ORIGINAL **PROF-1245**

CIRCUMCISION;

CAUDAL EPIDURAL BLOCK WITH SINGLE DOSE BUPIVACAINE COMPARED WITH TRAMADOL FOR POST OPERATIVE ANALGESIA IN CHILDREN.

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ABSTRACT… faridi_279@yahoo.com. **Objectives:** To compare the quality of postoperative analgesia with single dose Bupivacaine and that of Tramadol in caudal epidural block for circumcision in children. **Study design:** Interventional experimental study. **Settings:** This study was carried out in the department of anaesthesia and pain management at Combined Military Hospital Peshawar. **Duration:** Jun 30, 2004 to Mar 2005 & then from Dec 2006 to Feb 2007. **Subjects and Methods:** Sixty (60) children between the ages of 2-6 year were included in study. They were divided into two groups by convenience non-probability technique and each group had 30 children. Group A (n=30) was given 1.25mg/kg Bupivacaine, 0.25% solution, whereas Group B (n=30) received 2mg/kg of Tramadol. The volume of drug in each group was 0.5ml/kg. Standard monitoring was done perioperatively. The analgesic effects were evaluated by using Hannallah pain score scale6, which had maximum score of 10 and minimum of 0 (zero). The score of 3 or <3 was considered as adequate analgesia. Sedation was assessed by using 5-point sedation test. 0 - Awake, 1 - mild sedation, 2 - feeling sleepy, 3-sleepy but able to wake, 4 - Deep sleep difficult to wake. **Results:** Both the groups were comparable with respect to age, sex and duration of surgery. Insufficient pain control was observed in 4 patient's in-group B (Tramadol group), 13% and 7 patient's in-group A (Bupivacaine group), 23%, 30 minutes after caudal administration of drug. Adequate postoperative analgesia was maintained in all other patients for 12 hrs. Only 6 patients in Tramadol group had light sedation (p=0.0l2). Weakness of lower limbs was found in 4 patient's in-group A. there was no difference in vital signs and there was no complication related to technique in both groups. **Conclusion:** Caudal administration of Tramadol in the dose of 2mg/kg when compared with 0.25% Bupivacaine in children under going circumcision provided similar quality of analgesia for 12 hours with out any requirement of rescue analgesic.

Key words: Bupivacaine, caudal, Analgesia, and Tramadol.

INTRODUCTION

It has long been acknowledged that postoperative pain is poorly treated due to one or the other reason. These include the lack of knowledge regarding the effective dose range and the duration of action of different analgesics. Failure of relief of postoperative pain is also blamed invariably on medical staff; technique used and unfound fear of respiratory depression.

Being the major threat and fear for the patient under going surgery, postoperative pain is an important concern of the treating team. Different techniques and methods are always worked out to abolish or decrease this major cause of morbidity.

Routinely used analgesic technique like narcotic analgesics for postoperative pain relief have their own side effects like respiratory depression, dulled reflexes, nausea, vomiting, constipation and even urinary retention.

Caudal anaesthesia for postoperative pain relief after genital or inguinal operations is technically safe and simple procedure for indoor as well as outdoor patients.

After caudal injection of Bupivacaine the duration of analgesia in these patients ranges from 4-12 hours depending upon time of injection and analgesic agent used.

Additional prolonged effects of Bupivacaine can be achieved by adding adjuncts like adrenaline or narcotic analgesics.

Epidural administration of morphine provides excellent postoperative analgesia for up to 24 hours, however its use is limited, because of its untoward effects which could be life threatening like respiratory depression.

Tramadol is an analgesic agent assumed to lack respiratory depressant effect and has been shown to provide affective and long lasting analgesia after epidural administration[1,2,3].

Tramadol through its multiple mechanisms of action has low risk of respiratory depression[4]. It also has the advantage that it does not lead to abuse, tolerance or addiction[5].

Comparative study of caudal Bupivacaine and caudal Tramadol for postoperative pain relief in children was carried out in the department of Anaesthesiology at Combined Military Hospital Peshawar.

OBJECTIVES OF THE STUDY

The objective of the study was to;
To compare the quality of postoperative analgesia with single dose Bupivacaine and that of Tramadol in caudal epidural block for circumcision in children

Hypothesis

Postoperative analgesia after caudal administration of Tramadol would be equally good in quality as with that of caudal Bupivacaine for postoperative analgesia in children undergoing circumcision.

