

## Comparison of caudal bupivacaine with and without tramadol for postoperative analgesia in paediatric inguino-scrotal surgeries

Saleem Sabbar, Rehan Abbas Khan, Munir Ahmed Siddiqui, Fawad Ahmed Khan

### Abstract

**Objective:** The aim of the study was to determine the postoperative analgesic effect of tramadol when given with caudally administered bupivacaine in children undergoing inguino-scrotal surgeries.

**Study Design:** Quasi experimental

**Place and Duration:** The study was conducted in Department of Anaesthesia, Sindh Govt Lyari General Hospital over a period of 6 months from January 2009 to July 2009.

**Materials & Methods:** In this double blind comparative study we included total hundred children undergoing inguino-scrotal surgeries. They were aged from 2 to 10 years. Our inclusion criteria were the children ASA I and II group. The patients were allocated into two equal groups. The patients in Group A (n=50) received 0.25% bupivacaine 0.75 ml/kg and the children in group B (n=50) were given 0.25 % bupivacaine 0.75 ml/kg and tramadol 2 mg/kg through caudal route after induction of general anaesthesia. The postoperative pain was evaluated by using visual analogue pain scale in children over 6-7 years and observation of behavior in preverbal children. Sedation was assessed by 4 points sedation score, heart rate, mean arterial pressure, arterial oxygen saturation, respiratory rate. Pain and sedation scores were recorded immediately after awakening from anaesthesia till 24 hours postoperatively at periodic intervals. Acetaminophen was administered rectally (20 mg/kg) if the pain score was more than 4.

**Results:** Addition of tramadol with caudally administered bupivacaine resulted in significantly longer postoperative analgesic period ( $10.4 \pm 2.2$  hours) in group B while in group A in which only bupivacaine was used, mean duration of analgesia was ( $2.85 \pm 0.84$  hours). There were no significant changes in heart rate, arterial pressure and oxygen saturation between groups. Except nausea and vomiting, no other side effects like respiratory depression, pruritis, urinary retention were found.

**Conclusion:** Caudal tramadol with bupivacaine provides prolonged and good quality postoperative analgesia compared to plain bupivacaine in children undergoing inguino-scrotal surgeries.

**Key Words:** Post operative Analgesia, Caudal, Tramadol, Bupivacaine.

### Introduction

Caudal epidural block has been commonly used in pediatric postoperative pain management. Postoperative analgesia through the caudal route is considered to be the most appropriate and satisfactory analgesia for small children undergoing anoperineal, inguinal and urogenital surgeries<sup>1,2</sup>. It is usually provided by injecting bupivacaine which is a long acting local anaesthetic.

Lack of adequate co-operation by paediatric patients means caudal block is performed under general anaesthesia or during deep sedation. Caudal block reduces the amount of anaesthetic needed, provides a more rapid and comfortable awakening, reduces time spent in the recovery room and decreases the possible complications

Sindh Govt. Lyari  
General Hospital, Dow  
Medical College, Dow  
University of Health  
Sciences, Karachi  
S Sabbar  
R A Khan

Dow International  
Medical College, Dow  
University of Health  
Sciences, Karachi  
M A Siddiqui

Sindh Govt Lyari General  
Hospital, Karachi  
F A Khan

**Correspondence:**  
Dr Saleem Sabbar  
Dow International Medical  
College, Dow University of  
Health Sciences, Karachi  
Cell: 0333-3392043

of deeper anaesthesia and need for post-operative analgesia.<sup>3-5</sup> The maximum analgesic effect of bupivacaine is upto 6-12 hours.<sup>6,7</sup>

Different adjuvants are used to prolong the analgesic period. The use of caudal morphine provides strong analgesia but at the cost of serious side effects like respiratory depression, nausea, vomiting and urinary retention<sup>8,9</sup>. Ketamine, an anaesthetic agent with an unusual pharmacological profile, has also attracted some interest in this context, as in subanaesthetic doses it provides marked analgesia without inducing respiratory depression. Other combinations such as tramadol, clonidine and midazolam have also been used as adjuvant to bupivacaine for caudal analgesia; all of them provide improved analgesia without any serious side effects.<sup>10</sup>

Pharmacologically, tramadol is synthetic 4-phenyl piperidine analogue of codeine without having respiratory depressant effect<sup>11</sup>. Tramadol is a centrally acting analgesic that has a low affinity for opioid receptors and its about 5-10 times less potent than morphine as an analgesic. Its analgesic potency is equal to pethidine. It provides effective long lasting analgesia after extradural administration in both adults<sup>12</sup> and children.<sup>13-16</sup>

The aim of this study was to know the analgesic efficacy and potential side effects of caudally administered tramadol with bupivacaine in children undergoing inguinoscrotal surgeries.

