

Effectiveness of 0.5% Levobupivacaine and 0.75 % Ropivacaine for Epidural Anesthesia for Elective Lower Limb Orthopedic Surgeries: A Retrospective Study

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Abstract

Aim: The aim of the present study was to compare the effectiveness of 0.5% Levobupivacaine and 0.75 % Ropivacaine for epidural anesthesia for elective lower limb orthopedic surgeries.

Methods: This study was performed at Shree Narayan Medical Institute and Hospital, Saharsa, Bihar, India for one year. Subjects included sixty adult patients (age between 18 and 55 years), scheduled to undergo orthopedic surgery of lower extremity. All patients were in ASA class I and II.

Results: There were male predominance and most of the patients belonged to 21-40 years of age group. In group R, the baseline mean HR was 86.34 ± 15.865 bpm. Mean HR at 0 minute, 1 minute, 3 minutes, 5 minutes and 10 minutes were 83.58 ± 9.7658 , 81.32 ± 9.200 , 78.96 ± 8.942 , 76.81 ± 9.480 , 75.30 ± 8.879 bpm respectively. In group L, the baseline mean HR was 92.14 ± 8.846 bpm. Mean HR at 0 minute, 1 minute, 3 minutes, 5 minutes, and 10 minutes were 124.62 ± 9.354 , 116.74 ± 7.556 , 113.76 ± 7.257 , 109.23 ± 6.725 , 96.63 ± 8.160 bpm respectively. In group R, the baseline SBP was 128.42 ± 12.758 mmHg. The mean SBP at 0 minute, 1 minute, 3 minutes, 5 minutes and 10 minutes were 115.32 ± 9.334 , 112.11 ± 9.006 , 105.35 ± 18.112 , 105.25 ± 10.895 , 102.90 ± 8.816 mmHg respectively. In group L, the baseline SBP was 130.00 ± 6.464 mmHg. SBP at 0 minute, 1 minute, 3 minutes, 5 minutes and 10 minutes, were 159.04 ± 4.372 , 152.36 ± 4.464 , 143.57 ± 5.645 , 138.12 ± 7.820 , 127.80 ± 6.261 mmHg respectively. In group R, the baseline DBP was 75.45 ± 4.496 mmHg. The DBP at 0 minute, 1 minute, 3 minutes, 5 minutes and 10 minutes were 81.12 ± 9.842 , 78.16 ± 8.662 , 74.76 ± 7.293 , 68.96 ± 7.690 , 72.64 ± 8.036 mmHg respectively.

Conclusion: It can be deduced from the study that for epidural anaesthesia both Levobupivacaine 0.5% and Ropivacaine 0.75% are comparable in most of their anaesthetic properties. Both these agents have been compared individually with commonly used Bupivacaine and have been found to be safe and effective alternate to Bupivacaine.

Keywords: Ropivacaine, Levobupivacaine, Epidural Anesthesia, Lower Extremity, Orthopedic.

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Introduction

Traditionally, bupivacaine has been the drug of choice for the subarachnoid block. However, significantly long duration of action delays recovery of motor function and prolongs post-anesthesia care unit stay. In addition, several studies have shown that bupivacaine produces higher neurological and cardiac toxicity compared to other local anaesthetics. [1] The problems associated with the toxicity of racemic bupivacaine triggered the development of alternative suitable 'single enantiomeric' local anesthetic agents with low cardiac and CNS toxicity. Levobupivacaine

and Ropivacaine are two relatively new amide local anesthetic agents that have been produced in order to address the issues of bupivacaine toxicity.

Levobupivacaine is a high potency, long-acting local anesthetic with a relatively slow onset of action. [2] It has a lower propensity to block inactivated sodium and potassium channels along with faster rate of dissociation compared to its racemic form. [3] The majority of in vitro, in vivo and human pharmacodynamic studies of nerve block indicate that levobupivacaine has similar potency, yet lower risk of cardiovascular and CNS

toxicity than bupivacaine. [4] So, having a higher threshold for cardiac and neurotoxicity compared to racemic bupivacaine, anesthetists feel safer working with levobupivacaine [5] and has the potential to replace bupivacaine as the standard drug. [6]

