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Original Research Article

Ropivacaine with Tramadol and Ropivacaine with Midazolam for Post-Operative Epidural Analgesia: Prospective, Single-Blind, Randomized Comparative Study

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Abstract

Aim: To study comparative study of ropivacaine with tramadol and ropivacaine with midazolam for post-operative epidural analgesia

Methods and Materials: This prospective, single-blind, randomized, comparative study conducted in the Department of Anaesthesiology and critical care, Patna Medical College and Hospital, Patna, Bihar, India, for 12 months. The mean duration of analgesia in the tramadol group (913±315.5 min) was more than the midazolam group (769.2± 331.9). The confidence level is estimated at 95%, power of study at 80%, the minimum sample size required for the study was calculated as 100 subjects (n=50 in Group R, n=50 in Group L). Patients within 18-60 years of both the gender undergoing elective surgeries below the umbilicus under Epidural block who have given valid informed consent were included in the study.

Results: Comparison of onset of sensory, motor blockade, and duration of sensory-motor blockade among the two groups showed a statistically significant difference in the onset of sensory, motor blockade, and duration of sensory blockade across the group ($p<0.005$). The results also showed no statistically significant difference in heart rate across the group ($p>0.005$). There was also no statistically significant difference in MAP (Mean arterial pressure) across the group ($p>0.005$). There was no statistically significant difference in spO2 across the group ($p>0.005$). During the comparison of VAS scores across the two groups. The result showed a statistically significant difference in VAS score at 12 hr across the group ($p<0.005$). Our result also revealed opioid requirement analysis across the two groups. The result showed a statistically significant difference in opioid requirement across the group ($p<0.001$).

Conclusion: The mean duration of analgesia was more among ropivacaine with the Tramadol group.

Keywords: ropivacaine, Tramadol, epidural analgesia

Introduction

Historically, children have been undertreated for pain and painful procedures. Although caudal epidural block was described by Campbell in 1933, [1]. Prolongation of analgesia with caudal technique has been achieved with addition of various adjuvants to local anaesthetic agents, opioids being the most widely used adjuvant medication.Caudal block is probably the most easily learned and mastered technique of all regional anaesthetic procedures. [2,3] A major limitation of this technique is the relatively short duration of post-operative analgesia even with long-acting local anaesthetics. Catheter placement into the caudal space adds to the risk of infection and tends to prevent early mobilisation and hence is not very popular. [4] needy in India), [5,6] due to strict regulations, and some of its unpleasant side effects compel the clinician to seek non-opioid drugs such as clonidine, s-ketamine, neostigmine, midazolam and dexmedetomidine as adjuvant for caudal epidural anaesthesia. Some of these newer agents such as dexmedetomidine have unwanted haemodynamic effects.

Material and methods

This prospective, single-blind, randomized, comparative study conducted in the Department of Anaesthesiology and critical care, Patna Medical College and Hospital, Patna, Bihar, India, for 12 months. The mean duration of analgesia in the tramadol group (913±315.5 min) was more than the midazolam group (769.2± 331.9). The confidence level is estimated at 95%, power of study at 80%, the minimum sample size required for the study was calculated as 100 subjects (n=50 in Group R, n=50 in Group L).

Inclusion Criteria

Patients within 18-60 years of the gender undergoing elective surgeries below the umbilicus under Epidural block who have given valid informed consent were included in the study.

Exclusion criteria

Patients with an allergy or sensitivity to local anaesthetics/ Tramadol/ Midazolam, with bleeding disorders, with pre-existing peripheral neuropathy of lower limb, with history of severe cardiac, respiratory, hepatic, or renal disease, or who does not satisfy inclusion criteria were excluded from the study.

Methodology

Pre-anesthetic assessments of all the patients were done the day before surgery. Patients were premedicated with tablet alprazolam 5mg and tablet ranitidine 150 mg at night before surgery. After shifting the patient to an operating table, standard anaesthesia monitoring in the baseline measurement of heart rate, noninvasive arterial blood pressure, and oxygen saturation were observed. Blinding was assured by drug preparation by a consultant anaesthesiologist not involved in the further follow-up of the study. Patients were divided into two groups of 50 patients of each as:

Group R: Epidural 0.75% Ropivacaine (30ml) with Tramadol (2mg/kg).

Group L: Epidural 0.75% Ropivacaine (30ml) with Midazolam (50mcg/kg).

Intravenous access was secured with an 18-gauge cannula. After aseptic precaution, an epidural catheter was placed, and an epidural test dose was given. Sensory and motor block evaluation was done every 5 minutes after giving block until complete motor blocks. Sensory block and Motor block were assessed with a 23 G hypodermic needle in all nerves' distribution, for the surgeries below the umbilicus, desired level of block T10.

The onset time for sensory and motor block and Complete Motor block, duration of motor block was monitored closely.

The pain was assessed every 30 minutes for the first 2 hours and then 1 hour till 24 hours in the recovery phase. Testing for sensory and motor block regression was done every 15 minutes until complete resolution. The time between the end of local anesthetic administration and first rescue analgesic administration is recorded as the duration of analgesia, (rescue analgesia-visual analogue scale >4, on patient request.)

Statistical analysis

Descriptive statistics were done for all data and analyzed with the unpaired t-test and ANOVA single factor test. Statistical significance was taken as $P<0.05$. The data was analyzed using SPSS version 25.0.

