

Original Research Article

# Comparison of caudal tramadol versus caudal fentanyl with bupivacaine for prolongation of postoperative analgesia in pediatric patients

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## Abstract

**Introduction:** Caudal block is one of the most popular and commonly used regional anaesthetic procedures in paediatric patients for most surgeries below the umbilicus. Because of the short duration of analgesia with bupivacaine alone various additive have been used to prolong the action of bupivacaine.

**Aim:** The present study was aimed to evaluate the analgesic effect of tramadol or fentanyl added to bupivacaine for infraumbilical surgeries in pediatric patients.

**Materials and methods:** It was a prospective study, 80 patients randomly selected belonging to American Society of Anesthesiologist physical status I-II, in the age group of 1-12 years, of either sex undergoing infraumbilical surgery under general anesthesia were divided into two groups. Group BT received 1 ml/kg of 0.25% bupivacaine with tramadol 2 mg/kg in normal saline and Group BF received 1 ml/kg of 0.25% bupivacaine with fentanyl 2 mg/kg in normal saline with maximum volume of 12 ml in both groups. All patients were assessed intraoperatively for hemodynamic changes, pain score and sedation score.

**Results:** The mean duration of analgesia was 10-18 h in Group BT while in Group BF it was 7-11 h. The postoperatively period up to 10 h, Group BF had higher sedation score up to two as compared to that below one on Group BT.

**Conclusion:** Caudal tramadol compared to caudal fentanyl significantly prolongs the duration of analgesia without any side effects.

## Key words

Caudal tramadol, Caudal fentanyl, Bupivacaine, Post-operative analgesia, Pediatric patients.

## Introduction

Caudal block is one of the most popular and commonly used regional anaesthetic procedures in paediatric patients for most surgeries below the umbilicus. The block can be practised by a single-shot injection or as a continuous infusion through a caudal epidural catheter. For continuous infusion, use of a caudal catheter is usually not preferred due to high risk of catheter contamination from faecal soiling [1]. To extend the duration of post-operative analgesia provided by the 'single shot' caudal technique, various additives, such as tramadol, ketamine, ephedrine, morphine, fentanyl and clonidine with local anaesthetics, have been investigated. Tramadol, a synthetic 4-phenyl-piperidine analogue of codeine, is a racemic mixture of two enantiomers, both of which contribute to the analgesic activity through different mechanisms enhancing inhibitory effects on pain transmission in the spinal cord. The (+) enantiomer has moderate affinity for the opioid  $\mu$ -receptor, which is greater than that of the (-) enantiomer. In addition, the (+) enantiomer stimulates the pre-synaptic release of serotonin and inhibits serotonin reuptake, and the (-) enantiomer is a norepinephrine reuptake inhibitor [2]. The complementary and synergistic actions of the two enantiomers improve the analgesic efficacy and tolerability profile of the two. Tramadol has a striking lack of respiratory depressant effect despite having analgesic potency approximately equal to that of pethidine [3, 4].

Tramadol is a centrally acting analgesic effect via opioid receptors [5]. The main site of action of epidurally administered fentanyl is the substantia gelatinosa on the dorsal horn of spinal cord [6]. We evaluated the duration of postoperative analgesia, intraoperative hemodynamic changes, the requirement of

inhalational agent and any side effect while using caudal block bupivacaine with tramadol versus fentanyl in pediatric patients undergoing infraumbilical surgery.

## Materials and methods

This prospective and randomized controlled, single-blind study were conducted in the pediatric surgical ward between August 2014 and December 2014, and total 80 children of either sex scheduled for elective infraumbilical surgeries under general anesthesia.

**Inclusion criteria:** American Society of Anesthesiologist (ASA) physical status I and II, aged 1-12 years, weighing 5-30 kg.

**Exclusion criteria:** Patients are having a local infection at the caudal site, neurological disorder, the history of allergic reaction to local anaesthetics, sacral/vertebral abnormalities, and bleeding diathesis.

Inform consent from patient and ethical clearance was obtained. An intravenous access was secured, and glycopyrrolate injection (0.004 mg/kg) and ondansetron injection (0.15 mg/kg) were administered. Standard monitoring including an electrocardiogram (ECG), noninvasive blood pressure (NIBP) measurement, pulse oximetry, capnography, and temperature were applied. All patients were induced with either inhalational agent sevoflurane (1-6%) with 50% nitrous oxide in oxygen or intravenous thiopental in a dose of 5-6 mg/kg. Caudal block was performed using 22-gauge epidural needle under complete aseptic precaution.

Group BT received 1 ml/kg of 0.25% bupivacaine with 2 mg/kg of tramadol in normal saline Group BF received 1 ml/kg of 0.25%

bupivacaine with 2 mg/kg of fentanyl in normal saline with maximum volume of 12 ml in both the groups. The anesthesiologist performing the caudal block was blinded to the identity of the drug used.

