SINGLE DOSE CAUDAL TRAMADOL VERSUS BUPIVACAINE FOR POSTOPERATIVE ANALGESIA IN PERINEAL SURGERY

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ABSTRACT

Objective: To compare the postoperative analgesic effects of caudally administered Tramadol and Bupivacaine in adults undergoing perineal surgery.

Study Design: Randomized control trail.

Place and Duration of Study: Department of Anaesthesia Combined Military Hospital Quetta from July 2001 to June 2003.

Patients and Methods: A total of 100 adult patients undergoing perineal surgery, aged 20-50 years, American Society of Anaesthesiology (ASA) 1 and 2 were included. The patients were divided into two equal groups. Group B was given 20 ml 0.25% Bupivacaine while the group T was given 100mg Tramadol through caudal route after induction of general anaesthesia. No other analgesic was given intraoperatively. The postoperative pain was evaluated by using visual analogue scale (VAS) at immediate postoperative period and then every hour for first 12 hours. Pulse rate, blood pressure, O2 saturation (SpO2), respiratory rate, expired CO2 (ETCO2) and any side effects were monitored. The cut-off point for study was VAS 6, when additional analgesic was administered.

Results: Caudally administered Bupivacaine and Tramadol provided good postoperative analgesia but mean duration of analgesia was longer in group B (10.5±2.02 hrs) compared to group T (7.14±1.77 hrs). There were no clinically significant haemodynamic and respiratory changes observed in either group; however nausea and vomiting were more in group T. The demand for supplemental analgesia was more in the patients belonging to T group than B group.

Conclusion: Bupivacaine and Tramadol are safe when used caudally in adults but Bupivacaine provided longer and better quality of postoperative analgesia than Tramadol after perineal surgery.

Keywords: Caudal, Bupivacaine, Tramadol, Perineal surgery.

INTRODUCTION

Pain is a highly unpleasant sensory and emotional experience. Various pharmacological agents and analgesic delivery systems have been employed to avoid under-treatment of pain. Perineal surgery is generally associated with considerable pain of long duration. Caudal extradural blockade is a popular regional anaesthetic technique to control such pain. It is generally considered a simple and safe procedure and its main disadvantage is its relatively short duration of action [1]. Bupivacaine is the local anaesthetic with longest duration of action currently available and provides satisfactory analgesia in post operative period after inguinal, urogenital and perineal surgery. However analgesic effect of bupivacaine lasts for 4-12 hours [2, 3]. Various methods have been devised to extend the duration of regional analgesia with local anaesthetics. Placement of catheter poses an inherent risk of infection [4]. Many drugs including epinephrine [5], opioids [6, 7], clonidine [8], ketamine [9], midazolam [9, 10], neostigmine [9, 11] have been co-administered with caudal bupivacaine to maximize and extend the duration of analgesia. Caudal midazolam have been associated with prolonged sedation [10]. Behavioral side effects were reported with the use of the caudal ketamine [9], and an increased incidence of postoperative hypotension was observed with the use of caudal clonidine [8].

There is high number of opiate receptors located at the gelatinous substance of the medullary horn. Epidural injection of opiates

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allow saturable and competitive binding to the receptors, thus providing analgesia and reducing the risk of side effects associated to their parenteral administration [12]. However, potential side effects must be taken into account, the major complication being respiratory depression [13] Morphine is the μ agonist opiate most commonly used for the management of acute and chronic pain. Tramadol is the most recent synthetic opiate. However, its analgesic power compared to morphine is 1/10 when parentally administered and 1/30 when epidurally administered. It is centrally acting analgesic with both opioid and non opioid properties. It has low affinity for Mu, Kappa and Delta receptors. In addition, it stimulates neuronal serotonin release and weakly inhibits re-uptakes of norepinephrine and serotonin. Its respiratory depressant activity is less than that of morphines. The drug undergoes extensive metabolism, and one of its metabolite is active. It provides long lasting post-operative analgesia in children and adults after epidural administration [14]. Recent studies have shown that single dose of tramadol with or without bupivacaine provide effective analgesia intra-operatively that extends well into the post-operative period without any serious side effects [15]. Different doses of tramadol have been administered caudally to evaluate the analgesic efficacy in providing post-operative pain relief [16].

The aim of this study was to determine the analgesic efficacy and potential side affects of caudally administered tramadol and bupivacaine in adults undergoing perineal surgery.

PATIENTS AND METHODS

This double blind randomized control trail (RCT) was conducted in the Department of Anaesthesia, Combined Military Hospital Quetta from July 2001 to June 2003. After approval from the hospital ethical committee and informed consent, 100 patients, age 20-50 years of either sex undergoing perineal surgery, ASA 1 & 2 were included in the study. Active infectious process, bleeding diathesis, anticoagulant therapy, CNS disease, abnormalities of vertebral column, raised intracranial pressure and infection at site of injection were taken as the exclusion criteria. All the patients were examined a day before surgery. Pulse rate, blood pressure, respiratory rate were recorded and thorough neurological examination was carried out. No pre-medication was administered.