Result

The study included 100 patients divided into two groups Ropivacaine with Tramadol and with Midazolam 50 samples in each group, respectively. The age of the patients was in the range of 20 years to 60 years. 30% of the total population was in the age group of 20-40, whereas 60% were in the age group of 41-60. The study includes 42% of the females and 58% of the males. Results showed that mean weight was 60.71kg, mean height was 158.15cm, and mean BMI was 25.21 Kg/m2. Results showed that the mean duration of surgery was 127.29±17.6 minutes, the mean onset of surgery was 17.6±7.3 minutes, the mean onset of sensory blockade was 17.60 minutes, the mean onset of motor blockade was 28.88±9.64 minutes, mean duration of sensory blockade was 387.40 ±56.03 minutes and mean duration of motor blockade was 200.7±17.52 minutes. Our results also showed no statistically significant difference in the demographic comparison of mean age, height, and weight of both the different groups studied. Mean age, weight, height, and duration of surgery among Ropivacaine with Tramadol group was 42.21±12.49 years, 60.71± 6.1 kg, 158 ±4.61cm, and 127.28± 17.8 minutes, respectively. The mean age, weight, height, and duration of surgery among Ropivacaine with Midazolam group was found to be 44.21±11.58 years, 60.74±5.9 kg, 157.82±5.17cm, and 127.31±17.5 minutes, respectively. The patients were given rescue analgesia when they themselves complained about pain and their VAS was 7/10. Our results also showed mean time to first rescue analgesia in group Ropivacaine with Tramadol was 426.75± 42.6 minutes and in group Ropivacaine with Midazolam was 343.5 ±50.4 minutes respectively, which depicts statistically significant difference across the group ($p<0.001$).

Comparison of Onset of sensory, motor blockade, and duration of sensory-motor blockade among the two groups showed a statistically significant difference in the onset of sensory, motor blockade, and duration of sensory blockade across the group ($p<0.005$).

The results also showed no statistically significant difference in heart rate across the group ($p>0.005$). There was also no statistically significant difference in MAP (Mean arterial pressure) across the group ($p>0.005$). There was no statistically significant difference in spO2 across the group ($p>0.005$).

During the comparison of VAS scores across the two groups, the result showed a statistically significant difference in VAS score at 12 hr across the group ($p<0.005$). Our result also revealed opioid requirement analysis across the two groups. The result showed a statistically significant difference in opioid requirement across the group ($p<0.001$).

Table 1: Duration of surgery

Ropivacaine with Tramadol	Ropivacaine with Midazolam
125.20 minutes	125.28 minutes

Table 2: Comparison of 'Time to first rescue analgesia.'

Ropivacaine with Tramadol	Ropivacaine with Midazolam
422.70 minutes	340.2 minutes

Table 3: Comparison of Onset of sensory, motor blockade and duration of sensory, motor blockade the two groups

	Ropivacaine withtramadol	Ropivacaine withmidazolam	P-value
Onset of sensory blockade	10.43 ±1.48	24.73 ±2	0.046
Onset of motor blockade	19.73 ±2.33	37 ±3.4	0.002
Duration of sensory blockade	437.35 ±27.67	335.45 ±17.15	<0.0001
Duration of motor blockade	200.20 ±17.15	200.28 ±17.96	0.379

Discussion

The short duration of action (4–8 h) [7] of local anaesthetics alone in caudal block has forced the anesthesiologist's to search for additives to enhance the duration of analgesia in children. Continuous caudal analgesia with catheter technique has added risk of infection and delay in mobilisation. Although excellent analgesia with extradural opioids is well established, unpleasant side effects and restricted availability have been responsible for a decline in their popularity, especially in paediatrics. In a retrospective study, clinically significant respiratory depression was observed when 0.07 mg/kg morphine was given caudally. [8-11]

Hypertension, tachycardia, inadequate coughing, basal atelectasis, deep vein thrombosis, and sleeplessness are all symptoms of poor post-operative pain management. Aside from that, it prevents early ambulation and lengthens hospital stays. [12]

In the present study, we have attempted to compare the two commonly used, easily available, and relatively inexpensive agents, Tramadol and Midazolam, as an adjuvant in caudal anaesthesia along with ropivacaine, an amino amide local anaesthetic agent. The present study was conducted among 100 participants, with 50 in Ropivacaine with Tramadol group and 50 in Ropivacaine with Midazolam, respectively. In the present study majority of the participants were from the 41-60 year of age group (60%), and 30% were from the 20-40 years of age group. 58% of the participants were males, and 42% were females. The study participants' mean weight was 60.72 kg, mean height was 158.16 cm, and mean BMI was 25.22 kg/m2.

In a study conducted by Krishnadas A et al., all the study participants in the various group had no statistically significant difference with respect to patient age, sex, weight, and duration of surgery. Even the baseline vital parameters were comparable between the groups. [11]

In a study conducted by Chandrakant P et al, 10 there was no significant difference in intraoperative and post- operative heart rate and mean arterial pressure, which is quite similar to our study. Comparison of heart rate, mean arterial pressure, and SPO2 showed no statistically significant difference in both groups.

In a study conducted by Krishnadas A et al, [11] the mean duration of time to rescue analgesia was significantly longer (P < 0.001) in Group RT (913 315.5 min) and Group RM (769.2 331.9 min). However, there was no significant difference in the duration of time to rescue analgesia between RT and RM groups.

Our study established the efficacy of Tramadol and Midazolam as an effective adjuvant with ropivacaine for prolonging the duration of post-operative analgesia. Similar to earlier studies, the unpleasant tramadol side effects of nausea and vomiting were not seen in our study. [12] There was no incidence of respiratory depression or sedation, and the motor block was also minimal. There was no incidence of pruritus or bladder retention in any group. [11,13]

Conclusion

Tramadol or Midazolam's addition to caudal epidural block with ropivacaine showed significant prolongation of post-operative analgesia compared to ropivacaine alone. On studying the comparison of the onset of sensory, motor blockade, and duration of the sensory-motor blockade,in the two groups, found that onset of sensory blockade, motor blockade, and duration of motor blockade was more among ropivacaine with midazolam group.

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