During surgery, adequate analgesia was assessed by hemodynamic stability, as indicated an increase in heart rate and systolic blood pressure of no more than 15% compared with baseline values obtained just before the surgical incision with decreased requirement of sevoflurane concentration, at approximately 0.6%. An increase in heart rate and systolic blood pressure within 20 min of skin incision indicated failure of caudal anesthesia.

Intraoperatively required concentration of sevoflurane was recorded at every 15 min. Heart rate, NIBP, SpO<sub>2</sub>, EtCO<sub>2</sub>, and temperature were recorded at every 15 min interval till the end of surgery and every hourly interval postoperatively till rescue analgesic was given.

Duration of surgery, duration of anesthesia, and perioperative complications such as brady/tachycardia, hypo/hypertension, vomiting, and urinary retention were recorded.

In the recovery room, hemodynamic parameters, sedation, and pain score were recorded at hourly interval till rescue analgesic was given. Postoperative sedation was assessed by using four point sedation score (0 - spontaneous eye opening, 1 - eye open on speech, 2 - eye open on shake, 3 - unarousable), and pain was evaluated by using FLACC (F = Face, L = Leg, A = Activity, C = Cry, C = Consolability), score (maximum score of 10) at 1 h interval for first 3 h and thereafter every 2 h interval till score >4, and rescue analgesic was given. The use of FLACC is a valid and reliable tool for assessing procedural pain in children aged 5-16 years.

Using Microsoft Office Excel 2010 and Graph Pad Prism 6.05 (GraphPad Software, Inc., La Jolla, CA, USA) (QuickCalc) Software,  $P < 0.05$  was considered statistically significant.

## Results

All the demographic parameters were insignificant in the study when compared to each other (**Table – 1**).

Baseline heart rate, systolic blood pressure, and diastolic blood pressure recorded before the induction of general anesthesia were similar in both groups. Compared with the baseline value after caudal block, heart rate decreased significantly in Group BT compared to Group BF. No patients in either group had a drop in heart rate to <80 beats/min. After 15 min of caudal blocks, systolic blood pressure decreased below 100 mmHg in Group BF while in Group BT systolic blood pressure remained above 100 mmHg. Diastolic blood pressure did not decrease significantly (**Table – 2**).

The difference was statistically significant at 4, 6, 8, and 10 h after surgery. Mean hourly pain score in the recovery room in both the groups without requiring additional analgesic were similar for 4 h. Thereafter, the mean score in Group BF was significantly higher than that in Group BT s. The duration of analgesia was 7-11 h for Group BF and 10-18 h for Group BT (**Figure – 1**).

Group BF had higher sedation score up to two in immediate postoperative period (\*shows  $P < 0.05$ ). Sedation score was between one and two (opening eye on shake) in Group BF for first 1½ h. In Group BT, sedation score was below one. All children were opening eye on the speech from the immediate postoperative period in Group BT (**Figure – 2**).

## Discussion

Being unpleasant, pain is a subjective sensation, which in children can only be experienced and not expressed, because they depend on their care givers for their well-being [7, 8]. Over the recent years, the concept of providing adequate post-operative analgesia in paediatric patients is well established, however, various methods showed side effects limiting their use such as respiratory

depression with IV opioids [3]. With a high success rate, caudal analgesia was proved to be a simple and effective technique in children. Caudal block is usually placed after the induction of general anaesthesia and is used as an adjunct to both intraoperative and postoperative analgesia in children undergoing surgical procedures below the level of the umbilicus [9, 10].

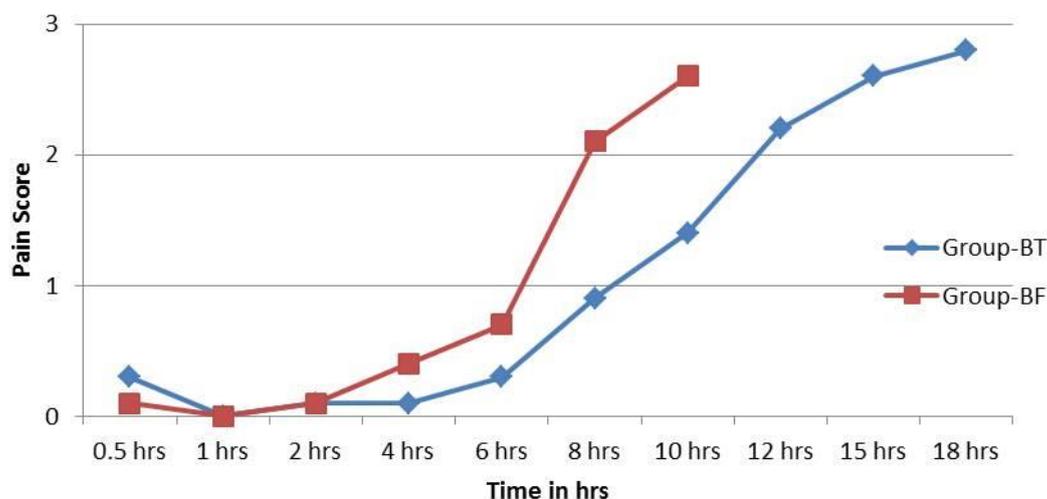
**Table - 1:** Demographic details.

