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Original Research Article

Comparative study of ropivacaine with tramadol and ropivacaine with midazolam for post-operative epidural analgesia

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ABSTRACT

Background: Epidural analgesia is the most commonly used method for surgical anesthesia, obstetric analgesia, post-operative pain control, and chronic pain management. These epidurals are used either as a single-shot technique or with the catheter that allows intermittent boluses or continuous infusion, or both. All of these variables are controlled by choice of drug concentration, dosage, and level of injections.
Aim: To compare the onset and duration of sensory block, motor block, and post-operative analgesia duration using Ropivacaine with Tramadol and Ropivacaine with Midazolam in the Epidural technique.
Materials and Methods: In this prospective, non-randomized, comparative study, the total of 160 patients who underwent surgeries below the umbilicus did under epidural technique at Govt. Kilpauk Medical college hospital a Govt. Royapettah hospital, Chennai, was screened. Patients were divided into two groups. Patients in Group R received an epidural injection of 0.5% Ropivacaine (30ml) with Tramadol 2 mg/kg, whereas patients in Group L received an epidural injection of 0.5% ropivacaine (30ml) with Midazolam (50mg/kg).
Results: On studying the comparison of the onset of sensory, motor blockade, and duration of the sensory-motor blockade in the two groups, the onset of sensory blockade, motor blockade, and duration of motor blockade was more among ropivacaine with midazolam group. In comparison, the duration of sensory blockade was more among ropivacaine with tramadol group. A statistically significant difference in onset of sensory, motor blockade, and duration of sensory blockade across the group was found ($p<0.005$).
Conclusion: Tramadol or Midazolam's addition to caudal epidural block with ropivacaine showed significant prolongation of post-operative analgesia compared to ropivacaine alone. The mean duration of analgesia was more among ropivacaine with the Tramadol group.

1. Introduction

International Association for the study of pain shows that "Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage." Continuous epidural anesthesia is a neuraxial technique offering a wider than single-dose spinal anesthesia. An epidural block can be performed at the lumbar, thoracic, or cervical, and sacral epidural anesthesia is referred to as a caudal block.[1] Caudal block is probably the most easily learned and mastered technique of all regional anaesthetic procedures.[2] A significant limitation of this technique is the relatively short post-operative analgesia duration. Epidurals can be used as a single-shot technique or with the catheter that allows intermittent boluses or continuous infusion, or both.[3] The motor block can range from none to complete. The epidural space surrounds the dura mater posteriorly, laterally, and anteriorly. Nerve roots travel in this space as they exit laterally through the foramen and course outwards to become peripheral nerves.

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Spinal, epidural, and caudal neuraxial blocks result in a combination of sympathetic blockade, sensory blockade, or motor blockade depending on the dose, concentration, or volume of local anesthetic administered. Spinal anesthesia requires a small mass (i.e., volume) of the drug that is almost devoid of systemic pharmacological effects to produce rapid (20 minutes) after a large mass of local anesthetic that produces pharmacologically active systemic blood levels, which may be associated with side effects and complications unknown to spinal anesthesia. Epidural anesthesia is slower in onset (10-20min) and may not be as dense as spinal anesthesia, a feature that can be useful clinically. For example, using relatively dilute concentrations of a local anesthetic combined with opioids and epidural analgesia without motor block.[4,5]

Epidural anesthesia is a focal neuraxial block strategy with numerous applications. Its adaptability implies it can be utilized as a sedative, as a pain-relieving adjuvant to general sedation. The post-operative absence of pain in methodology includes the lower appendages, perineum, pelvis, mid-region, and chest.[6,7]

Ropivacaine is a synthetic local anaesthetic agent with a propyl group to which hydrogen is added to the carbon of piperidine ring at the carboxy chain, enhancing its ability with low cardiotoxicity. Ropivacaine blocks impulse conduction in nerve fibers by reversible inhibition of sodium ion channels.[8] Tramadol is a synthetic opioid of the amino cyclohexanol group. It also inhibits neuronal uptake of noradrenaline and enhances serotonin (5-HT) release.[9] Midazolam is a water-soluble imidazobenzodiazepine that acts throughout CNS but is concentrated especially in the cortex and midbrain.[10]

The study is aimed to compare the effectiveness of 0.5% ropivacaine with Tramadol and 0.5% ropivacaine with Midazolam in the Epidural technique. The study focuses on assessing the onset and duration of sensory block, motor block, and post-operative analgesia duration.

