DOI: https://doi.org/10.53350/pjmhs221651427

ORIGINAL ARTICLE

A Randomized Controlled Trial on the Effectiveness of Tramadol as an Adjunct to Bupivacaine for Caudal Analgesia in Children

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ABSTRACT

Introduction: The purpose of analgesia in postoperative period is to minimize pain with the fewest probable side effects and to obtain the highest possible cost-effectiveness in our environment. In children, caudal anesthesia is often given in combination with general anesthesia for postoperative and intraoperative anesthesia. To extend the length of anesthesia; adjuvants can be further added to local anaesthetics. This research was performed to determine the caudal bupivacaine anesthesia duration given in combination with tramadol.

Study Design: A prospective, comparative, randomized, double-blinded study

Place and duration: In the department of Anesthesia, Khyber Teaching Hospital, Peshawar for one-year duration from 21st January 2021 to 20th January 2022.

METHODS: 80 patients, 3-8 years of age, enduring elective urological, lower limb and lower abdominal surgery. Patients were randomised in to group A (n = 40) given 0.25% bupivacaine 1 ml / kg and group B (n = 40) receiving bupivacaine 0.25% in dose of 1 ml / kg plus 1 mg / kg tramadol. The hemodynamic responses, side effects and analgesia total duration were observed and analyzed.

Results: The patients were comparable in groups A and B in terms of hemodynamic response and demographics and were not significant statistically (p greater than 0.05). It was detected that the analgesia mean time was longer significantly in B group (464.2 ± 167.1 minutes vs 238.1 ± 71.5 minutes, P <0.001). The postoperative vomiting was perceived in two cases, one in each group.

Conclusions: One mg / kg Tramadol adjuvant to 0.25% bupivacaine for caudal anesthesia in children effectively lengthens the analgesia duration deprived of increasing side effects.

Keywords: bupivacaine; tramadol and caudal analgesia.

INTRODUCTION

At its 15th annual meeting in Louisiana, the Society for Pediatric Anaesthesiology clearly defined pain relief as a "fundamental humanoid right" regardless of age, health, medical institution or treatment[1-2]. The purpose of analgesia in postoperative period is to eliminate or reduce pain with as few side-effects as possible, and in our case, the most profitable option[3-4]. Various regional anesthesia procedures that provide analgesia, reduce the need for intraoperative general anesthesia without significant side effects and keep the intraoperative and postoperative period without complications, have gained popularity among postoperative analgesia[5-6]. The caudal anesthesia in children is often given in combination with general anesthesia to enhance postoperative or intraoperative analgesia. It is widely given for surgeries performed under the diaphragm such as rectal, urogenital, lower limb and inguinal surgery. Caudal anesthesia is a regional anesthesia category in which epidural space is injected with local anesthesia[7-8]. It is the utmost prevalent analgesia given regionally with a probable level of blockage cast-off in pediatric procedures[9]. The core disadvantage of analgesia given caudally is the brief period of action of the local anaesthetic in a single dose. To overwhelm this delinquent, in addition to local anesthesia, several preparations can be supplementary to extend the anesthesia duration. As an adjuvant; tramadol is acting centrally with synthetic opioid palliative properties equivalent to pethidine without respiratory depressant properties[10]. Its performances on the receptors of opioid and as well improve the function of downstream pathways of inhibition by inhibiting the reuptake of monoamines by neurons. Tramadol is two-enantiomorphs with racemic combination and complementary properties, resulting in a synergetic antinociceptive effect[11]. Moreover, the tramadol biotransformation in the liver leads to the formation of several metabolites, of which major one is O-desmethyl tramadol with moderate pain-relieving activity. We usually administer tramadol intravenously for anesthesia, but the exercise of epidural tramadol administration is not widely practiced in our environment. Likewise, many researches in various countries using epidural administration of tramadol as an adjuvant for bupivacaine, but these are not strong enough studies from our institution[12]. These studies have revealed that tramadol given epidurally lengthens the time of the analgesic effect. Therefore, this study was directed to determine the caudal bupivacaine anesthesia duration given in combination with tramadol and its routine use for the patients benefit.

