

To Compare the Duration and side effects of Caudal Tramadol Bupivacaine versus Ketamine – Bupivacaine for Postoperative analgesia in the pediatric age group

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ABSTRACT

Aim: To compare and contrast the side effect profile and the duration of action for Tramadol-Bupivacaine and Ketamine-Bupivacaine, as post operative pain management in the pediatric age group.

Method: The type of study is a randomized control trial, conducted at a Tertiary care Hospital in Karachi, Pakistan, from February 2013 to August 2013. The study sample is of 36 children, age range from three to eight years of age, who underwent inguinoscrotal operations and were divided in to two groups randomly, one group receiving Tramadol-Bupivacaine (2mg per kg and 0.5mg per kg of 0.25%) and the other group receiving Ketamine and bupivacaine (1mg per kg and 0.5mg per kg of 0.25%), right after anesthesia. No pain management treatment was utilized during the surgical procedure. Modified objective pain scoring system was used to assess the postoperative analgesic effect. Sedation effect was assessed at five time intervals. Side effect profile including but not limited to, Cardiac issues, respiratory depression, psychomotor effects, retention of urine, nausea and vomiting were evaluated for all the patients under study.

Results: Caudal Tramadol with bupivacaine produced significantly increased postoperative analgesia. The duration of postoperative analgesia was 18.01 +/- 1.85 hours in Tramadol - bupivacaine group as compared to 11.92 +/- 1.69 hours in Ketamine - bupivacaine group. The sedation score was high in Tramadol - bupivacaine group only during 1st hour postoperatively. No other side effects like respiratory depression, urinary retention, pruritus were found in any group. The demand for rescue analgesia was high (2.39+/-0.51) in Ketamine- bupivacaine group as compared to Tramadol-bupivacaine group (0.40+/-0.60) Four children in Ketamine - bupivacaine group experienced psychomotor effects.

Conclusion: Based on the results of our study, Tramadol-Bupivacaine combination provided a long time post operative pain relief, had a lower side effect profile and had a higher sedation score (at 1 hour interval) when compared to Ketamine-bupivacaine combination.

Keywords: Caudal analgesic effect, Tramadol, Bupivacaine, Ketamine, Side effect profile.

INTRODUCTION

The most distressing symptom experienced by patients undergoing any major surgery is the post operative pain, it induces a myriad of effects including but not limited to a metabolic, hormonal and cardio respiratory response that might affect the outcome post operatively¹. A sudden metabolic stress response can be duly avoided if the patient is given pain medication half an hour before surgery, and can save the patient from having a disastrous neuroendocrinal stress response². Children are at an increased risk of this hazard, as they do not express

pain like adults³ In recent years this fact has received consideration from anesthetists and regional anesthetic techniques have been given consideration because of their minimal effect on body chemistry and stress response⁴. The most commonly used anesthetic in pediatric age group is bupivacaine whose action lasts between 4 and 12 hours before wearing off. To compensate for this effect, various other drugs like morphine, Tramadol, Ketamine, clonidine, fentanyl and midazolam, are added into the caudal space to prolong the anesthetic effect of bupivacaine, and different concentrations of these drugs are used to achieve the maximum effect^{5,6,7,8}. But this addition of another drug causes increase in the side effects, like respiratory system depression, nausea and vomiting⁹ Combinations like clonidine and midazolam, have side effects such as hypotension, and increased sedation, even though they provide increased analgesic effect^{10,11}. Similarly morphine addition provides excellent analgesia but its

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side effects are detrimental including urinary retention, respiratory depression, nausea and vomiting⁹. Several studies demonstrate analgesic effect of combination of caudal Tramadol bupivacaine and caudal Ketamine bupivacaine, but their different doses produce different results. Our study compares and efficacy and side effect profile of Tramadol bupivacaine and Ketamine bupivacaine to determine which is the better option for post operative pain relief in the pediatric age group.

MATERIALS AND METHODS

The type of study is a randomized control trial, conducted at a Tertiary care Hospital in Karachi, Pakistan, from February 2013 to August 2013. The study sample is of 35 children, age range from three to eight years of age, ASA status I and II, were selected to be studied. The exclusion criteria for the study was, an active infectious process, neurological abnormalities, bleeding disorders, and patients taking anticoagulant therapy aspirin (One week before) abnormalities of the vertebral column, raised Intra cranial pressure, and those having any known contraindication for caudal anesthesia. The patients did not receive any pre medication. The induction of anesthesia was with inhalation of halothane with Oxygen, and Nitrous Oxide, with IV propofol and appropriate size Endotracheal tube was passed after injection atracurium 0.5 mg per kg was used. Intraoperative benzodiazepines and opioids were not used. Monitoring was done at 5min interval of SPO₂, blood pressure and respiratory rate, and post operatively at an interval of 30mins for the initial six hours and every 2 hourly after that. After induction Caudal analgesia was performed using a 23 gauge needle under complete aseptic conditions, aspiration for blood and CSF was checked, and drugs were duly injected into the epidural space. The patient population was divided into two groups, one group A receiving Tramadol-Bupivacaine (2mg/Kg and 0.5mg/kg of 0.25%) and the other group B receiving Ketamine and bupivacaine (1mg per kg and 0.5mg/kg of 0.25%), both groups had a total of 18 children each. The anesthetist knew which drug was given to which child. After determining the block is completed incision was give. Anesthesia was maintained till application of dressing. The time from first incision to the final dressing was applied was duly noted, so was the time when anesthetic agent was stopped and the time spontaneous eye opening was established. Sedation was noted at 5 intervals of time, at 30min, 1hour, 2hour, 4hour, and 6hours using a score basing on eye opening observed (Spontaneous eye opening=0, eye opening on verbal stimulation=1, eye

