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Original Article

A RANDOMISED CONTROLLED TRIAL COMPARING ADJUNCTIVE ACTION OF TRAMADOL WITH ROPIVACAINE

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ABSTRACT

Background: Epidural nerve block is extensively used for analgesia during the postoperative period. Unmanaged pain harvests upsetting results therefore good postoperative pain administration is vital part of good anaesthetic training.Various trials have been conducted that prove tramadol to be an effective and safe during epidural analgesia. The present study was aimed to compare adjunctive action of tramadol with ropivacaine for postoperative epidural analgesia following lower limb surgeries. **Materials and methods**: A randomised controlled trial was conducted in a prospective manner. All the subjects were informed about the study and a written consent was obtained from them in their vernacular language. Cardiac monitors were attached on shifting the patient to operation theatre. Baseline parameters were recorded. Epidural block was administered under complete aseptic condition in sitting position. Assessment of sensory block was done till T_9-T_{10}. A score of 2 was regarded as complete anaesthesia. Chi square test was applied as a test of significance. P value of less than 0.05 was considered significant. **Results:** A total of 48 candidates took part in this randomised study. Age and weight are expressed as mean +/- standard deviation. Ratio of male and female candidates in Group I is 15/9 and in Group II is 19/5. The onset of both sensory and motor block did not show any significant difference between the two groups. Pain scores were lesser in Group II subjects but there was no significant difference between the two groups. **Conclusion:** We came to the conclusion that combination of ropivacaine and tramodol gives improved results compared to ropivicaine alone.

Keywords: Analgesia, Bupivacaine, Pain, Ropivacaine

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INTRODUCTION

Epidural nerve block is extensively used for analgesia during the postoperative period. Unmanaged pain harvests upsetting results therefore good postoperative pain administration is vital part of good anaesthetic training.[1] Epidural analgesia with or without additives has given different advantages over other treatment modalities.[2] Bupivacaine was initially used for epidural analgesia but has been now replaced by ropivacaine due to its fewer side effects on CNS at comparable plasma levels.[3] But the motor block with ropivacaine is moderately lesser than bupivacaine.[4] Combination of local anaesthesia and opoids provided a better analgesia. Tramadol is an opoid agonist that interacts with the central nervous system and inhibits the removal of nor adrenaline and serotonin.[5] Various trials have been conducted that prove tramadol to be an effective and safe during epidural analgesia.[6,7] Initially fentanyl was used as an adjuvant[8] but various side effects were associated with fentanyl that constrained its use in the perioperative treatments.[9] Some studies have been undertaken to compare epidural analgesia with or without tramadol during the postoperative analgesia period but many of them have been used in labour setting.[10] The present study was aimed to compare adjunctive action of tramadol with ropivacaine for postoperative epidural analgesia following lower limb surgeries.

MATERIALS AND METHODS

A randomised controlled trial was conducted in a prospective manner. All the subjects were informed about the study and a written consent was obtained from them in their vernacular language. The study was approved by the institutional ethical board. A total of 48 patients belonging to ASA grade I and ASA

grade II who underwent lower limb surgery under spinal epidural anaesthesia were enrolled in the study. Subjects with history of heart disease, liver disease, allergy to regional analgesia, with spinal deformities were excluded from the study. Subjects were randomly divided into two groups. Group I patients were given 0.2% ropivacaine and Group II subjects received 0.2% ropivacaine along with 5 mg/ml of tramadol. Intraoperative and postoperative drug administration was given according to the condition. The drug administration step was blinded, the anaesthetic was not aware of the drug that was administered. Premedication with 0.5 mg alprazolam and 150 mg ranitidine 10-12 hours before surgery. Cardiac monitors were attached on shifting the patient to operation theatre. Baseline parameters were recorded. Epidural block was administered under complete aseptic condition in sitting position. Assessment of sensory block was done till T_9-T_{10}. A score of 2 was regarded as complete anaesthesia. Sensory tests were performed at regular intervals and regarded successful if it happened in 25 minutes. The duration of sensory block was regarded from the time of onset till the return of sensation. Motor block was assessed by movement of lower limb. Time of onset of motor block and duration of motor block was evaluated. Pain was recorded on a 5-point scale with 0 meaning no pain and 5 meaning unbearable pain. The time of first analgesia was recorded. All the data was arranged in a tabulated form and analysed using SPSS software and expressed as mean +/- Standard deviation. Chi square test was applied as a test of significance. P value of less than 0.05 was considered significant.

