Original Research Article

Comparison of 0.5% levobupivacaine and 0.75% ropivacaine in spinal anaesthesia for urological surgeries - Randomised double blinded study

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Abstract

Background: bupivacaine is commonly used drug for spinal anaesthesia in urological surgeries. Levobupivacaine and Ropivacaine are comparatively newer drug with lesser side effects. Though both these drugs were widely used, their effectiveness in achieving motor blockade remains a debate. **Objective:** To evaluate the efficacy of Isobaric 0.5% Levobupivacaine and Isobaric 0.75% Ropivacaine in producing motor blockade in spinal anaesthesia in urological surgeries. **Methods:** This study was conducted in the department of Anaesthesiology in Meenakshi Medical College Hospital and Research Institute, Kanchipuram during the period of February 2017 to August 2018. A total of sixty participants undergoing urological surgical procedures with 30 participants in group A (0.5% Levobupivacaine 3ml) and another 30 participants in group B (0.75% Ropivacaine 3ml) were included in the study. Patients with in the age of 1860 years, weighing between 50100 kgs, belongs to ASA physical status I and II were included in the study. Patients who were known hypersensitivity to either Levobupivacaine and Ropivacaine, contraindicated for spinal anaesthesia, poor LV function, IHD, any degree of AV block and arrhythmias were excluded from the study. **Results:** Mean time for onset of sensory function was 5.9±1.3 minutes and 6.3±1.2 minutes in group A and B respectively. Mean time for onset of motor function after spinal anaesthesia was found to be 13.4±1.2 minutes in group A and 12.5±1.5 minutes in group B and also it was found to be statisti cally significant (p=0.031). Time for maximum sensory loss was 13.6±1.1 minutes and 12.4±1.1 minutes in group A and group B respectively and it was found to be statistically significant (0.001). Though there were minimal changes noted in pulse rate, systolic and diastolic blood pressure in both the groups, the changes were found to be statistically insignificant. Total duration of motor blockade in group A and group B was found to be 95.6±24.5 minutes and 115.3±13.3, minutes respectively. This was found to be statistically significant between the groups. Total duration of sensory blockade was found to be 89.7±16.2 minutes and 94.4±15.1 minutes in group A and group B respectively. It was found to be statistically insignificant. **Conclusion:** We concluded that Ropivacaine is comparatively better than Levobupivacaine in terms of providing motor blockade without altering the haemodynamic parameters like pulse rate, systolic and diastolic blood pressure and oxygen saturation.

Key Word: Levobupivacaine, Ropivacaine, Motor Block, Urological surgeries

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Levobupivacaine, the pure S(–) enantiomer of racemic Bupivacaine, has recently been introduced for spinal, epidural anaesthesia, peripheral nerve blocks[1] and infiltration analgesia[2]. Levobupivacaine has a lower risk of cardiovascular and CNS toxicity than Bupivacaine in both animal and human studies. It has less of a negative inotropic effect, less effect on the duration of the QRS complex and at intravenous doses in excess of 75 mg, produces less prolongation of the QTc interval and less decrease of the stroke index when compared to Bupivacaine[3,4]. Because of the low affinity to cerebral

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tissues, Levobupivacaine causes fewer changes indicative of CNS depression on EEG than Bupivacaine does[5,6]. Based on these data, Levobupivacaine seems to be a suitable alternative to racemic Bupivacaine for spinal anaesthesia or analgesia. In fact, since they share many pharmacokinetic properties, both local anaesthetics are equally effective. Ropivacaine is a longacting, amide class of local anesthetics with local anesthetic properties closely similar to those of Bupivacaine. Ropivacaine was synthesized simultaneously with Bupivacaine by afEkenstam almost 50 years ago[7] and it was first launched in 1996, being the first pure S() enantiomeric local anaesthetic to be clinically introduced. The reason for introducing Ropivacaine was the need for a long acting local anaesthetic that is lesser cardiotoxic than Bupivacaine[8,9]. Several experimental and clinical studies confirm Ropivacaine‟s lower and different toxicity profile compared to Bupivacaine[8,10]. Ropivacaine has been used for local infiltration, epidural, brachial plexus, and peripheral nerve blocks and clinical data show that Ropivacaine is also effective and safe for regional anesthesia [11]. The lipid solubility of Ropivacaine is lesser than that of Bupivacaine, which explains its somewhat lower potency compared with Bupivacaine[8]. In an equal milligram dose Ropivacaine provides a shorter duration of analgesia and a less profound motor block than Bupivacaine, especially when small concentrations are used. Spinal anesthesia with Ropivacaine is well documented in adults, [1214] and preservative free isobaric Ropivacaine 0.75% was recently approved for intrathecal administration for surgery[15]. Levobupivacaine and Bupivacaine are commonly used for spinal anaesthesia in urological surgeries. However profound myocardial depression and even cardiac arrest can occur due to accidental intravascular injection. Resuscitation from Bupivacaine induced cardiovascular collapse is difficult and may be unsuccessful. Search for a novel anaesthetic agent is going on. Ropivacaine is an effective alternative with fewer side effects. But Ropivacaine is found to produce lesser intense motor blockade than Bupivacaine. So many anaesthetists hesitate to use Ropivacaine. Many studies comparing Levobupivacaine and Ropivacaine for various modes of anaesthesia for various purposes have been done but none of the studies to our knowledge used Isobaric 0.5% Levobupivacaine and Isobaric 0.75% Ropivacaine in spinal anaesthesia for urological cases. To achieve more information on this indication, we conducted this prospective, randomized, doubleblind study to compare the adequacy and recovery profile of spinal block produced by Ropivacaine and Levobupivacaine.