MATERIAL AND METHODS

Setting

This study was carried out in main operation theatre of Combined Military Hospital Peshawar.

Duration

Jun 30, 2004 to Mar 2005 & then from Dec 2006 to Feb 2007.

Sample Size

Sixty ASA-1 children from the age of 2-6 years were divided into two groups. Group A (n=30) & Group B (n=30).

Sampling Technique

Convenience non-probability technique.

SAMPLE SELECTION

Inclusion criteria

- Children between the ages of 2 to 6 year.
- ASA-1.
- Parents consenting for study.

Exclusion criteria

- Mentally retarded or subnormal children.
- Children suffering from neurological or spinal diseases
- Patients with the H/O allergic reactions to local anaesthetics or opioids.
- Patients with bleeding diathesis.

Study Design:

Interventional Experimental Study.

DATA COLLECTION PROCEDURE

- **Pre-operative Assessment**

Pre-operative assessment of every patient was done on evening before surgery. They were reassured and an informed consent was taken from the parents. Patients were thoroughly examined and investigated.

- **Preparation**

Patients were kept nothing by mouth for at least 6 hours preoperatively.

- **Procedure**

Informed consent was taken from the parents of the children and study was conducted. According to inclusion criteria children were included in study and none of them were premedicated.

Induction was done with sevoflurane 5-6% in O_2 and anaesthesia was maintained with 50%N_2O / 50%O_2 and l%Halothane. Ringer's lactate was given as replacement fluid. Once operation was over patient was placed in lateral position for caudal block. Under strict aseptic measures standard drip needle (21 G) was used for caudal administration of drugs. The dose of the analgesic was according to patient's weight.

Children were divided into two groups. Group A (n=30) was given 1.25mg/kg Bupivacaine, 0.25% solution, whereas Group B (n=30) received 2mg/kg of Tramadol. The volume of drug in each group was 0.5ml/kg.

Standard monitoring was done perioperatively. Pain and level of sedation were recorded at 5, 15 and 30 min, then at 1, 3, 6 and 12 hrs following recovery from anaesthesia.

The analgesic effects were evaluated by using Hannallah pain score scale[6], which has maximum score of 10 and minimum of 0 (zero). Where 0 indicates no pain and 10 indicates maximum pain.

Duration of analgesia was defined as the time from caudal administration of drugs to the first requirement of systemic analgesic. The score of 3 or <3 was considered as adequate analgesia.

Sedation was assessed by using 5-point sedation test. 0 - awake, 1 - mild sedation, 2 - feeling sleepy, 3 - Sleepy but able to wake, 4 - Deep sleep - difficult to wake.

DATA ANALYSIS

The data collected was analyzed by using SPSS version 10. Means and standard deviations for Age, weight and duration of surgery in both groups were calculated as shown in Table-I.

Postoperative pain was rated on the ordinal scale (Hannallah pain scoring scale) and then pain score $\leq$3 and pain score>3 in both groups at 30 minutes, 1 hour, 6 hours and 12 hours postoperatively was compared and analyzed by chi-square test to establish the significance of the reading. P-value of <0.05 was taken as significant as shown in Table-II.

Frequencies in the both groups with adequate analgesia, different postoperative complications and sedation test score were also compared. Percentage of the patients with adequate and inadequate postoperative analgesia and also with nausea/vomiting & slight sedation was calculated as shown in Figure-1,2, 3,4.

RESULTS

The following results emerged as a consequence of this study.

The age range was from 2-6 years with the mean age of

the group A was 3.40 ± 1.28 years and that of the group B was 3.33 ± 1.22 years. The mean weight of the group A was 10.71 ± 1.9 kg while mean weight of the group B was 11.00 ± 2.2 kg. Mean duration of the operation in-group A was 21.96 ± 2.4 min, while in-group B it was 21.83 ± 2.3 min (Table-I).

Table-I. Demographic data of the patients

Variables	Group A (Bupivacaine) (n=30)	Group B (Tramadol) (n=30)
Age (years) mean ± SD	3.40 ± 1.28	3.33 ± 1.22
Weight (kgs) mean ± SD	10.71 ± 1.9	11.00 ± 2.2
Duration of operation (mins) mean ± SD	21.96 ± 2.4	21.83 ± 2.3

Out of 30 patients in-group B (Tramadol group), only 4 patients (13%) experienced pain 30 minutes after caudal administration of drug. While 26 patients had sufficient pain control. Where as in group A (Bupivacaine Group), 7 patients (23%) out of 30 experienced inadequate pain control, while 23 patients had good postoperative analgesia (Fig-1 & Table-II). Almost similar results found after 1 hour, 6 hour and 12 hour (table-2& Fig-3).

