

# Comparison of Analgesic Efficacy of Nalbuphine Versus Tramadol as Adjuvant to Local Anaesthetic in Caudal Block in Children

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## ABSTRACT

**Objective:** To compare the mean time of first analgesia with nalbuphine versus tramadol as adjuvant to bupivacaine for caudal block in children.

**Patients and Methods:** In this randomized clinical trial, a total number of 60 children who were planned for caudal block after infra-abdominal surgeries having age 3-12 years were included. A caudal block was performed under general anaesthesia immediately after surgery for postoperative analgesia. Tramadol 2mg/kg body weight was given caudally to individuals in group A. Group B patients had 0.125 percent bupivacaine with 0.1mg/kg nalbuphine caudally. Time of requirement of first analgesia was noted in all patients. Paracetamol 10 mg/kg was given as rescue analgesic in all patients.

**Results:** Mean age of patients was 8.30±3.03 years. Mean weight of patients was 23.33±6.92 Kg. There were 26 (43.33%) female patients and 34 (56.67%) male patients. There were 50 (83.33%) children who were having ASA status I, and remaining 10 (16.67%) children were having ASA status II. Mean pain score was 3.53±1.43 in tramadol group and 1.86±1.25 in Nalbuphine group (p-value <0.001). Mean time of first rescue analgesia was significantly prolonged in Nalbuphine group, mean time was 6.13±1.07 hours in Nalbuphine group versus 4.03±1.03 hours in tramadol group (p-value <0.001).

**Conclusion:** Single dose of nalbuphine as an adjunct to bupivacaine is superior as compared to tramadol in reducing the post-operative pain, it also significantly prolongs the duration of analgesia in children.

**Keywords:** Caudal Block, Nalbuphine, Tramadol, Post-operative pain, Time of first rescue analgesia.

## INTRODUCTION

The first reported caudal block for paediatric surgery was in 1933. Since then, studies have authorized the caudal block in specific surgeries and have defined level of analgesia and anaesthesia, recommended doses, pharmacokinetics of local anesthetics used in caudal block and the common or specific advantages and disadvantages of this technique in children. Caudal block is used as adjunct to general anesthesia and has an opioid-sparing effect, which enables fast and smooth recovery from anesthesia. A single shot caudal block provides an increase in efficacy and the duration of postoperative analgesia.<sup>1</sup> In day care procedures, i-e herniotomy, circumcision etc in children, caudal block is used to reduce the pain in a good manner.<sup>2</sup>

Different drugs have been used in order to improve the duration as well as the quality of analgesia of the local anaesthetic used in the single shot caudal block technique such as opioids, epinephrine, clonidine and ketamine.<sup>3</sup> Besides to overcome the side effects of a single agent administration with high dose, two agents in low doses is proved superior in achieving the result.<sup>4</sup>

Tramadol is a centrally acting opioid analgesic.<sup>5</sup> It is a synthetic analogue of codeine which is almost as potent as pethidine but without respiratory depression.<sup>4</sup>

Nalbuphine is an opioid agonist-antagonist analgesic originated from phenanthrene group, and structurally similar to naloxone and oxymorphone. The drug is used for the management of moderate to severe pain.<sup>5,6</sup>

Now a days, Nalbuphine is gaining access as an adjuvant with bupivacaine to increase the analgesic activity in caudal block. So the purpose of the present study was to determine the analgesic efficacy of tramadol versus

Nalbuphine given as an adjunct to bupivacaine for caudal block in children.

## MATERIALS AND METHODS

In this randomized controlled trial, we included 80 patients in whom caudal analgesia was given after surgery. The study was arranged in a tertiary care hospital from March-2020 to July-2021. Children of age 3-12 years with ASA status I and II who underwent infra-abdominal surgeries were included. Children taking analgesics before surgery were excluded. Informed written from parents or guardian of each child was obtained.

These children were divided randomly into two groups A and B by lottery method. For postoperative analgesia, a caudal block was administered under general anesthesia immediately after surgery. Tramadol 2mg/kg body weight was administered caudally to the patients in group A, who received 0.125 percent bupivacaine 1ml/kg. Bupivacaine/nalbuphine 0.1mg/kg body weight caudally was administered to participants in Group B. At 3, 6, and 10 hours postoperatively, pain ratings were obtained for individuals who had had general anesthesia. The pain was measured using the FACES scale. Post-operative pain score and time of requirement of first rescue analgesia was noted. All patients received paracetamol 10 mg/kg as rescue analgesic. In addition to the patient's age, weight, sex, and pre-operative ASA status, all research variables were recorded.

SPSS version 20 was used to input and evaluate the data. In order to compare between groups A and B the time of the need for initial rescue analgesia, an independent

sample t-test was performed. A significant difference was defined if p-value of  $\leq 0.05$  was obtained.

**RESULTS**

Mean age of patients was  $8.43 \pm 3.21$  years. Mean weight of patients was  $22.43 \pm 6.87$  Kg. Regarding gender there were 26 (43.33%) female patients and 34 (56.67%) male patients (Figure 1). There were 50 (83.33%) children who were having ASA status I, and remaining 10 (16.67%) children were having ASA status II (Figure 2).

On comparison of post-operative pain score between the groups, mean pain score was  $3.53 \pm 1.43$  in tramadol group and  $1.86 \pm 1.25$  in Nalbuphine group ( $p$ -value  $< 0.001$ ). Mean time of first rescue analgesia was significantly prolonged in Nalbuphine group, mean time was  $6.13 \pm 1.07$  hours in Nalbuphine group versus  $4.03 \pm 1.03$  hours in tramadol group ( $p$ -value  $< 0.001$ ) [Table 1].