Patient characteristics	Group-BT	Group-BF	P-value
Age(in years)	4.9±2.5	3.9±2.1	>0.05
Sex	23/17	28/17	>0.05
Body weight(kg)	15.3±2.3	13.5±2.8	>0.05
ASA grade 1 and 2	20/20	22/18	>0.05
Duration of surgery( IN HRS)	1.4±0.5	1.2±0.43	>0.05
I-gel /ET tube insertion	24/16	21/19	>0.05

**Table - 2:** Comparison of Hemodynamic parameters in study.

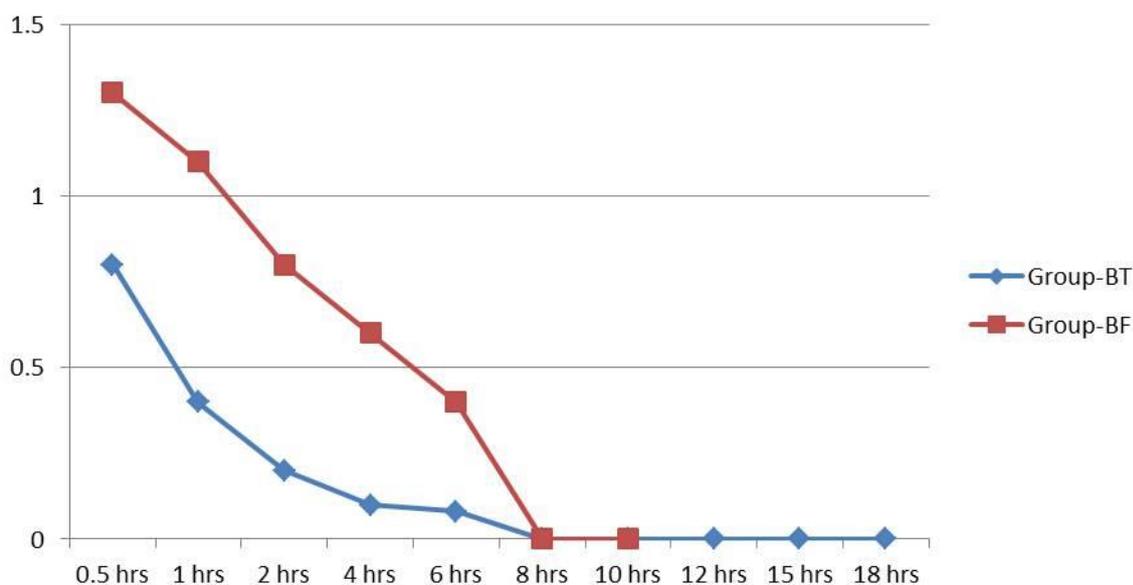
<b>Respiratory rate per minute</b>			
Duration(Time)	Group-BT	Group-BF	P-value
Basal	23.45±2.5	23.45±2.5	>0.05
5 min after caudal	22.4±2.6	23.7±2.8	<0.05
15 mins	20.8±2.0	22.1±3.2	<0.05
30 mins	19.9±1.8	21.2±2.2	<0.05
45 mins	19.0±1.2	22.2±2.0	<0.05
60 mins	19.0±1.2	19.8±2.0	<0.05
<b>Pulse rate per minute</b>			
Basal	135±22	144±19	>0.05
5 min after caudal	127±19	23.7±2	<0.05
15 mins	119±20	130±19	<0.05
30 mins	115±19	123±17	<0.05
45 mins	112±18	121±15	<0.05
60 mins	110±19	117±22	>0.05
<b>systolic blood pressure (mmHg)</b>			
Basal	109±12	105±11	>0.05
5 min after caudal	104±13	101±10	>0.05
15 mins	102±13	94±10	<0.05
30 mins	101±14	94±12	<0.05
45 mins	102±14	94±12	<0.05
60 mins	101±15	95±11	<0.05
<b>Diastolic blood pressure (mmHg)</b>			
Basal	65±10	62±9	>0.05
5 min after caudal	63±10	60±9	>0.05
15 mins	60±9	58±10	>0.05
30 mins	58±10	56±10	>0.05
45 mins	59±11	56±11	>0.05
60 mins	61±11	58±10	>0.05