Nausea and vomiting was more common in-group B (Tramadol group). Where as Weakness of lower limbs were found in 4 patient's in-group A (Bupivacaine group). (Fig-2).

Light sedation assessed by 5 points sedation test was found in 6 patients in B (Tramadol group) with the P-value <0.012. No patient in-group A (Bupivacaine Group) had the sedation (Fig-4).

There was no difference in vital signs and no complication related to technique in both groups. No arrhythmias or difficulty was observed in both groups (Fig-2).

Table-II. Hannallah pain scoring after surgery.

Time. (Post operative)	Groups	No. Of pts. With pain score ≤ 3	No. Of pts. With pain score > 3	* P-Value
30 Minutes	A	23	7	0.253
	B	26	4	
01 hour	A	23	7	0.253
	B	26	4	
06 hours	A	24	6	0.236
	B	27	3	
12 hours	A	25	5	0.500
	B	26	4	

Group A (n=30): Bupivacaine group. *Group B (n=30): Tramadol group.* **p-value calculated by chi-square test.*

Fig-1. No. Of patients with adequate postoperative analgesia in both groups

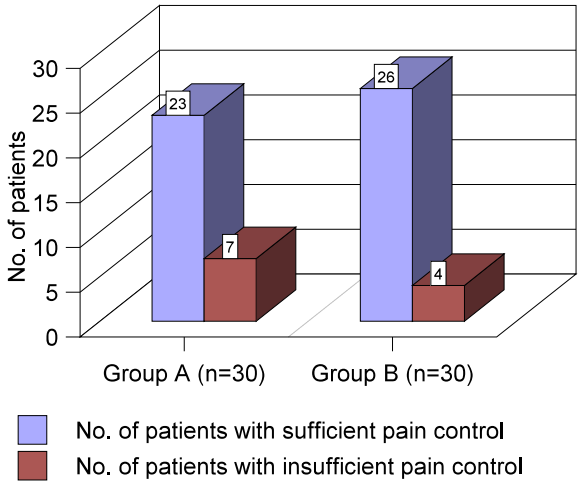
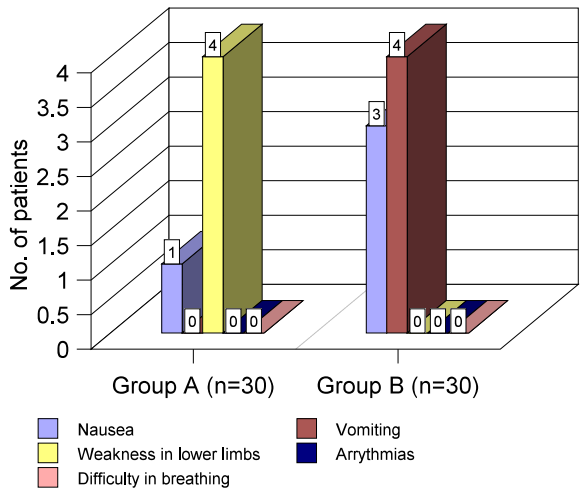


Fig-2. Postoperative complications in both groups



DISCUSSION

Pediatric pain management had been notorious for it's all due to often inadequacy. Many reasons have contributed to this including young children's inability to convey their discomfort, false notions that children do not experience pain, and lack of knowledge of analgesic administration by medical personnel. As the rate of surgical interventions in children increases, safe and effective means of analgesic administration is warranted.