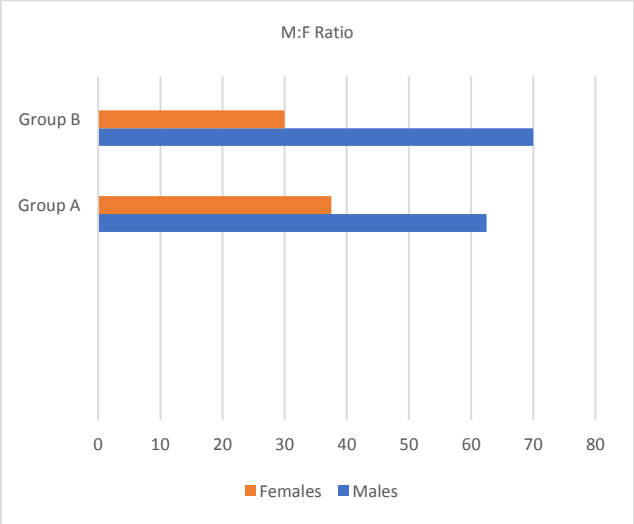
METHODS

This prospective, comparative, randomized, double-blinded study was conducted in the department of Anesthesia, Khyber Teaching Hospital, Peshawar for one-year duration from 21st January 2021 to 20th January 2022. This research was performed to assess the caudal analgesia duration of tramadol adjuvant to bupivacaine as the main outcome and to equate the haemodynamic response as secondary outcome and to evaluate the study drugs with their adverse effects. The children met the criteria were included and consent in written form was taken from the parents. 80 patients, 3-8 years of age, ASA physical status type-I and II enduring elective urological, lower limb and lower abdominal surgery. The criteria of exclusion encompassed parental rejection, mental retardation, neurological deficit, allergy to study drugs, coagulopathy, injection site infection, and significant spinal or skeletal deformity. Patients were randomised in to group A (n = 40) given 0.25% bupivacaine 1 ml / kg and group B (n = 40) receiving bupivacaine 0.25% in dose of 1 ml / kg plus 1 mg / kg tramadol. The day before surgical procedure, patients were assessed prior to anesthesia with a detailed physical examination, history and related laboratory tests. Children were not given anything by mouth for minimum 6-hours prior to operation, but were permissible to drink milk for up to 4-hrs prior to surgery and water for up to 2-hrs prior to surgical procedure. Standard monitors, counting ECG, temperature and pulse oximetry, non-invasive blood pressure is provided in the operating room. Induction was performed with an intravenous anesthetic (propofol or sodium thiopental) following an induction with halothane and appropriate size intravenous cannulation. Heart

rate, diastolic BP, systolic BP, electrocardiogram, mean arterial pressure, temperature and arterial saturation of O2 were observed. The study patients were randomly alienated into 2 groups by drawing lots from a consecutively numbered ampule by trained personnel. After random assignment sequences were generated by trained personnel, participants were enrolled by the anaesthetist and assigned to interventions that did not include the observation of variable outcomes. Basic haemodynamic parameters were recorded prior to the application of the caudal block. Qualified personnel were requested to formulate the drugs so that subjects and investigator were unaware of the study group. The drug volume to be inoculated was considered as recommended by Armitage at 1 mL / kg for lumbosacral block. The analgesia duration (time from the caudal direction of drugs to the 1st dosage of rescue anesthesia) was recorded. FLACC scale was used to determine the degree of analgesia (Face Legs Activity Cry Consolability). Assessments were performed every thirty-mints for 2-hrs and then every hour until the subjects had given the 1st dosage of rescue analgesia. The tested drugs side effects (vomiting, arrhythmia and nausea) were also observed. The results of FLACC interpretation: 0 = comfortable and relaxed; 1-3 = slight discomfort; 4-6 = moderately pain; 7-10 = severe discomfort or pain or both. Emergency painkillers were given to patients with a score of 4 or greater. 0.5 mg / kg injection Pethidine was inoculated intravascularly as a rescue pain reliever. The data collected was analyzed using the SPSS 20 statistical software and related tests. For categories such as gender and the frequency of adversative events; chi-square test was applied. The continuous parametric data was determined with Student's t-test such as weight, age, blood pressure, heart rate and analgesia duration. P < 0.05 was considered statistically significant.

RESULTS

80 patients were selected for this study. The patient details are given in Figure-I



It was detected that the analgesia mean time was longer substantially in B group (464.2 ± 167.1 minutes vs 238.1 ± 71.5 minutes, P <0.001). The postoperative vomiting was seen in 2 patients, one in each group.

