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Original research article

Evaluation Of Therapeutic Efficacy of Two Different Combinations of Local Anaesthetics: Ropivacaine-Fentanyl Versus Bupivacaine-Fentanyl In Lower Limb Orthopaedic Surgeries – A Randomised Controlled Trial

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ABSTRACT

Background: Spinal anaesthesia is the most commonly performed anaesthetic technique. It has many advantages over general anaesthesia, such as a reduced stress response and better pain relief after surgery. Spinal bupivacaine causes a long-lasting block of movement and delays home discharge after ambulatory surgery. The aim of the present study was to evaluate the therapeutic efficacy of two different combinations of anaesthetics like ropivacaine-fentanyl and bupivacaine-fentanyl and also to note the adverse drug reactions in the two groups.

Materials and methods: The study was done with 40 people over a period of 8 months. They were split into two groups of 20 patients each by a computer randomization table. Group B received 3 ml (15 mg) of 0.5% bupivacaine with 25 mcg fentanyl and Group R received 3 ml of (15mg) of 0.5% ropivacaine with 25 mcg fentanyl. Hemodynamic parameters, sensory and motor block characteristics and adverse effects were noted in both the groups.

Results: There was no significant difference in both the groups with regard to hemodynamic parameters. Regression of motor block was earlier in ropivacaine group and the duration of analgesia was longer in bupivacaine group.

Conclusion: As ropivacaine is providing very shorter period of motor and sensory block in comparison with bupivacaine, it is more beneficial for the patients and it decreases the time of non-ambulatory phase.

Keywords: Anaesthesia, Ropivacaine, Bupivacaine, Fentanyl, lower limb surgeries

INTRODUCTION:

Spinal anaesthesia is the most convenient and commonly preferred anaesthetic technique. [1,2] It has many advantages over general anaesthesia, such as a reduced stress response and better pain relief after surgery. [3,4] Spinal lignocaine not only has a shorter duration of anaesthetic blockade but can also cause short-term neurological symptoms, so it has been banned. [5,6] Spinal bupivacaine, on the other hand, causes a long-lasting block of movement and delays home discharge after ambulatory surgery. [7,8] Ropivacaine, which is an amide local anaesthetic, has been used recently and has worked well for epidural analgesia for labouring women, caesarean delivery, and post-operative analgesia. [9,10] This has been extensively used for day care because it gives enough sensory blockade and allows the patients to get back to work quickly. [11,12] Ropivacaine has a better safety profile than bupivacaine because it has less effect on the central nervous system and the heart. [13,14]

The aim of the study was to evaluate the therapeutic efficacy of two different combinations of local anaesthetics – ropivacaine with fentanyl and bupivacaine with fentanyl and to note the adverse drug reactions in the two groups.

Materials & methods:

After the Institutional Ethical Committee approved the study, 40 patients who underwent major lower limb orthopaedic surgery, were recruited for the study. There was written consent from all the patients. Patients belonging to American Society of Anaesthesiologists' physical status I or II who were between the ages of 18 and 60 were included in the study. People who were not ideal candidates for spinal anaesthesia, who had a resting heart rate of less than 60 beats per minute, who were are allergic to amide local anaesthetics, who had a history of substance abuse, or were pregnant were excluded from the study. The study was done on 40 people over a period of 8 months. They were split into two groups of 20 patients each by a computer randomization table. Group B received 3 ml (15 mg) of 0.5% bupivacaine with 25 mcg fentanyl and Group R received 3 ml of (15mg) of 0.5% ropivacaine with 25 mcg fentanyl. All the patients were pre operatively assessed. After shifting to the operation theatre, an intravenous access was secured with a 18 G cannula. Baseline parameters were recorded. All participants were pre-loaded with 20 ml/kg of Ringer Lactate solution over ten minutes before spinal anaesthesia. Under aseptic precautions, the lumbar puncture was done with a 25G Quincke spinal needle at L3-L4 interspace in the midline. The free flow of cerebrospinal fluid was confirmed and the test drug was introduced into the intrathecal space at the rate of 0.2 ml/sec. The anaesthesiologist was blinded to the test drug. The patients were immediately placed in the supine position. Heart rate, blood pressure, respiratory rate, and oxygen saturation were monitored during the study. Hypotension was defined as a systolic blood pressure (SBP) less than 20% from the baseline and was treated with intravenous ephedrine in 6 mg boluses. Bradycardia was considered when the heart rate dropped below 50 beats per minute and was treated with intravenous atropine 0.5 mg. The highest level of sensory block was assessed by pin prick with a 27G bevelled needle along the mid-clavicular line on both sides. The highest level of motor block was assessed by modified Bromage scale. The operation was allowed to begin once sensory block had reached at least T10, but if this had not occurred after 15 minutes, general anaesthesia was induced. Intraoperative complications if any were also recorded. The total duration of surgery was noted in both the groups. After the surgery, the patients were shifted to the post-operative ward and the wearing off time for the sensory and motor block were recorded by the staff nurses who were blinded to the drug used.