Fig-3. Percentage of the patients with adequate and in adequate postoperative analgesia after 12hours of surgery

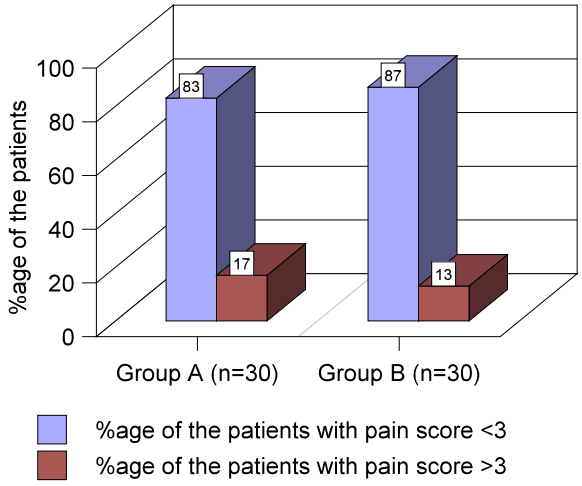
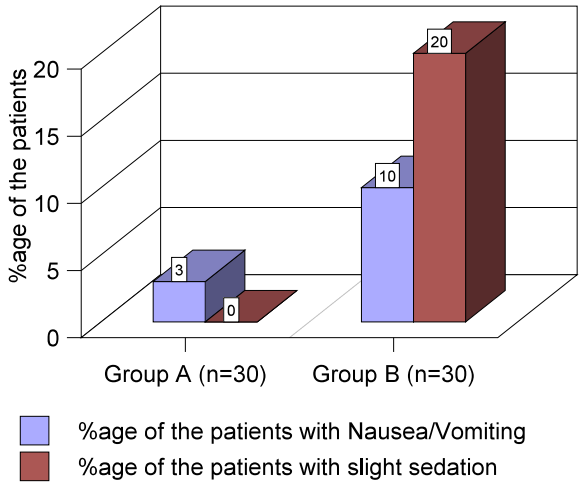


Fig-4. Percentage of the patients in both groups with nausea/vomiting/slight sedation



Much interest and discussion has surfaced as to the most appropriate means of managing pediatric pain post operatively. With the effective utilization of epidurals in

adults, the practice of epidural indwelling catheters and epidural single-injection in pediatric patients has become prevalent as well. This method of analgesia has since proven to be an effective means of pediatric pain management in the postoperative setting. Benefits include superior analgesia with minimal and most often manageable side effects. Epidural analgesic administration has proven to be an invaluable tool in both day surgical procedures as well as in-patient procedures. Numerous studies have explored the insertion, medications, effectiveness, and potential side effects of epidural pain management in children.

Pediatric patients, regardless of their ability to verbalize discomfort, deserve adequate pain management in the postoperative period. Indwelling epidural catheters as well as single injection epidural techniques offer excellent analgesic administration to the population.

Various drugs like local anaesthetics, opioids, NSAIDS, ketamine, and benzodiazepines have been tried and used caudally for postoperative pain relief in children. These drugs have been used either alone or in combination to achieve the desired effects. Among them opioids and local anaesthetic agents got the popularity. Serious complications like nausea, vomiting, respiratory depression, pruritis, itching, and urinary retention have been observed with he use of opioids.

Tramadol when given via intravenous route for postoperative analgesia is associated with higher incidence of nausea and vomiting as compared to the epidural administration[7]. Aygun S, Kocoglu H, Goksu S, Karaca M and Oner U in their study proved that although adequate pain relief was achieved with all regimens that were used in the study, intravenous tramadol and intravenous fentanyl are associated with a high incidence of nausea and vomiting.

Yavuz L, Eroglu F, Ozsoy M in their study compared the analgesic effects of this relatively new agent when given either through intravenous route or through epidural administration with patient controlled analgesia in gynecological cancer pain. Forty patients undergoing elective cancer surgery, included in the American Society of Anesthesiologists (ASA) class II and III were randomly placed into two groups. The patients in the intravenous (IVA) group were administered a 20 mg bolus of tramadol intravenously and the patients in the epidural analgesia (EA) group epidurally five minutes before induction. The PCA equipment was programmed to deliver 20 mg of tramadol as a bolus dose, with a lock-out time of 15 minutes, at a 10 mg/hour infusion rate in both groups. A visual analogue scale (VAS) and patient satisfaction as well as haemodynamic and respiratory parameters were determined at given times postoperatively. They concluded that epidural administration of tramadol through the PCA method following gynecologic cancer surgery was found to be a more effective analgesia in lower doses when compared to the intravenous administration[8].