A nurse not otherwise involved in the study prepared the study medication, either 0.25% Bupivacaine in 20 ml normal saline or 100 mg of Tramadol in 20 ml of normal saline. A total of 100 patients were divided equally into two groups by using computer generated randomized table. The anaesthetist and nursing staff involved in the care of the patients during the study period were blinded to the type of drug. Intravenous access was made with 18-20 gauge IV cannula. The patients were induced with propofol 1.5-2.0 mg/Kg body weight, 60% N2O in O2 and isoflurane. Trachea was intubated after paralysis with atracurium 0.5 mg/ kg body weight and lungs were ventilated mechanically. The patients were placed in left lateral position with both legs flexed at hip and knee joints. Caudal block was performed using a 22-gauge hypodermic needle under sterile conditions. Group B was given 0.25%, 20 ml bupivacaine while group T received tramadol 100 mg in 20 ml normal saline. The patient was repositioned and surgical intervention was allowed 15 min after caudal injection. No other analgesic was given.

Heart rate, electrocardiogram (ECG), expired CO2 (ET CO2) and O2 saturation (SpO2) were monitored continuously and blood pressure was monitored every five minutes during surgery. Duration of surgery was recorded. Patients were observed for two hours in the recovery room before returning to the ward. ECG and pulse oximetry were monitored continuously. Blood pressure, heart rate, respiratory rate, neurological variables (deep tendon reflexes, muscle tone and power in the limbs) were recorded hourly for 12 hours.

The postoperative pain was evaluated by using visual analogue scale (VAS) measured hourly [0= no pain (patient sleeping, lying comfortably), 10= worst pain imaginable or maximum pain ever felt, 6= moderate pain (patient frequently asking for analgesia but still it was bearable, sitting in bed or walking difficult)]. When VAS = 6, additional analgesic was given and further data collection for that patient was stopped. Nausea, vomiting, sedation and other adverse effects, if any, were also recorded. Postoperative sedation was assessed according to 5 points sedation score (0 =fully awake, 1 = slightly drowsy, 2 = asleep but easily arousable, 3 = fully asleep but arousable and 4 = fully asleep, not arousable) as used by Maunukscla et al [17]. Duration of analgesia was defined as the time interval between placement of the caudal block to the first demand for supplemental analgesia, that is, the perception of moderate pain (VAS =6). The quality of analgesia was assessed by measuring VAS and descriptive pain scale (VAS 0-1= no pain, VAS 1.1-3 = mild pain, VAS 3.1- 6 = moderate pain). VAS = 6 would be the cut off point. The quality of analgesia would be better if larger number of patients scored lesser VAS over a certain period of time.

Statistical analysis was performed using SPSS version 10. Descriptive analysis were done comparing B and T group. T-tests were performed for continuous variables, and Chi-square tests for categorical variables with significance at $p<0.05$.

RESULTS

The number of patients were equal in both the groups B and T. Median age, weight, gender distribution, physical status were comparable. There was no difference in baseline SpO2, heart rate and respiratory rate between the groups (Table).

The mean duration of analgesia among group B was 10.5±2.02 hours, while in group T was 7.14±1.77 hours ($P< 0.05$). At 2, 4, 6, 8 and 12 hours greater number of patients scored lower VAS in group B compared to those in group T (Fig. 1). By 8th hour after caudal injection, only 2 (4%) patients scored VAS ≥ 6 in group B, whereas in group T, 33 (66%) patients scored VAS ≥6. In Group B, 6(12%) patients crossed the study limit of 12 hours before their VAS reached the cut –off point of 6. Out of these, 2(4%) scored VAS=6 at 16th hour after injection. In T Group none of the patients could cross the 12 hour limit. The mean VAS for group B was 2.73±2.09 and for group T was 3.72±2.16 ($P< 0.05$). Hourly mean VAS at different assessment times was lower in Group B compared to Group T (Fig. 2). The time for discontinuation of anaesthesia to the awakening with spontaneous eye opening was similar. Sedation scores were comparable in two groups with none of the patients having a sedation score of >2 at any time. None of the patients had any episodes of fall in SpO2, hypotension, bradycardia or motor weakness. No other complication (respiratory depression, pruritis, urinary retention) occurred except emesis. Total of eight patients (16%) had nausea & vomiting in Tramadol group as compared to none in Bupivacaine Group ($P<0.05$).