Table-1: shows the demographic features of patients

Variables	Group A (n=40)	Group B (n=40)	P value
Age in months	43.67±20.2	53.79±24.1	0.161
Sex (M/F)	28/12	26/14	0.258
Weight in kg	14.30±5.2	16.88±4.7	0.231

No additional side-effects such as hypotension, arrhythmia, convulsions, bradycardia, urinary retention and respiratory depression were observed.

Table-2: shows the heart rate at various time intervals

Heart rate (beats/ mint)	Group A	Group B	P value
Baseline	110.0±15.1	108.1±15.2	0.88
Just after study drug administration	110.2±15.5	108.9±15.8	0.98
3 min after study drug administration	108.2±13.9	109.1±15.9	0.85
5 min after study drug administration	109.5±13.1	107.2±16.1	0.60
10 min after study drug administration	110.5±14.8	111.8±14.6	0.92

Table-3: shows Mean arterial pressure at various time intervals

Mean arterial pressure (mm of Hg)	Group A	Group B	P value
Baseline	62.1±8.1	66.8±7.7	0.061
Just after study drug administration	60.1±8.8	64.4±8.8	0.08
3 min after study drug administration	58.2±6.7	63.8±7.0	0.048
5 min study drug administration	60.5±7.9	65.2±6.9	0.049
10 min after study drug administration	60.5±7.8	66.2±8.5	0.12

DISCUSSION

Uncontrolled post-operative pain can lead to a number of side effects, such as delayed recovery from surgery, restricted exercise, risk of thromboembolism, and elevated blood sugar levels[13-14]. These effects lead to paralytic ileus, poor immune system and wound healing. The subjects with insufficient analgesia cannot take deep breaths, they have an ineffective cough, which results in numerous pulmonary complications postoperatively[15]. In this way, by reducing nociceptive stimuli to the CNS and preserving analgesia perioperatively, the surgical stress responsecan be prevented, facilitating early recovery and reducing complications[16-17]. Regional anesthesia methods have been cast-off successfully for acute pain treatment following various operations. The regional anesthesia techniques benefits comprise unnecessary use of opioids given perioperatively and their side effects, excellent pain relief and early movement. Caudal anesthesia is the utmost prevalent analgesia given regionally with a probable level of blockage cast-off in pediatric procedures[18-19]. Numerous remedies can be supplementary as adjuvants to local anaesthetics to extend the caudal anesthesia duration providing with single dose. Tramadol is the drug used in conjunction with bupivacaine for caudal block, a pethidine-equivalent opioid palliative that has no side-effects like respiratory depressant and is also economical and can be cast-off in our configuration to benefit patients for a variety of treatments[20].

This study showed that 1 mg / kg Tramadol can be given as an additive to 0.25% bupivacaine in children for caudal analgesia with 1 ml / kg of total volume and can be used to extend the time of analgesia given postoperatively without increasing the side effects[21]. Md Shafiqul Islam et al reported similar results in research of children enduring inguinal surgery with a combination of caudal bupivacaine and tramadol and perceived that when a mixture of tramadol and bupivacaine was used, the mean pain relief duration was longer significantly (P <0.001) in comparison to bupivacaine given solitary[22]. Meena Doda et al conducted research in children to equate the duration and quality of pain relief afterwards single injection of caudal block using bupivacaine alone at 0.5 ml / kg and bupivacaine 0.25% with 2 mg / kg tramadol and noticed that the mean time between the 1st analgesic dosage and caudal blockage was longer significantly with the mixture of tramadol and bupivacaine[23]. The tramadol doseage given was higher and the total volume was lower, but the bupivacaine concentration was comparable to this study. The common epidural

tramadol side effects are vomiting and nausea. However, in our study, the vomiting incidence was the equivalent in both groups at 3.3%. A Shahid Khan et al study found a higher prevalence of nausea when using the grouping of bupivacaine and tramadol, in contrast to our study[24-25]. The vomiting incidence was 11% in the combination group in comparison to 6.70% in the bupivacaine alone group.

CONCLUSION

This study concluded that for caudal anesthesia total of 1 ml / kg of tramadol can be added to 0.25% bupivacaine to extend the time of post-operative analgesia in children enduring abdominal, lower extremity and lower urological surgery without upsurge in side-effects.

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