RESULTS

A total of 48 candidates took part in this randomised study. Table 1 demonstrates the demographic data associated with the patients. Age and weight are expressed as mean +/- standard deviation. Ratio of male and female candidates in Group I is 15/9 and in Group II is 19/5. The mean weight in Group I was 62.83 +/- 5.37 and in Group II was 58.94 +/- 5.21. The mean age in group I was 44.3+/- 10.7 and in Group II was 40.8 +/- 11.5. The onset of both sensory and motor block did not show any significant difference between the two groups. The duration of sensory block in Group II (7.18 +/- 1.57) was much more than Group I (3.57 +/-0.98). The p value was significant amongst the two groups. The duration of motor block was also higher in Group II (5.60 +/- 1.05) compared to Group I (3.53+/- 1.15) ($p<0.05$). (Table 2) Pain scores were lesser in Group II subjects but there was no significant difference between the two groups. The mean first analgesic time was 6.9 +/- 1.65 hours in group II compared to 5.1 +/- 2.60 hours in Group I, which was significantly higher as compared to Group I (Table 3)

Table 1: Demographic Data

	Group I	Group II
Age	44.3+/- 10.7	40.8 +/- 11.5
Weight	62.83 +/- 5.37	58.94 +/- 5.21
Male: Female	15/9	19/5

Table 2: Sensory and Motor Block

		Group I	Group II	P value
Sensory Block	Onset (mins)	11.17 +/- 2.66	10.47 +/- 2.21	>0.05
	Duration (hrs)	3.57 +/-0.98	7.18 +/- 1.57	<0.05
Motor Block	Onset (mins)	14.47 +/- 2.72	12.73 +/- 2.84	>0.05
	Duration (hrs)	3.53+/- 1.15	5.60 +/- 1.05	<0.05

Table 3: Pain scale and First analgesia time

	Group I	Group II	P value
Pain scale	0.43 +/- 0.51	0.40 +/- 0.33	>0.05
First analgesia time (hrs)	5.1 +/- 2.60	6.9 +/- 1.65	<0.05

DISCUSSION

Regional anaesthesia is very famous now a days in orthopaedic practice due to the various advantages it bids. It gives better pain relief, lesser side effects and decreased risk as compared with general anaesthesia.[11] As ropivacaine was introduced, there has been increased interest to evaluate its safety and efficacy. Different studies have been done to compare 0.125% ropivacaine and 0.125% bupivacaine as epidural block.[12] Combination of anaesthesia with opoids is used vividly to increase the onset of sensory and motor block.[13] Tramadol and fentanyl are the two most widely used adjunctive agents.[14] Tramadol is a synthetic agonist that inhibits the transmission of nociceptive stimuli by enhancing the inhibitory action of descending pain pathway.[15] According to our study The duration of sensory block in Group II (7.18 +/- 1.57) was much more than Group I (3.57 +/-0.98). The p value was significant amongst the two groups. The duration of motor block was also higher in Group II (5.60 +/- 1.05) compared to Group I (3.53+/- 1.15) ($p<0.05$). The results of the study were similar to the study performed by Sawhney et al.[16] As per the study conducted by Berti et al[17] amongst patients who underwent major surgery, no difference in hemodynamic status was seen. According to our study Pain scores were lesser in Group II subjects but there was no significant difference between the two groups. The mean first analgesic time was 6.9 +/- 1.65 hours in group II compared to 5.1 +/- 2.60 hours in Group I, which was significantly higher as compared to Group I. The study performed by Ravi Madhussudhara showed better VAS scores &enhanced duration of block. The major difference being that in this study, supraclavicular brachial plexus block was given.[18] Geze et al did a study to compare tramadol and fentanyl as in adjunctive agents to local anaesthesia while giving axillary nerve block and concluded that tramadol provides better postoperative analgesia and enhanced

quality of block.[14] According to a study by yunxia fan et al[19] on comparing tramadol & fentanyl as adjunctive to ropivacaine in epidural analgesia for labour pain, they concluded that tramadol was more effective as compared to fentanyl . The study performed by Krishan Yogesh Sawhney et al[16] who presented a similar incidence of side effects in all their groups. The few side effects associated with our study was smaller sample size and the degree of ambulation was not evaluated.

CONCLUSION

We came to the conclusion that combination of ropivacaine and tramodol gives improved results compared to ropivicaine alone. The duration of motor and sensory block was also enhanced and it provided a safer postoperative analgesia with fewer side effects and good analgesia.

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