DISCUSSION

The lumber epidural injection for post-operative analgesia either with local anaesthetic, opioid or a combination of the two is an established technique used world over for abdominal, perineal and lower limb surgeries [6, 8, 9]. The technique is costlier and requires more expertise. The technique of caudal epidural injection is simple, effective as well as cost effective. In last two decades the caudal epidural technique solely or with light general anaesthesia has evolved as an established method to control perioperative and postoperative pain. Caudal bupivacaine alone has been used for postoperative analgesia after urogenital, rectal and lower abdominal surgery in adults and children but as the block wears off additional analgesics are required. Epidural opioids, notably morphine have been widely used for postoperative analgesia in adults. However many side effects such as nausea, vomiting, pruritis, urinary retention and delayed respiratory depression have been reported [18]. Tramadol a synthetic opiate in equi-

Table: Demographic and Clinical Characteristics of the Patients (n=100)

	Group B (n=50)	Group T (n=50)	
	Mean + SD	Mean + SD	P – Value
Age (Yrs)	34.20 + 9.03	32.96 + 8.04	0.532
Weight (Kg)	58.45 + 7.24	55.83 + 9.04	0.815
Gender			> 0.05
Male	36 (72%)	35 (70%)	
Female	14 (28%)	15 (30%)	
ASA	I & II	I & II	
Duration of Surgery (Min)	54.26 + 17.43	57.67 + 13.75	> 0.05

B = Bupivacaine T = Tramadol

Age, Weight, duration of Surgery are given as meant + SD

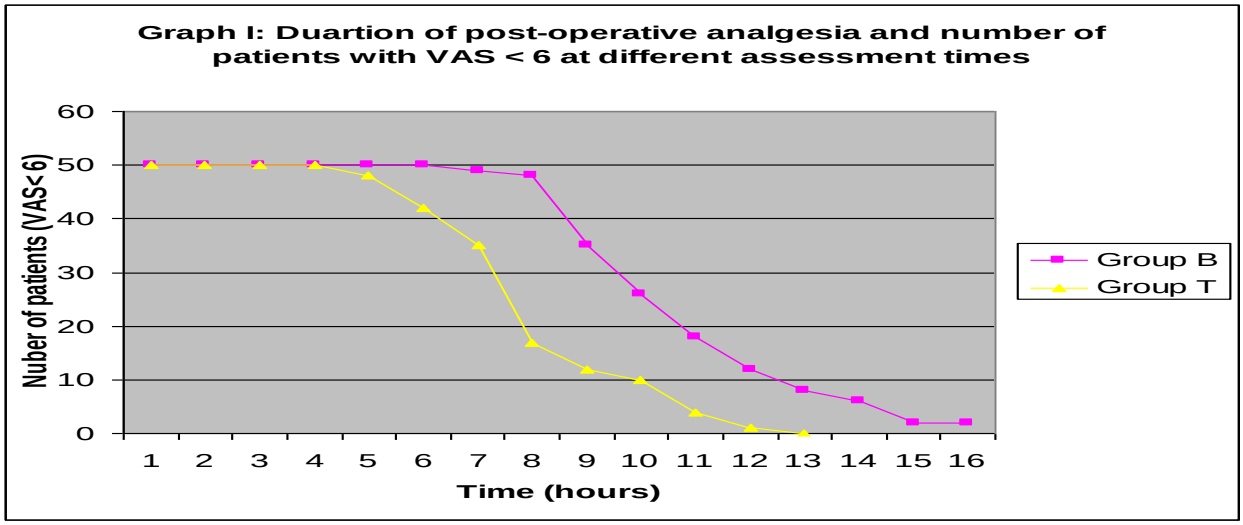

Fig. 1: Duration of post-operative analgesia and sumber of patients with VAS < 6 at different assessment times.