2. Materials and Methods

In this prospective, randomized, double-blinded comparative study total of 160 samples were studied. Patients who underwent surgeries below the umbilicus were done under the epidural technique at Govt. Kilpauk Medical College hospital and Govt. Royapettah Hospital, Chennai, between November 2019 and April 2020, was assessed for inclusion and exclusion criteria and included in the study after obtaining written informed consent. Institutional ethics committee approval was obtained.

The sample size is determined based on the study done by Krishnadas K et al.[7] 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 160 subjects (n=80 in Group R, n=80 in Group L).

Inclusion Criteria: 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.

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.

2.1. Methodology

After obtaining the institutional research and ethics committee approval (EC.No.270/2019), written informed consent was obtained with respect to the type of anaesthesia, the study being conducted, mode of pain relief, and nature of surgery. Pre-anesthetic assessments of all the patients were done the day before surgery. Patients were premedicated with tablet diazepam 5mg and tablet ranitidine 150 mg at night before surgery and in the morning of surgery with a water sip. 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 80 patients of each as:

Group R: Epidural 0.5% Ropivacaine (30ml) with Tramadol (2mg/kg).

Group L: Epidural 0.5% 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 or 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.

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 16 and Microsoft Excel 2007.

3. Result

The study included 160 patients divided into two groups Ropivacaine with Tramadol and with Midazolam 80 samples in each group, respectively. The age of the patients was in the range of 18 years to 60 years. 33.8% of the total population was in the age group of 20-40, whereas 66.2% were in the age group of 41-60. The study includes 41.9% of the females and 58.1% of the males. Results showed that mean weight was 60.72kg, mean height was 158.16cm, and mean BMI was 25.22 Kg/m^2. Results showed that the mean duration of surgery weight 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 for 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 SPO_2 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).

No ADR reported in both groups.

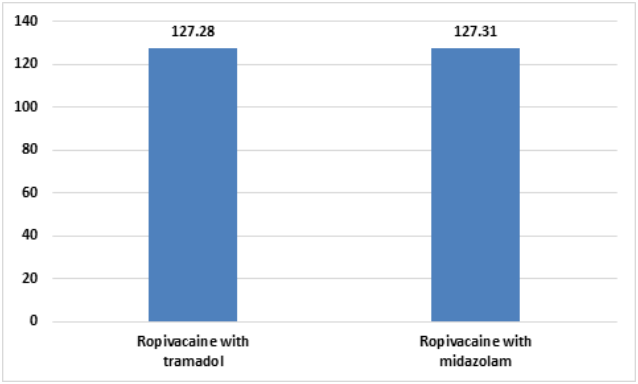

Fig. 1: Duration of surgery

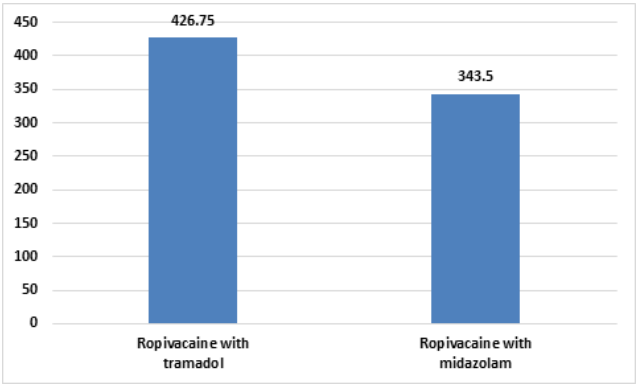

Fig. 2: Comparison of 'Time to first rescue analgesia.'