Ropivacaine is the 'S' isomer of the propyl analogue of bupivacaine with longer duration of action, low lipid solubility, low potency and low cardiovascular and CNS toxicity. [7] Ropivacaine blocks nerve fibers involved in pain transmission (A and C fibers) to a greater degree than those controlling motor function (A β fibers). [8] Therefore, ropivacaine has been found to induce less intense motor blockade than bupivacaine. Hence, its comparatively shorter duration, faster recovery of motor function and lower toxicity profile have been identified as a potential benefit for surgery of intermediate duration as well as for ambulatory surgery in day care surgical units. Epidural anesthesia is nowadays considered as the gold standard anesthetic technique for lower limb orthopedic surgeries. An epidural block is usually performed as a sole technique using local anesthetic agents or can be performed in combination with spinal or general anesthesia. Epidural anesthesia has a high success rate and patient satisfaction. [9] There is evidence for reduced blood loss and low risk of other complications in orthopedic surgeries; hence in recent years, the epidural technique has gained widespread popularity and has been well accepted by both the patient and surgeon. [10]

The aim of the present study was to compare the effectiveness of 0.5% Levobupivacaine and 0.75 % Ropivacaine for epidural anesthesia for elective lower limb orthopedic surgeries.

Materials and Methods

This study was performed at Shree Narayan Medical Institute and Hospital, Saharsa, Bihar, India for one year. Subjects included sixty adult patients (age between 18 and 55 years), scheduled to undergo orthopedic surgery of lower extremity. All patients were in ASA class I and II.

Patients with co-morbid conditions like hypertension, diabetes mellitus, ischemic heart disease and obesity with body mass index (BMI) more than 30 were excluded. Other exclusion criteria were pregnancy, emergency surgery, height less than 150 cm and more than 180 cm, raised intracranial pressure, severe hypovolemia, coagulopathy and local infection. After an informed consent was taken, patients were divided into two groups, each comprising 50 patients, using a computerized model to randomize.

Injection Ropivacaine 0.75% - Group R (n=50)
Injection Levobupivacaine 0.5% - Group L (n=50)

Pre-anesthetic examination on the evening before surgery assessed history and general condition of the patient, airway Mallampati grading, nutritional status, height and weight, detailed examination of the Cardiovascular, Respiratory and Central nervous systems and examination of the spine. Investigations done in all patients were hemogram, routine examination of urine, standard 12-lead electrocardiogram, random blood sugar, blood urea and serum creatinine and coagulation profile. An anxiolytic (Alprazolam 0.5 mg) and an H₂ receptor blocker (Ranitidine) were given as premedicate and patients kept fasting overnight. Basal hemodynamic parameters (pulse and blood pressure) were noted preoperatively. Patients were given 1.0 mg of injection Midazolam and preloaded with half a liter of Ringer's Lactate before epidural anesthesia. Basal hemodynamic parameters (pulse and blood pressure) were noted preoperatively. Patient was connected to a multiparameter monitor to record oxygen saturation (SPO₂) and blood pressure (systolic-SBP, diastolic-DBP and mean-MAP). Under asepsis, midline approach was used to enter epidural space through second and third lumbar interspinous space using loss of resistance method. The space was catheterized and tested by a solution of lignocaine-adrenaline. First dose of study drug (5.0 ml) was injected with patient in sitting position, patients were shifted to supine position after one minute and remaining 10 ml of the drug was given. Drugs were prepared and administered by an anesthetist blinded to study. Blockade parameters (motor and sensory) were noted at one minute interval after injection. Time taken to reach block and maximum level achieved were noted. A fine needle (22 gauge) was used to assess blockade of pain. Bromage scale was the criteria for motor block assessment (0 – Able to perform a full straight leg raise over bed for 5 sec, 1– Unable to perform leg raise but able to flex knee, 2– Unable to flex the knee but can flex ankle, 3 – Unable to flex ankle but can move toes, 4 – Unable to move toes i.e total paralysis)4 Hemodynamic and respiratory (rate and oxygen saturation) parameters were recorded at regular intervals. Intraoperative and postoperative complications like decreasing blood pressure, variation in heart rate were noted and treated as required. Intervention (injection Mephentermine, fluid infusion) was done if systolic blood pressure fell below 90 millimeters of mercury, or there was a fall of more than 30% from preoperative level. Atropine was used to treat bradycardia. Postoperatively, time elapsed till patients complained of pain at surgical site (analgesia duration) was noted and pain relieved by epidural injection. Time taken for complete recovery of motor power was noted. Record was made of time taken to achieve loss of pin prick sensation at L1 (onset of sensory block) and also time taken to attain highest sensory block. For

motor blockade, time taken to attain Bromage scale 1 was taken as onset and Bromage scale 4 as time taken for maximum motor block. Return of patients motor power to Bromage zero was noted as duration of motor block. SPSS version 15.0 was used for statistical analysis. Quantitative variables in both the groups were expressed as mean \pm sd and compared using unpaired t-test between groups and paired t-test within each group (comparison with

baseline values) at follow-up. The qualitative variables were expressed as frequencies/percentages and subjected to Chi-square test. P-value of less than 0.01 was taken as highly significant and more than 0.05 as non significant. Values less than 0.05 were considered as statistically significant.

