to compare the effectiveness of Bupivacaine and Bupivacaine-Tramadol mixture administered caudally for postoperative analgesia. They concluded that Tramadol 1 mg/kg with 0.25% Bupivacaine caudally, when given in a total volume of 0.5 ml/kg, provides prolonged and good quality postoperative analgesia compared to Bupivacaine only. The total volume of the drug used in their study was less than that in our study with a similar dose of Tramadol. Another study was done by Shrestha SK *et al*. [7] and they also concluded that the addition of Tramadol 1 mg/kg to 0.25% Bupivacaine caudally provided longer duration of analgesia and lesser need for rescue analgesics postoperatively compared to Bupivacaine only with total volume being 0.5 ml/kg. This might be because of the lower volume of the drug used by them although the concentration of Bupivacaine and the dose of Tramadol are same. Similar results were also found in the study done by S Prakash *et al*. [8] and A.C. Senel *et al*. [9]. The most frequent side effects of epidural Tramadol are nausea and vomiting. But the incidence of vomiting was same in both groups in our study which was 3.3%. Contradictory to our study, the study done by Shahid Khan *et al*. [10] showed increased incidence of vomiting when Bupivacaine-Tramadol combination was used. The incidence of vomiting was 10% in the combination group compared to 6.66% in the group receiving Bupivacaine only. Similar results were seen in a study done by S Prakash *et al*. [8] to evaluate the analgesic efficacy of three doses of Tramadol administered caudally with Bupivacaine.

CONCLUSION

In conclude, that Tramadol 1 mg/kg can be added to 0.25% Bupivacaine for caudal analgesia with total volume of 1 ml/kg to prolong the duration of postoperative analgesia in children undergoing lower abdominal, urological, lower extremity surgery without an increase of adverse effects.

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