METHODOLOGY

Approval was obtained for this study from the Institutional Human Ethics Committee in Meenakshi Medical College and Research Institute, Enathur, Kanchipuram. and This study was conducted in the Department of Anaesthesiology in Meenakshi Medical College and Research Institute, Enathur, Kanchipuram, This prospective, randomised, doubleblind, controlled, equivalence trial was conducted on sixty ASA grade I/II patients of either sex, aged between 18 and 60 years undergoing spinal anaesthesia for urological surgery. Patients with contraindication for spinal anaesthesia, known allergy to local anaesthetic drugs and patients having h/o neurological or musculoskeletal diseases that could make our technique difficult were excluded. The patients were randomly divided into two groups of 30 each (group A and group B) by computergenerated randomisation . Patients in group A received 3 ml Isobaric Levobupivacaine 0.5% while in group B received 3ml Isobaric Ropivacaine 0.75%. Patients had standard monitoring including electrocardiography, pulse oximetry and noninvasive blood pressure monitoring (NIBP). Baseline heart rate (HR), NIBP and arterial oxygen saturation (SpO_2) were measured. All patients received oxygen via Hudson mask at the rate of 6l/min until the surgery ends. Patients were asked to be on nil per oral at least for 6 hours before surgery. All the patients in the study group were pre medicated with Tab. Alprazolam 0.5 mg and Tab. Raniditine 150 mg on the night before surgery. Informed written consent was taken from all patients. On arrival in the operating theatre 18 gauge venous cannula was placed and 10 mL/kg of Ringer‟s lactate solution was infused, Under strict aseptic precautions, skin was infiltrated with lidocaine 2% and lumbar puncture was performed in lateral position with a 25G Quincke spinal needle, using a midline approach at the $L_{3–4}$ intervertebral space. Correct needle placement was identified by free flow of CSF and confirmed by aspiration and reinjection of CSF before and after the administration of the study drug solution. The study drug was injected over 20 s. After the injection of the spinal medication, the patients were placed supine immediately, the time of which was recorded as ‘zero’. The level of sensory block was assessed every 5min till the loss of sensation to pinprick, using a 22guage hypodermic needle with 2 mm protrusion through the guard. Assessments continued at 30 min intervals. Motor block in the lower limbs was graded according to the modified Bromage scale(Grade 0 = No motor block, Grade 1 = Inability to raise extended leg, able to move knees and feet, Grade 2 = Inability to raise extended leg and move knee, able to move feet, Grade 3 = Complete motor block of the lower limbs) . Thereafter, it was performed every 5min till the attainment of MB grade 3 followed by every 30min until complete recovery (MB grade 0). HR, NIBP and SpO_2 was

recorded before induction, every 3 min till 30 min, then, every 10 min until discharge from the recovery room. For assessment of the onset of anaesthesia, the time for sensory block to develop to T_6 , maximum block height and time to achieve maximum height were noted. To assess the duration of the sensory block, time for regression to L_1 and duration of analgesia (primary outcome) were compared. Time to achieve maximum motor block, duration of motor block along with any side effects were also noted.

RESULTS

There were no significant differences between the two groups with respect to age, weight and duration of surgery (Table 1). Mean time for onset of sensory function was 5.9±1.3 minutes and 6.3±1.2 minutes in group A and B respectively. Mean time for onset of motor function after spinal anaesthesia was found to be 13.4±1.2 minutes in group A and 12.5±1.5 minutes in group B and also it was found to be statistically significant (p=0.031). Time for maximum sensory loss was 13.6±1.1 minutes and 12.4±1.1 minutes in group A and group B respectively and it was found to be statistically significant (0.001) (Table 2). Though there were minimal changes noted in pulse rate, systolic and diastolic blood pressure in both the groups, the changes were found to be statistically insignificant. Total duration of motor blockade in group A and group B was found to be 95.6±24.5 minutes and 115.3±13.3 minutes, respectively. This was found to be statistically significant between the groups. Total duration of sensory blockade was found to be 89.7±16.2 minutes and 94.4±15.1 minutes in group A and group B respectively. It was found to be statistically insignificant.