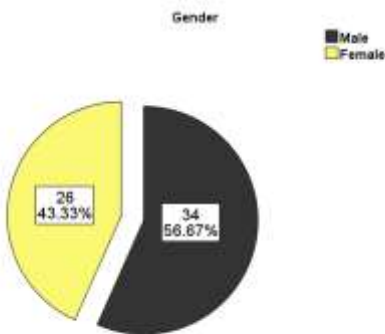


Figure 1: Frequency of Gender of Patients.

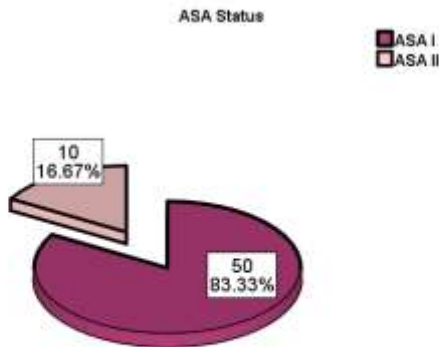


Figure 2: Frequency of ASA Status.

Table 4: Comparison of Post-Operative Pain Between the Groups.

	Study Group		P-value
	Tramadol (Group A)	Nalbuphine (Group B)	
Post-Op VAS Score (at 6 hours)	$3.53 \pm 1.43$	$1.86 \pm 1.25$	$< 0.001$
Time of First Analgesia	$4.03 \pm 1.03$	$6.13 \pm 1.07$	$< 0.001$

**DISCUSSION**

Children's postoperative pain is a big issue, but it has received little attention. 15–60% of children have moderate to severe acute post-surgical pain (APSP).<sup>7</sup> APSP management alternatives are being rolled out in a variety of ways. Narcotic analgesics, local infiltration, and caudal and regional blocks have all been the subject of several studies to see which one was the most effective.<sup>8</sup>

Narcotic analgesics are the most often prescribed medication for the treatment of APSP, especially in children undergoing major surgery. Alternative agents, on the other hand, are now being tested in pediatric daycare surgery. When compared to other opioid analgesics, tramadol is a centrally acting synthetic opioid analgesic that exhibits less respiratory depression.<sup>9</sup>

It is difficult to measure pain in children, despite the availability of several methods and evaluation charts. Children under the age of one are especially challenging to evaluate. Patients less than one year old were included in the study so that APSP could be assessed in a universal manner, avoiding the difficulties associated with utilizing two or more methods.<sup>10</sup>

In our study we found significant difference in post-operative pain between the groups, mean pain score in  $3.53 \pm 1.43$  in tramadol group and  $1.86 \pm 1.25$  in Nalbuphine group. Mean time of first rescue analgesia was significantly prolonged in Nalbuphine group, mean time was  $6.13 \pm 1.07$  hours in Nalbuphine group versus  $4.03 \pm 1.03$  hours in tramadol group.

A recent study conducted by Liaqat et al. found that initially intensity of pain is low in patients receiving Nalbuphine as compared to tramadol but after 2 hours, there is no difference in pain scores in between the Nalbuphine and tramadol group. Mean time of requirement of first analgesia in that study was  $6.5 \pm 0.5$  hours in Nalbuphine group versus  $5.3 \pm 1.7$  hours in tramadol group.<sup>11</sup>

In another study conducted by Hassain et al. in laparotomy patients, mean time of requirement of first analgesia was prolonged in tramadol group as compared to Nalbuphine  $1.06 \pm 1.46$  versus  $0.57 \pm 0.48$  respectively.<sup>12</sup>

In a study conducted by Moyao-Garca et al., they compared the use of nalbuphine versus tramadol for postoperative pain control in children. The children were randomly assigned to receive either an intravenous bolus dose of nalbuphine 100 g/kg immediately before the end of surgery followed by an infusion of 0.2 g/kg/min for 72 hours, or an intravenous bolus dose of tramadol. Postoperative pain control was assessed by using CHEOPS (Children Hospital of Eastern Ontario behavioral scale) for children less than 6 years and VAS for patient more than 6 years every 1 h for 24 h then every 4 h until the end of 72 h, the following parameters were also recorded: heart and respiratory rates, diastolic and systolic blood pressure, SaO2 and, sedation was also assessed. They found that three patients in the nalbuphine group received bolus dose of nalbuphine in the first 12 h postoperatively versus one patient in the tramadol group received bolus dose of tramadol; however, in a similar number of patients the infusion rate was increased within the 72 post-surgery hours in the two study groups, sedation was observed in two children in the nalbuphine group and

in one child in the tramadol group; no significant differences were observed between the two groups regarding respiratory rate and SpO<sub>2</sub> and no patient required postoperative tracheal intubation.<sup>13</sup>

Pascal García et al. studied the effect of nalbuphine in obstetric analgesia when given in epidural space. The nalbuphine group was administered epidurally 100 µg/kg of nalbuphine in 12 ml of normal saline, and the bupivacaine group received 12 ml of solution saline with 15 mg of bupivacaine concentrated 0.125%. The pain was evaluated at 5, 15, 30, 60, 90, and 120 min after injection by a VAS. In addition, the presence of side effects such as pruritus, urinary retention, respiratory depression, hypotension, nausea, vomiting, or bradycardia were recorded. It was concluded that the use of nalbuphine, in doses of 100 µg/kg epidurally, is effective to obtain adequate analgesia during labor. It is as effective as the administration of bupivacaine (0.125%). The use of epidural nalbuphine is also clinically safe for both the mother and the newborn.<sup>14</sup>

## CONCLUSION

Single dose of nalbuphine as an adjunct to bupivacaine is superior as compared to tramadol in reducing the post-operative pain, it also significantly prolongs the duration of analgesia in children.

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