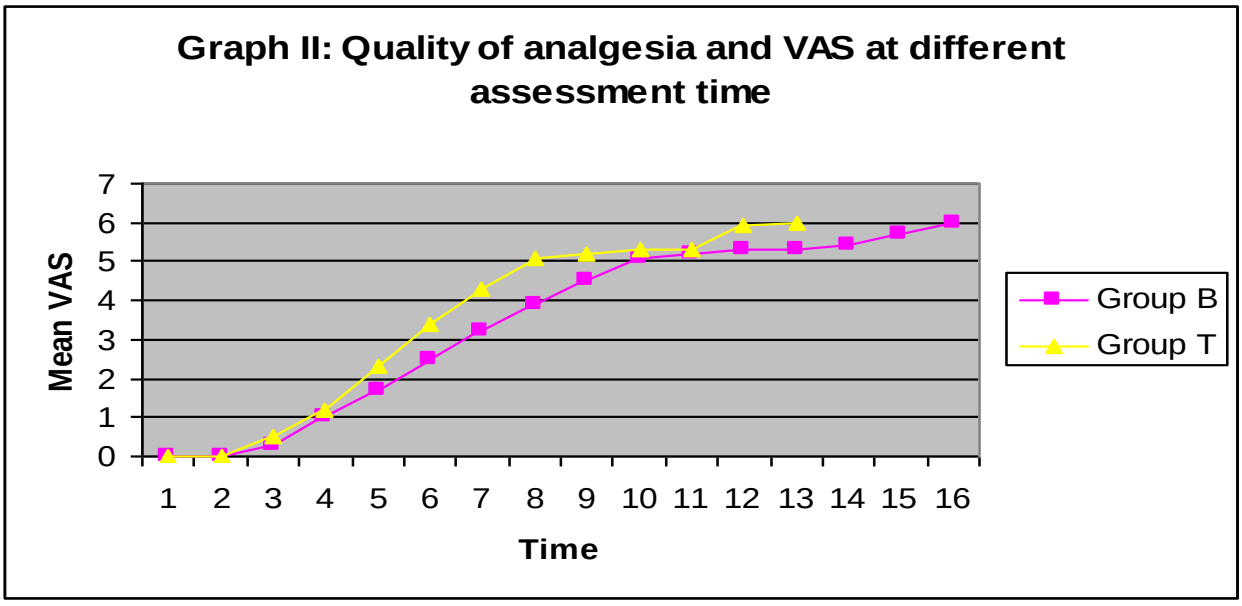

Fig. 2: Quality of analgesia and VAS at different assessment times

analgesic doses to morphine is strikingly free of delayed respiratory depression; this may be attributed to different mechanism of action than that of morphine [14].

The present study demonstrated that caudal bupivacaine 0.25% produced an excellent postoperative analgesia with significant reduction in pain score after

perineal surgery in adults. Caudal tramadol 100 mg also produced good analgesia; however there was a statistically significant difference in the duration of analgesia of the two drugs. The mean duration of analgesia of caudal bupivacaine 0.25%, 20ml was 10.5±2.02h compared to tramadol 100mg, 20ml 7.14±1.77h. There were no side effects like respiratory depression, pruritis, constipation but increased frequency of vomiting was noted in tramadol group.

The findings of many other authors support the study. In a study carried out by Salim [19] comparing the analgesic effects of epidural 1%, 10ml xylocaine and 0.25%, 10ml bupivacaine, the mean duration of later was 10h. In a study comparing caudal 0.5%, 20ml bupivacaine by Mansab and colleagues [20], the analgesic duration of bupivacaine was 19.8±2.1h that was almost double the duration of bupivacaine in present study. This was obviously due to double the concentration of bupivacaine in Mansab's study. There were no clinically or statistically significant side effects in above studies. In present study, bupivacaine again did not cause any clinically or statistically significant side effects.

The study by Baraka and colleagues revealed adequate and prolonged postoperative analgesia without respiratory depression with epidural tramadol 100mg in 10ml normal saline in patients undergoing major abdominal surgery [21]. Similarly, Gonzalez and colleagues compared epidural with intramuscular tramadol for postoperative analgesia after abdominal hysterectomy and concluded that epidural tramadol offers superior analgesia with fewer side effects [22]. In our study, good quality and reasonably long duration of analgesia was achieved without respiratory depression in Tramadol group. Gunduz and colleagues compared the effects of single dose caudal tramadol, bupivacaine and tramadol plus bupivacaine for management of postoperative pain [15]. They found caudally administered tramadol as effective as bupivacaine and administration of tramadol to bupivacaine did not prolong the duration of action of bupivacaine. Similarly Prosser and colleagues found no significant difference in analgesic duration of two drugs [23]. Contrary to above, Snell and colleagues found significantly longer duration of analgesia in bupivacaine and bupivacaine plus tramadol group compared to tramadol alone [24]. Our study findings were similar in that bupivacaine provides longer duration of analgesia compared to tramadol. Parkash and colleagues found dose related increase in postoperative analgesia of caudally administered tramadol [16].

Batra et al disagree with above studies [25]. They worked on analgesic periods of bupivacaine and tramadol. They pointed towards a significantly lower pain score with caudal bupivacaine in the immediate postoperative period, whereas caudal tramadol resulted in a significantly lower pain score in the later postoperative period and caudal tramadol has longer duration of action as compared to caudal bupivacaine. Similarly Ozkan and colleagues found caudal tramadol superior to bupivacaine in analgesic efficacy [26].

Both tramadol and bupivacaine are effective to control postoperative pain when administered caudally but their use is limited due to short duration. However, in the absence of longer- acting drugs, and until such time alternative methods of prolonging postoperative analgesia, the use of caudal bupivacaine and tramadol is likely to continue.

CONCLUSION

Based on this study and with support of previous studies it can be concluded that caudally administered bupivacaine and tramadol provide safe and good quality of postoperative analgesia. However bupivacaine provides superior quality and longer duration of analgesia compared to tramadol and later also causes more nausea and vomiting.

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