**Figure - 1:** Post-operative pain score during first 24 h in both groups.



(F = Face, L = Leg, A = Activity, C = Cry, C = Consolability score)

**Figure - 2:** Post-operative sedation score during first 24 h in both groups.



Caudal analgesia could reduce the amount of inhaled and intravenous (IV) anaesthetic administration, attenuate the stress response to surgery, facilitate a rapid, smooth recovery, and provide good immediate postoperative analgesia. In our study, single shot caudal epidural using 1 ml/kg of 0.25% bupivacaine with 2 mg/kg tramadol or 2 mg/kg fentanyl with a maximum volume of 12 ml were given.

Fentanyl is a synthetic opioid agonist. It exerts its analgesic action by binding to mu receptor, as

well as to kappa and delta receptors within the spinal cord, producing spinal analgesia. It easily crosses the lumbar dura and penetrates quickly the lipid phase of the underlying tissue of the cord with minimal migration of opioids in rostral direction, hence, avoiding central nervous system depression of respiratory and cardiovascular system [11].

Caudal bupivacaine with tramadol 1 mg/kg provides prolonged, and good quality postoperative analgesia compared to plain

bupivacaine in children. Caudal tramadol 2 mg/kg with 0.5 mg/kg of 0.25% bupivacaine provided longer duration of postoperative analgesia up to 16 or 18 h without having significant side effects but with higher sedation score for 1 h postoperatively [5]. Similarly in our study, the duration of postoperative analgesia was more than 10 h up to 18 h without significant side effects in caudal bupivacaine 0.25% 1 ml/kg with tramadol 2 mg/kg.

Greater epidural use of tramadol 2 mg/kg may be preferred to morphine 0.1 mg/kg for postoperative analgesia in children undergoing urological surgery without any significant side effects [12].

Caudal tramadol 2 mg/kg combined with bupivacaine 0.25% 0.75 ml/kg provided longer duration of postoperative analgesia and reduced requirement for rescue analgesic compared with tramadol 1 mg/kg or 1.5 mg/kg in children undergoing inguinal herniotomy [13].

El Hamamsy, et al. observed analgesia for up to 4.5 and 5 h with caudal fentanyl 2 mg/kg and tramadol 2 mg/kg, respectively. The mean duration of surgery was 140 min. They also observed that if the period of time between performing the caudal injection and recovery of the child from anesthesia was <2 h, the incidence of immediate pain (requiring rescue analgesia) was high (30%), demonstrating a slow onset of action of caudal tramadol. However, with a longer duration surgery, caudal tramadol produced good quality analgesia for an average of 10.7 h. The slow onset of action of caudal tramadol may imply that there is little advantage in injecting tramadol into the extradural space. Bupivacaine tramadol may prove more useful in young children and infants than other opioids because of its lack of respiratory depressant effects. A bupivacaine-fentanyl mixture as a single caudal epidural injection does not change the onset, quality and duration of analgesia, and sedation score [14].

We observed analgesia for up to 11 h and 18 h with caudal fentanyl 2 mg/kg and tramadol 2 mg/kg, respectively. The time for onset of analgesia in both groups was respectively same. Prosser, et al. observed no significant effects of tramadol on prolongation of analgesic effects of bupivacaine when administered caudally after hypospadias surgery [15].

Solanki N M, et al. [16] observed Caudal tramadol significantly prolongs the duration of analgesia as compared to caudal fentanyl without any side effects.

In our study, we observed that caudal fentanyl 2 mg/kg prolong the duration of analgesia with mild sedation in an immediate postoperative period without any side effects. Khalid mentioned postoperative analgesia up to  $16 \pm 4$  h with increased incidence of vomiting with tramadol 2 mg/kg [17]. In our study, nausea and vomiting were observed in four patients of Group BT, and respiratory depression and pruritus were not observed in any patients of both the groups. About 70-75% patients in both groups were catheterized intraoperatively. Remaining patients did not have a problem to void urine postoperatively.

The addition of caudal epidural analgesia to general anesthesia inhibits the stress responses from the lower part of the body during surgery and reduces the neurohormonal responses. It was demonstrated that small doses of a mixture of bupivacaine 0.25% alone or with fentanyl 1 mg/kg when administered through the caudal epidural does not have any beneficial effect on pain scores and catecholamine levels [18, 19].

## **Conclusions**

Caudal bupivacaine 0.25% with tramadol 2 mg/kg provided longer duration of postoperative analgesia and reduced requirement for rescue analgesic with lesser sedation in immediate postoperative period compared to caudal bupivacaine 0.25% with fentanyl 2 mg/kg.

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