Results

Table 1: Demographic data

Parameters	Group R	Group L
Gender		
Male	38	40
Female	12	10
Age groups in years		
<20	2	4
21-30	18	17
31-40	16	12
41-50	10	10
>50	4	7

There were male predominance and most of the patients belonged to 21-40 years of age group.

Table 2: Comparison between the groups according to Heart Rate (bpm)

Heart Rate bpm	Group R	Group L
Baseline	86.34 \pm 15.865	92.14 \pm 8.846
0 minute	83.58 \pm 9.7658	124.62 \pm 9.354
1 minute	81.32 \pm 9.200	116.74 \pm 7.556
3 minutes	78.96 \pm 8.942	113.76 \pm 7.257
5 minutes	81 \pm 9.480	109.23 \pm 6.725
10 minutes	75.30 \pm 8.879	96.63 \pm 8.160

In group R, the baseline mean HR was 86.34 \pm 15.865 bpm. Mean HR at 0 minute, 1 minute, 3 minutes, 5 minutes and 10 minutes were 83.58 \pm 9.7658, 81.32 \pm 9.200, 78.96 \pm 8.942, 76. 81 \pm 9.480, 75.30 \pm 8.879 bpm respectively. In group L, the

baseline mean HR was 92.14 \pm 8.846 bpm. Mean HR at 0 minute, 1 minute, 3 minutes, 5 minutes, and 10 minutes were 124.62 \pm 9.354, 116.74 \pm 7.556, 113.76 \pm 7.257, 109.23 \pm 6.725, 96.63 \pm 8.160 bpm respectively.

Table 3: Comparison between the groups according to Systolic BP (mmHg)

SBP	Group R	Group L
Baseline	128.42 \pm 12.758	130.00 \pm 6.464
0 minute	115.32 \pm 9.334	159.04 \pm 4.372,
1 minute	112.11 \pm 9.006	152.36 \pm 4.464
3 minutes	105.35 \pm 18.112	143.57 \pm 5.645
5 minutes	105.25 \pm 10.895	138.12 \pm 7.820
10 minutes	102.90 \pm 8.816	127.80 \pm 6.261

In group R, the baseline SBP was 128.42 \pm 12.758 mmHg. The mean SBP at 0 minute, 1 minute, 3 minutes, 5 minutes and 10 minutes were 115.32 \pm 9.334, 112.11 \pm 9.006, 105.35 \pm 18.112, 105.25 \pm 10.895, 102.90 \pm 8.816 mmHg respectively.

In group L, the baseline SBP was 130.00 \pm 6.464 mmHg. SBP at 0 minute, 1 minute, 3 minutes, 5 minutes and 10 minutes, were 159.04 \pm 4.372, 152.36 \pm 4.464, 143.57 \pm 5.645, 138.12 \pm 7.820, 127.80 \pm 6.261 mmHg respectively.

Table 4: Comparison between the groups according to Diastolic BP (mmHg)

DBP	Group R	Group L
Baseline	75.45 \pm 4.496	79.41 \pm 6.254
0 minute	81.12 \pm 9.842	98.42 \pm 4.432
1 minute	78.16 \pm 8.662	97.33 \pm 4.936
3 minutes	74.76 \pm 7.293	93.06 \pm 5.284
5 minutes	68.96 \pm 7.690	87.48 \pm 7.263
10 minutes	72.64 \pm 8.036	78.06 \pm 6.832

In group R, the baseline DBP was 75.45 ± 4.496 mmHg. The DBP at 0 minute, 1 minute, 3 minutes, 5 minutes and 10 minutes were 81.12 ± 9.842 , 78.16 ± 8.662 , 74.76 ± 7.293 , 68.96 ± 7.690 , 72.64 ± 8.036 mmHg respectively. In group L, the baseline DBP was 79.41 ± 6.254 mmHg. DBP at 0 minute, 1 minute, 3 minutes, 5 minutes and 10 minutes were 98.42 ± 4.432 , 97.33 ± 4.936 , 93.06 ± 5.284 , 87.48 ± 7.263 , 78.06 ± 6.832 mmHg respectively.