#### **Materials & Methods:**

This prospective double blind study was conducted in Department of Anaesthesia, Sindh Govt Lyari General Hospital, Karachi over a period of 6 months from January 2009 to July 2009. After approval by the ethical committee and written informed parental consent, we studied 100 children, both males and females, ASA I or II, aged between 2 and 10 years, who were undergoing inguino-scrotal surgeries. (Table 1). Active infectious process like sacral decubitus ulcer, obesity, bleeding diathesis, neurological disorder, active CNS disease, anticoagulant therapy, abnormalities of sacrum, vertebral column and spinal cord, convulsive disorders and

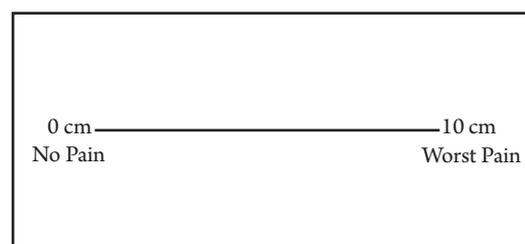
raised intracranial pressure were taken as the exclusion criteria.

No premedication was given. Intravenous access was made with 22 gauge cannulation. The patients were induced with sevoflurane or with propofol 2 mg/kg in nitrous oxide and oxygen. Laryngeal mask airway then inserted and checked carefully for ability to inflate lungs manually with any audible leak. The patients were carefully placed to the left lateral position with both legs flexed 90° at hip joints and knee joints. After all aseptic precautions, sacral hiatus was identified by palpating sacral cornua and short length short bevel needle of 23 gauge was penetrated at 90° until a pop was felt and then angled down to enter into sacral hiatus in the cephalic direction. After negative aspiration for blood and cerebrospinal fluid, the drugs were introduced into caudal epidural space. During injection any swelling over the sacral area due to extravasations of the drug in the soft tissues was ruled out by careful inspection and palpation of the area. Group A was given 0.25% bupivacaine 0.75ml/kg while group B received the same dose along with tramadol 2 mg/kg. The punctured site was covered with dry cotton gauze. The patient was repositioned supine and surgical incision was given after 15 minutes of caudal injection. No other analgesics were given. SpO<sub>2</sub>, pulse, blood pressure were monitored after every 5 minutes in all the patients intra operatively. Heart rate, respiratory rate, blood pressure were recorded in post operative period for 24 hours at various time intervals. The patients were also evaluated for any motor block. Duration of surgery and characteristics of all patients were recorded and entered in the proforma. No significant differences were noted in both groups in postoperative awakening from general anaesthesia. The time taken for spontaneous eye opening and spontaneous leg movements was noted. Sedation was assessed 30 minutes after arrival in recovery room and four hours after surgery using a simple objective scoring system (eye opening spontaneously=1, eye opening in response to verbal command=2, in response to physical stimulus=3, unresponsive=4). All the above parameters were noted including nausea, vomit-

ing, respiratory depression, pruritis, urinary retention, and time taken in first micturition were noted by staff nurse who was instructed but she was blinded for drug group. The patients stayed in the recovery room 30 minutes then shifted to pediatric surgical ward.

The post operative pain was evaluated by using standard 10 cm visual analogue pain scale in children over 6-7 years and observations of behavior in preverbal child including those who were too young to use visual analogue pain scale. In Visual Analogue Scale patient indicates the intensity of the pain by drawing a mark on a line 10 centimeter long (Figure 1). It is measured from no pain to the point indicated by the patient and then a numerical value is given (0=no pain to 10 cm =point of worst pain). A score of 0 means no pain while score 10 indicates that the child is in worst pain. In pre verbal children parents observed five aspects of children behavior. The children who were laughing and playing were given one point, happy were given two points, neutral were given three points, those who were crying and indicating pain had four points while

Figure 1: Visual Analogue Scale



who could not be distracted given five points. Duration of analgesia was taken as time between caudal block and first administration of rescue analgesia. Acetaminophen was administered rectally (20 mg/kg) if the pain score reached a level of four. Sedation was assessed by 4-point sedation score at immediate post operative period and then after 1,2,3,4,6,12 and 24 hours. Side effects like vomiting, urinary retention, sedation and motor weakness were evaluated by anaesthetist on call. Degree of pain was noticed by on duty anaesthetist who was blinded for the given drugs. None of the patients had motor block on emergence from anaesthesia. All the patients remained admitted for a minimum period of 24 hours after surgery with their parents. The parental observation and information about their children's comfort and sleep was noticed. There was no significant difference in duration of time from discontinuation of anaesthesia to spontaneous eye opening between the groups. No child required bladder catheterization.

#### Statistical analyses:

Statistical analysis was done by using SPSS version 11. Descriptive analyses were done comparing A and B groups. All results were expressed as mean  $\pm$  SD (standard deviation). T -tests were performed for continuous variables and chi-square tests for categorical variables.  $P < 0.05$  was considered statistically significant.