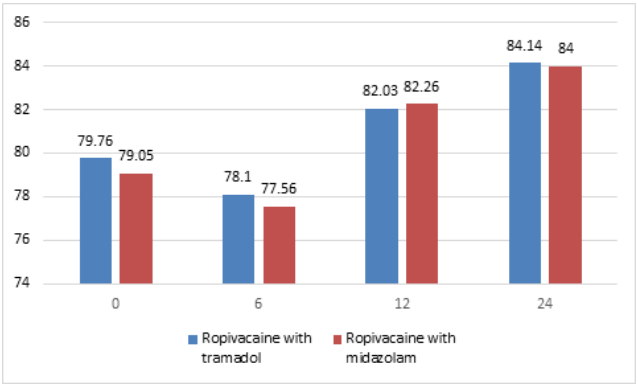

Fig. 3: Comparison of heart rate

4. Discussion

Pain is a body's response to an adverse input, whether or not there is actual tissue damage.[8] Individual differences in pain response may be influenced by age, gender,

Table 1: 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	10.45 ±1.50	24.75 ±2	0.047
Onset of motor blockade	19.75 ±2.35	38 ±3.6	0.002
Duration of sensory blockade	438.35 ±27.69	336.45 ±17.17	<0.0001
Duration of motor blockade	200.21 ±17.16	201.28 ±17.98	0.380

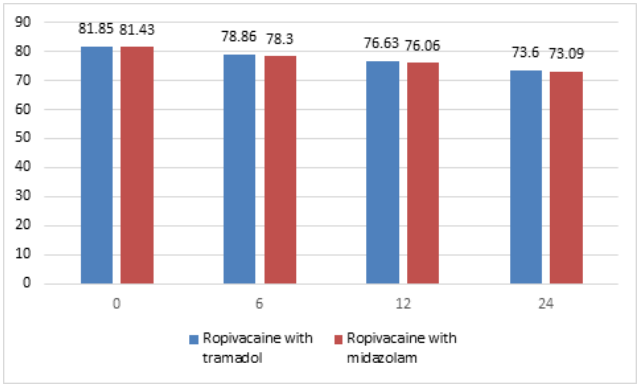

Fig. 4: Comparison of mean arterial pressure

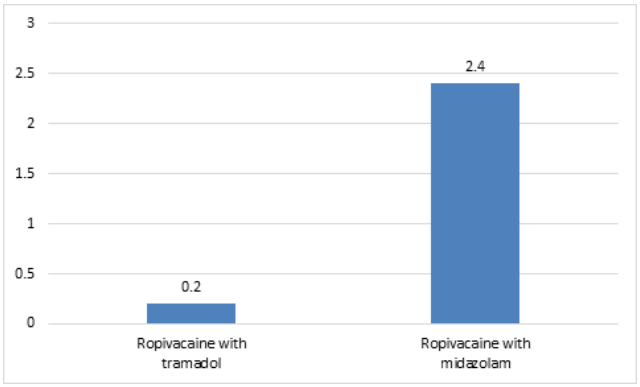

Fig. 5: Comparison of opioid requirement in 24 hours

genetic composition, and the surgical site.[9,10] Around 80–90% of surgical patients report moderate to severe pain after surgery.[11,12] The most common cause of post-operative morbidity in acute nociceptive discomfort caused by surgical incisions.

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.[13]

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 160 participants, with 80 in Ropivacaine with Tramadol group and 80 in Ropivacaine with Midazolam, respectively.

In the present study majority of the participants were from the 41-60 year of age group (66.3%), and 33.8% were from the 20-40 years of age group. 58.1% of the participants were males, and 41.9% were females. The study participants' mean weight was 60.72 kg, mean height was 158.16 cm, and mean BMI was 25.22 kg/m^2.

In the 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.[7]

In a study conducted by Chandrakant P et al,[11] 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 SPO_2 showed no statistically significant difference in both groups.

In a study conducted by Krishnadas A et al,[12] 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.[13] 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.[12]

5. 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, the two groups, found that onset of sensory blockade, motor blockade, and duration of motor blockade was more among ropivacaine with midazolam group. While the duration of sensory blockade was more among ropivacaine with tramadol group.

6. Source of Funding

None.

7. Conflict of Interest

The authors declare no conflict of interest.

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