Discussion

Regional anesthesia has lot of advantages over general anesthesia (GA) for lower limb orthopedic surgeries. [11] Epidural anesthesia is preferred technique [12] as it overcomes the limitations of intrathecal anesthesia such as less duration, rapid sympatholytic, non-extendable, short analgesia duration and spinal headache. Lignocaine and Bupivacaine have been the most commonly used agents for this technique. Duration of anesthesia with Lignocaine is intermediate whereas Bupivacaine can cause severe central nervous system (CNS) and cardiac side effects after inadvertent intravascular injection. Ropivacaine and Levobupivacaine have only recently started to be used in epidural anesthesia, with better therapeutic index. [13]

There were male predominance and most of the patients belonged to 21-40 years of age group. Study groups were similar with respect to demographic parameters. Study conducted by Peduto et al [14] also showed no statistically significant difference in onset of sensory block the times being 29 ± 24 min. and 25 ± 22 min. with Levobupivacaine and Ropivacaine respectively. In variance to our study, their patients depicted more time was taken in all subjects for sensory block onset, irrespective of the drug used, as they assessed absence of pain to pin prick at T10 in contrast to L1 in our study. Various studies comparing Bupivacaine with either RS Bupivacaine or Ropivacaine also did not find significant difference in sensory block onset time. [15-17]

In group R, the baseline mean HR was 86.34 ± 15.865 bpm. Mean HR at 0 minute, 1 minute, 3 minutes, 5 minutes and 10 minutes were 83.58 ± 9.7658 , 81.32 ± 9.200 , 78.96 ± 8.942 , 76.81 ± 9.480 , 75.30 ± 8.879 bpm respectively. In group L, the baseline mean HR was 92.14 ± 8.846 bpm. Mean HR at 0 minute, 1 minute, 3 minutes, 5 minutes, and 10 minutes were 124.62 ± 9.354 , 116.74 ± 7.556 , 113.76 ± 7.257 , 109.23 ± 6.725 , 96.63 ± 8.160 bpm respectively. In group R, the baseline SBP was 128.42 ± 12.758 mmHg. The mean SBP at 0 minute, 1 minute, 3 minutes, 5 minutes and 10 minutes were 115.32 ± 9.334 , 112.11 ± 9.006 , 105.35 ± 18.112 , 105.25 ± 10.895 , 102.90 ± 8.816 mmHg respectively. In group L, the baseline SBP

was 130.00 ± 6.464 mmHg. SBP at 0 minute, 1 minute, 3 minutes, 5 minutes and 10 minutes, were 159.04 ± 4.372 , 152.36 ± 4.464 , 143.57 ± 5.645 , 138.12 ± 7.820 , 127.80 ± 6.261 mmHg respectively. In group R, the baseline DBP was 75.45 ± 4.496 mmHg. The DBP at 0 minute, 1 minute, 3 minutes, 5 minutes and 10 minutes were 81.12 ± 9.842 , 78.16 ± 8.662 , 74.76 ± 7.293 , 68.96 ± 7.690 , 72.64 ± 8.036 mmHg respectively. In group L, the baseline DBP was 79.41 ± 6.254 mmHg. DBP at 0 minute, 1 minute, 3 minutes, 5 minutes and 10 minutes were 98.42 ± 4.432 , 97.33 ± 4.936 , 93.06 ± 5.284 , 87.48 ± 7.263 , 78.06 ± 6.832 mmHg respectively. Thompson GE et al [18] showed significantly higher duration of analgesia (6.5 ± 0.4 hours, 8.1 ± 0.89 hours, 6.6 ± 2.0 hours respectively) which could be because of higher volume (20 ml in contrast to 15 ml in our study) of drugs used in their studies. Brockway MS et al¹⁵ showed 272 mins as duration of analgesia while using 0.75% Ropivacaine, which is comparable with present study. Supplemental analgesia was required in 4 patients of Ropivacaine group and 5 patients in Levobupivacaine group, not different statistically. In a study by Peduto et al [14], supplemental analgesia was required in 1 patient receiving Levobupivacaine and in 2 patients receiving Ropivacaine (p value = 0.99) which compares with our study.

Conclusion

It can be deduced from the study that for epidural anesthesia both Levobupivacaine 0.5% and Ropivacaine 0.75% are comparable in most of their anesthetic properties. Both these agents have been compared individually with commonly used Bupivacaine and have been found to be safe and effective alternate to Bupivacaine. A finding that has emerged from this study is the Levobupivacaine produces a faster, longer lasting and more profound motor blockade/paralysis than Ropivacaine. With all other properties being similar, it can be postulated that Levobupivacaine may be better for patients in whom extensive osteo-muscular.

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