#### Results:

The patients were allocated into two equal groups. Median age, weight, gender, distribution; physical status and duration of surgery were comparable (Table 1). There was no difference in baseline  $SaO_2$ , heart rate and respiratory rate between the groups. Different types of inguino-scrotal surgeries like herniorrhaphy, urethroplasty for hypospadias and orchidopexy

Table 1: Demographic and clinical characteristics of the patients

Variables	Group A (n=50) Mean $\pm$ SD	Group B (n=50) Mean $\pm$ SD
Age (years)	6.7 $\pm$ 2.9	5.9 $\pm$ 2.2
Weight (kilograms)	15.6 $\pm$ 4.7	16.44 $\pm$ 5.37
Gender Male	45 (90 %)	40 (80%)
Female	5 (10%)	10(20 %)
ASA	1 & II	1 & II
Duration of surgery(minutes)	29.5 $\pm$ 5.2	26.7 $\pm$ 4.5
Intraoperative I/v analgesics	none	none

Table 2: Comparison between group A and Group B for post operative analgesia and complications

	Group A (n=50) Mean $\pm$ SD	Group B (n=50) Mean $\pm$ SD	P value
Duration of analgesia (Hours)	2.85 $\pm$ 0.84	10.4 $\pm$ 2.2	
Time to spontaneous eye opening (minutes)	10.0 $\pm$ 3.7	11.8 $\pm$ 1.9	
Sedation score at 30 minutes	1	1	
Respiratory rate (Breaths/min)	19.6 $\pm$ 1.9	21.8 $\pm$ 4.2	$P < 0.0005$
Time to spontaneous leg movements (Minutes)	15.5 $\pm$ 5.4	13.2 $\pm$ 3.54	
Time to micturition (Hours)	2.8 $\pm$ 1.0	3.17 $\pm$ 0.9	
Postoperative nausea and vomiting	2	1	

were included. There was no failure of caudal epidural block.

Mean duration of an analgesia in group A, as measured by the time taken for the pain score reaching was  $2.85 \pm 0.84$  hours, while in group B it was  $10.4 \pm 2.2$  hours. Duration of analgesia, with addition of tramadol in caudal bupivacaine, resulted in prolonged postoperative analgesia ( $p=0.0005$ ) (Table 2)

There were no significant changes in heart rate, arterial pressure and oxygen saturation between groups. Except nausea and vomiting, no other side effects like respiratory depression, pruritis, urinary retention were found.

Sedation score was not significantly different, as all patients were active and alert postoperatively in both groups. The time from discontinuation of anaesthesia to the awakening with spontaneous eye opening, time to spontaneous leg movement and first micturition was similar. The occurrence of vomiting was observed in only one patient in bupivacaine–tramadol group while two patients in bupivacaine group vomited postoperatively and were treated with intravenous injection of chlorpheniramine (Table 2).

#### **Discussion:**

Postoperative analgesia provided through the caudal route in children undergoing urogenital surgeries is used widely these days. Bupivacaine, a long acting local anaesthetic, is used because of its long duration of action i.e. upto 6-12 hours. Wide acceptance of caudal block is due to technical simplicity, reliability, safety and rapid performance in large series of infants and children. Pharmacokinetic and pharmacodynamic characteristics of available bupivacaine evaluated safe in hundred of studies in three decades. Caudal bupivacaine alone can provide excellent analgesia in early postoperative period<sup>17</sup>. Rescue analgesics are required when block wears off when bupivacaine is used alone in caudal epidurals. Recently, several adjuvants to bupivacaine are being used to further prolong the duration and improve the quality of analgesia in many surgical procedures in children. Addition of tramadol to

bupivacaine administered caudally provided a dose-related increase in postoperative analgesia. The present study demonstrated clinically and statistically significant postoperative analgesic period. In our study when tramadol used as an adjunct to local anaesthetic bupivacaine in caudal blocks, it significantly prolonged postoperative analgesic period.

Prosser et.al<sup>18</sup> reported that the addition of tramadol 2 mg/ kg to caudal bupivacaine 2 mg/ kg provided a mean duration of analgesia of 10 hours. The addition of tramadol did not prolong significantly the action of caudal bupivacaine. This is because the mean duration of action of caudal bupivacaine in their study was 9 hours which was much longer than that reported in other studies.<sup>19</sup>

Senel et.al<sup>20</sup> examined the analgesic efficacy of 0.25% bupivacaine 1 ml/kg, tramadol 1.5 mg/ kg in normal saline, or 0.25% bupivacaine 1 ml/ kg mixed with tramadol 1.5 mg/kg in children undergoing herniorrhaphy. Their results showed that patients who received bupivacaine and tramadol had a significantly longer time period to administration of first analgesic than either the bupivacaine group or the tramadol alone group. Young age, administrating different concentrations of perioperative inhalational agents, and using different methods to assess pain and sedation may account for the differences in total dose of analgesia administered in the different studies. In our study, pain and sedation scores were significantly lower in the tramadol group compared with the bupivacaine group during the 24 hours study period. Large-scale, multi-centre studies have demonstrated that caudal block is a practical and safe technique that provides excellent post-operative analgesia without causing complications. In our study, the only adverse post-operative event was nausea and/or vomiting. Inclusion of younger patients in our study, compared with other similar studies, may have resulted in a lower incidence of nausea/ vomiting due to the subjective nature of these symptoms.<sup>21</sup>

**Conclusion:**

On the basis of our study we can conclude that addition of Tramadol 2 mg/kg with caudally administered 0.25% Bupivacaine provides prolonged and safe analgesia.

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