Table 1: Mean age, weight and duration of surgery

Variable	Group A (Mean ± SD)	Group B (Mean ± SD)	p value
Age (years)	43.6±8.9	44.4±7.1	0.754
Weight (kilogram)	67.3±11.2	71.4±12.8	0.242
Duration of surgery (min)	74.7±16.2	79.4±15.1	0.296

Table 2: Duration of onset of sensory and motor loss in both groups

Variable	Group A (Mean ± SD)	Group B (Mean ± SD)	P value
Onset of sensory loss (min)	5.9±1.3	6.3±1.2	0.064
Onset of motor loss (min)	13.4±1.2	12.5±1.5	0.031*
Time for maximum loss (min)	13.6±1.1	12.4±1.1	0.001*

DISCUSSION

This study was conducted to assess the efficacy of Isobaric 0.5% Levobupivacaine and Isobaric 0.75% Ropivacaine in urological surgeries in a tertiary care hospital. In this study, mean age of the study participants was found to be 43.6±8.9 (Years) and 44.4±7.1 (Years) in group A and group B respectively. Also the mean and Standard Deviation (SD) for weight was 67.3±11.2 (Kg) in group A and 71.4±12.8 (Kg) in group B. Also the mean value for duration of surgery in group A was found to be 74.7±16.2 (min) and in group B it was 79.4±15.1 (min). In this study, mean (±SD) for onset of sensory function was 5.9±1.3 (min) and 6.3±1.2 (min) in group A and B respectively. The mean and SD value for onset of motor blockade was found to be 13.4±1.2 (min) in group A and 12.5±1.5 (min) in group B and it was found to be statistically significant. Time for maximum sensory loss was 13.6±1.1 (min) and 12.4±1.1 (min) in group A and group B respectively and it was found to be statistically significant. The motor block of Ropivacaine is less profound than that of Levobupivacaine, allowing for a better separation between sensory and motor block when the local anesthetic is given epidurally[5]. In a recent study in adults Whiteside *et al.*[17] also demonstrated that in a spinal application there is a greater degree of sensory motor separation when using Ropivacaine compared with Bupivacaine. However, further direct comparisons between these compounds are needed before any conclusions may be drawn. In contrast to our study, Malinovsky *et al.*[7]compared Ropivacaine with Bupivacaine in patients undergoing endoscopic urological surgery. Ropivacaine appeared to be less potent than Bupivacaine; inadequate intrathecal anesthesia was observed in 16% of patients with 0.2 mg/kg of Ropivacaine, whereas intensity and duration of motor blockade was not different in comparison to 0.14 mg/kg of isobaric Levobupivacaine. In contrast to this in our study Ropivacaine provided an adequate block for the proposed surgery in all patients and thus Ropivacaine appeared to be more potent than Levobupivacaine because the onset of motor block was faster and duration of motor blockade was high with Ropivacaine than with Levobupivacaine. There are several controversies still exists between the effects of Levobupivacaine and Ropivacaine like hyperbaric Levobupivacaine and racemic Bupivacaine on volunteers, Alley *et al.*[12] reported that Levobupivacaine and racemic Bupivacaine have a nearly equivalent clinical profile, and similar results have been reported by Glaser *et al.* [15] in patients undergoing total hip replacement. On the contrary,

when comparing the dose/effect relationship of hyperbaric Ropivacaine and Bupivacaine, McDonald *et al*.[7] reported a nearly 50% lower potency with Ropivacaine than Bupivacaine. However, Moizo *et al*.[11] recently reported that Levobupivacaine or Ropivacaine are acceptable alternatives to Bupivacaine when limiting spinal anesthesia at the operative side for inguinal hernia repair, but the use of a 1.5 to 1 equipotency ratio between Ropivacaine and Levobupivacaine resulted in a shorter duration of spinal anesthesia with Ropivacaine, even if this was not associated with faster home discharge. Similar results have been also reported by Danelli *et al*.[16] during spinal anesthesia for cesarean delivery. For this reason we considered both an equivalent and a supposed equipotent dose of 0.5% Levobupivacaine as compared to 0.75% Ropivacaine and the results

CONCLUSION

We concluded that Ropivacaine is comparatively better than Levobupivacaine in terms of providing motor blockade without altering the haemodynamic parameters like pulse rate, systolic and diastolic blood pressure and oxygen aturation.

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