Batra, Prasad, Arya, Chari, & Yaddanapudi compared this new agent to Bupivacaine[9]. Forty children between four and eight years of age undergoing hypospadias repair participated in this study. They were divided into two groups, group I was administered 1 mg/kg of Tramadol via single-injection in the caudal space. Group II received 0.5 ml/kg of 0.25% Bupivacaine via single-injection in the caudal space. Postoperative pain was assessed utilizing a modified Hanallah's objective pain score. The results revealed that pain scores were significantly higher postoperatively in-group I until the third hour. Interestingly, from hour five until hour sixteen, group II had significantly higher pain scores. Total consumption of rescue analgesia was significantly higher in-group II. It was suggested that the delay in adequate pain relief immediately postoperative was a result of Tramadol having lower lipid solubility and therefore a delay in uptake by the extradural space. No patient experienced respiratory depression or oxygen desaturation. It was suggested that Tramadol provided excellent prolonged pain relief after three hours postoperative.

Deliken et al also noted that lOOmg of Tramadol when administered epidurally had longer duration of action (9 hrs) and better analgesic efficacy when compared with

10 ml Bupivacaine 0.25% (6 hrs) in patients following abdominal surgery[10].

Began C et al reported that duration of analgesia with 0.25% Bupivacaine was 460+_ 439 minutes[11]. Contrary to these results our study revealed that Bupivacaine 0.25% provided adequate analgesia for 12-24 hours following caudal block. These discrepancies are probably due to differences in pain scoring method, procedure, and dose and volume of Bupivacaine.

Akyol A et al in their study found that caudal administration of Bupivacaine with the addition of Tramadol resulted in superior analgesia with a longer period without demand for additional analgesics compared with caudal Bupivacaine and Tramadol alone without an increase of side effects[12].

Regarding the quality of analgesia Mahmood F et al in their study concluded that caudal block either with Bupivacaine or Tramadol provides excellent postoperative analgesia after cicumcission[13]. In their study they compared two groups of children undergoing circumcision from age 1-10 years. In one group penile block was performed and in other caudal block was performed for postoperative analgesia.

Gunduz M et al concluded in their study that Tramadol used caudally is as effective as Bupivacaine in the management of postoperative pain in children. And the addition of Tramadol to Bupivacaine, when both drugs were administered caudally, did not prolong the duration of action of Bupivacaine and Tramadol is a safe agent in children[14].

Tramadol has been used caudally for postoperative analgesia alone or in combination with other adjuncts like clonidine or droperidol.

Tomatir E et al in their study concluded that epidural Tramadol in combination with droperidol or clonidine prolongs the duration of analgesia; however, droperidol appears to be a better alternative when adverse effects and antiemetic properties are taken into consideration[15].

Booker PB et al concluded that caudal Tramadol had a slow onset of action and that the addition of Tramadol to Bupivacaine, when both drugs were administered caudally, did not significantly prolong the duration of action of Bupivacaine[16].

Ozkan S et al in their study compared two groups of the pediatrics surgical patients. Group 1 consisting of 10 patients received 2mg/kg Tramadol and group II was given 0.25% Bupivacaine caudally. Heart rate, respiratory rate, pain and sedation score were recorded at 1, 2, 4, 6, 12, and 24 hour. There were no significant differences in heart rate, mean arterial pressure, arterial oxygen saturation and respiratory rate between the two groups. In conclusion, caudal Tramadol was superior to Bupivacaine in analgesic efficacy and in reducing the need for additional analgesia during the post-operative period in pediatric patients[17].

Qureshi SM et al in their study also came to the conclusion that Postoperative analgesia with caudal block provides effective and prolonged pain relief without such untoward effects. It is also technically safe and simple procedure in children for both indoor and outdoor patients[18].

CONCLUSION

The study was carried out to establish the fact that caudal Tramadol was equally good in quality when compared with caudal Bupivacaine for postoperative analgesia in pediatrics patients undergoing circumcision.

After conducting this study and by comparing with other studies we reached at the conclusion that a simple and effective means of postoperative pediatric analgesia for circumcision lies in epidural single-injections of local anesthetic or other drugs like Tramadol. The ease and high level of accuracy encourage the use of this method of analgesic administration. Caudal block improves pain relief, decreases the overall administration of analgesic, and aids in curtailing the potential side effects of systemic or oral medication.

Tramadol being the opioids agonist but devoid of most

serious side effects of narcotic analgesics like respiratory depression, when administered caudally in the dose of 2mg/kg and compared with 0.25% Bupivacaine in children under going circumcision provided similar quality of analgesia for 12 hours with out any requirement of rescue analgesic after first hour.

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