Table 1: Demographic data of the patients

opening on physical stimulation=2, Unresponsive=3). Modified objective pain score was used to assess the pain. It is a validated pain score¹² and includes the following five points, crying, agitation, movement, posture, localization of pain. Each is scored from 0 to 2, to get a total of 0 to 10 points. Due to difficulty in infants, the score is utilized well in children of three years of age and above. When the score was 4 intervention was done, and the patients were given 15mg/kg of syrup paracetamol, 6 hourly. Duration of analgesia was described as time interval between first causal dose and when the second was demanded. Patients remained in the hospital under observation along with a guardian. Side effects such as respiratory depression, motor block, urinary retention, nausea, vomiting, pruritus and psychomotor effects were duly noted. Duration of motor block was assessed from time the caudal injection was administered to when the patient started moving his legs spontaneously. Results were compared as means and standard deviations. Chi square test was used for categorical variables and student t test was used for continuous ones. P value significance was set at <0.05.

RESULTS

The two groups A & B were compared in respect of their, weight, age, gender, ASA physical status, and duration of surgery (Table 1). Respiration and hemodynamic data were similar in the two groups (Table 2). We did not observe any case of respiratory depression, however there was concern about it in the Tramadol group. The mean duration of analgesia was of longer duration in group A (18.01 +/- 1.85 hours) as compared to group B (11.92 +/- 1.69 hours), In group A 6 children received rescue analgesia in the first 24 hours postoperatively which in group B this need of supplementary analgesia was observed in all the children of the group. The doses were also variable among the groups, in group A being (0.40 +/- 0.60) in group B being (2.39 +/- 0.51), as shown in Table 3. One thing of difference among the two groups was the time from awakening from anesthesia that is spontaneous eye opening. Patients in group A took a longer duration of time for spontaneous eye opening (34.01 +/- 7 minutes) as compared to group B (20.22 +/- 2.98 minutes), at one hour interval the sedation score was the same in both the groups. Vomiting was observed in 3 patients in group A and 2 patients in group B. Other complications like respiratory depression, pruritus, urinary retention was not observed in any patient. There was no significant difference in the recovery characteristics of the two groups (Table4).

Drug group	GROUP B	GROUP A	p-value
Age in years	5.02 +/- 1.74	5.50 +/- 1.82	0.395
Gender Male : Female	13/5	14/4	0.657
Weight in kg	16.9 +/- 3.33	17.1 +/- 3.29	0.603
ASA Status	I	I	

Table 2: Changes in intraoperative variables as compared to baseline: (expressed as MEAN +/- SD)

Drug group	Group B	Group A	p-value
Mean Arterial Pressure (Baseline) (mm Hg)	70.69 +/- 4.71	68.46 +/- 4.08	0.148
Mean Arterial pressure (Intraoperative) (mm Hg)	69.12 +/- 6.29	66.10 +/- 3.96	0.106
Mean Heart Rate/ min (Baseline)	94.30 +/- 8.01	90.16 +/- 7.72	0.137
Mean Heart Rate/min (Intraoperative)	89.80 +/- 9	85 +/- 6.5	0.158
Mean Respiratory Rate/min (Baseline)	14.79 +/- 1.41	15.24 +/- 1.86	0.463
Mean Respiratory Rate/min (Intraoperative)	14.62 +/- 1.18	14.18 +/- 1.29	0.273

Table 3: Mean duration of analgesia and mean doses of analgesia required in first 24 hours post op.

	Group B	Group A	p-value
Duration of analgesia (hr) mean + SD	11.92 +/- 1.69	18.01 +/- 1.85	0.000
Doses of analgesia 24 hr after surgery mean+SD	2.39 +/- 0.51	0.40 +/- 0.60	0.000

Table 4: Characteristics of Recovery

Drug group	Group B	Group A	p-value
Duration of Surgery (min)	24.74 +/- 6.88	25.80 +/- 5.62	0.627
Time to Spontaneous Eye Opening (min)	20.22 +/- 2.98	34.01 +/- 7	0.000
Time to Spontaneous Leg Movement (hours)	2.36 +/- 0.47	2.39 +/- 0.48	0.835
Time to first Micturition (hours)	3.57 +/- 0.53	3.32 +/- 0.58	0.253
Number of patients requiring Anti-emetics (n)	3 (16.6 %)	2 (11.11 %)	0.647

DISCUSSION

According to the results of our study, Tramadol bupivacaine combination shows increased duration of analgesia, which are consistent with other studies^{13,14} Khan RA et al concluded that Tramadol as a single injection is more effective than bupivacaine when used as a caudal injection (single shot)¹⁵ Ozkan et al observed that caudal Tramadol when used as 2mg per kg injection showed improved efficacy when compared with caudal bupivacaine and decreased the need for post operative pain management¹⁶. According to study by Parkash et al Tramadol bupivacaine combination when used at 1mg, 1.5mg and 2mg per kg Tramadol and 0.5 mg per kg of 0.25% bupivacaine, showed that the group in which 2mg per kg Tramadol was used displayed long duration of post operative analgesic effect¹⁷. Similarly in a study conducted by Senel et al, when Tramadol bupivacaine combination is used at 0.25ml per kg bupivacaine and 1.5mg per kg of Tramadol, for children undergoing inguinal herniorrhaphy the combination at the select doses showed a longer time for analgesic effect (13+/- 2hours)¹⁸. The difference as compared to our study is due to the low concentrations of agents used.

CONCLUSION

Based on the results of our study, Tramadol-Bupivacaine combination provided a long time post operative pain relief, had a lower side effect profile and had a higher sedation score (at 1 hour interval) when compared to Ketamine-bupivacaine combination.

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