The visual analogue score (VAS) for pain was explained to the patients before surgery as a 10-point scale where '0' means no pain and '10' means the worst pain. The total duration of analgesia in both the groups was also recorded.

Statistical analysis was done using SPSS 16.0. Descriptive statistics was expressed in Mean +SD. Independent t test was applied for comparison between groups.

RESULTS:

The groups were comparable with respect to age, height, weight and hemodynamics as shown in Table 1 & Table 2. The type and duration of surgery did not differ significantly. In the operating room, there were no differences in hemodynamic parameters between the groups.

Table 1: Demographic characteristics of patients and duration of surgery

	Group B (n=20) Mean (SD)	**Group R (n=20) Mean (SD)**
Age (years)	43 (7)	39 (9)
Weight (Kg)	80 (10)	78 (10)
Height (cm)	172 (8)	174 (7)
Duration of surgery(min)	60 (22)	62 (24)

Table 2: Hemodynamics in the operating room

	Group B	**Group R**
Baseline HR (beats/min)	80 ± 9 (66-94)	77 ± 14 (56-97)
Maximum HR (beats/min)	82 ± 10 (61-98)	81 ± 12 (61-97)
Minimum HR (beats/min)	70 ± 10 (56-92)	68 ± 10 (51-88)
Baseline MAP (mm Hg)	88 ± 8 (66-108)	84 ± 7 (79-101)

Table 3 shows the details of the sensory and motor block. In group R, patients were mobilized more quickly. At the postoperative follow-up, no patient had any residual neurological deficit, post-dural puncture headache, or transient neurological symptoms.

Table 3: Spinal block characteristics

Parameters	**Group B Mean ± SD**	**Group R Mean ± SD**	**P Value**
Highest sensory level (range)	T6 (T5-T8)	T6 (T5-T8)	
Time to reach peak sensory level (min)	6.54 ± 3.22	6.99 ± 1.98	0.44
Time to reach peak motor block, Grade 3 (min)	5.98 ± 1.1	6 ± 3.2	0.29

Time to sensory regression to L1 (min)	227 ± 45.45	222 ± 47.4	0.39
Time to motor regression to Grade 1 (min)	260 ± 44.4	163 ± 48.8	0.03
Duration of analgesia (min)	254.4 ± 56.7	224.2 ± 62	0.021

Table 4: Adverse Effects

Parameters	**Group B N (%)**	**Group R N (%)**	**P Value**
Nausea/vomiting	1(5%)	1(5%)	0.5
Pruritis (Hypersensitivity symptoms)	4(20%)	4(20%)	0.5
Bradycardia	2(10%)	1(5%)	0.21
Shivering	1(5%)	0(0%)	0.150
Hypotension	1(5%)	0 (0%)	0.150

DISCUSSION:

This study showed that 0.5% ropivacaine can be used as an alternative to 0.5% bupivacaine in spinal anaesthesia where less motor blockade is preferred. This finding is congruent with the studies done by Danelli et al. [15] In all the patients, sensory block to the T10 dermatome or higher was achieved and was sufficient for surgery. The time from injection to regression of sensory block below the T10 dermatome, the highest level of sensory block, the two-dermatome regression time was insignificant between the two groups. In the first 15 minutes after the start of spinal anaesthesia, there were no significant differences in heart rate or systolic and diastolic blood pressure between the groups. One patient in group B, who had the most sensory block at the T4 dermatome, developed hypotension and needed intravenous ephedrine 24 mg treatment. Hypotension was not present in any of the patients in group R. Two patients in Group B and one patient in Group R developed bradycardia. Intraoperatively, no patients required additional analgesia. The duration of analgesia was prolonged in bupivacaine group which could be due to the less lipid solubility and lesser ability of ropivacaine to penetrate the myelinated fibers. This finding has also been observed in other studies. [16,17] In a meta-analysis study, [18] the findings indicated that intrathecal ropivacaine reduces the duration of motor block and it has a similar onset of sensory block. These findings are confirmed in our study too. Wang et al. [19] have demonstrated that ropivacaine is more recommended because of its shorter duration of motor block, and lower incidence rate of side effects, which are beneficial to the recovery and also provide safety to the patients.

Conclusion:

Both bupivacaine and ropivacaine provided satisfactory anaesthetic conditions for lower limb surgeries, with fentanyl as an adjuvant according to the findings of this study. The majority of subarachnoid block characteristics were similar. Ropivacaine provided significant early motor recovery, whereas Bupivacaine provided prolonged post-operative analgesia. As ropivacaine is providing very shorter period of motor and sensory block in comparison with bupivacaine, it is more beneficial for the patients. It decreases the time of non-ambulatory phase and facilitates its use in day care surgeries too.

Abbreviations:

HR= Heart rate in beats/minute

MAP= Mean arterial pressure (mmHg)

Data are mean (SD) or number (%)

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