Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

Comparison of Efficacy and Safety of Epidural 0.5% Bupivacaine and 0.5% Ropivacaine in Lower Extremities Surgery: A Prospective and Randomized Study

K Venkatesan[1], R Nandhikaa[2], A Arunsundar[3]

[1]Assistant Professor, Department of Anesthesiology and Critical Care, Government Villupuram Medical College, Viluppuram, Tamil Nadu, India, [2]Junior Resident, Department of Anesthesiology and Critical Care, Government Villupuram Medical College, Viluppuram, Tamil Nadu, India, [3]Associate Professor, Department of Anesthesiology and Critical Care, Government Villupuram Medical College, Viluppuram, Tamil Nadu, India

Abstract

Introduction: Epidural anesthesia is the anesthesia of choice in various surgeries where in general or spinal anesthesia carries a risk. It is a type of regional anesthesia in which spinal nerves are blocked in the epidural space as they emerge from Dura. Epidural techniques are widely used for operative anesthesia, obstetric analgesia, post-operative pain control, and chronic pain management.

Aim: The aim of the study was to compare the efficacy and safety between epidural bupivacaine and ropivacaine for lower extremities surgery.

Materials and Methods: Patients were divided into two groups, Group R – 20 ml of 0.5% ropivacaine and Group B – 20 ml of 0.5% bupivacaine. Continuously SpO_2, respiratory rate, and heart rate were monitored. Hemodynamic variables such as systolic blood pressure, diastolic blood pressure, mean arterial pressure, and pulse rate were recorded for 120 min.

Results: Ropivacaine group shows lesser motor blockade with a mean of 217.419 min than bupivacaine. The ropivacaine group shows lesser sensory blockade with a mean of 240.968 min than bupivacaine. The comparison of both the groups showed that no major differences in regression of blockade though ropivacaine showed earlier regression than bupivacaine. The ropivacaine group had less similar episodes of hypotension and was managed adequately with fluids.

Conclusion: The efficacy of both drugs, ropivacaine, has shown promising results of shorter duration of action, lesser hemodynamic effects on the cardiovascular system, and no significant change in the quality of anesthesia than bupivacaine.

Key words: Bupivacaine, Epidural anaesthesia, Lower limb surgeries, Ropivacaine

INTRODUCTION

An epidural anesthetic and analgesic technique is central neuraxial anesthesia, which involves injecting drugs and the epidural space, causing a reversible block of sensory and motor functions.[1] The most of the abdominal and lower limb surgeries are based on regional anesthetic techniques. It provides a hemodynamically stable operative course with effective pain management and chronic pain relief.[2]

The epidural is advantageous over other regional techniques as it is a reliable form of anesthesia that provides excellent operating conditions. It renders the ability to administer additional local anesthetics with increasing duration of surgery, and also we can use the catheter for effective post-operative analgesia.[1]

This study uses the bupivacaine and ropivacaine in the same concentration to assess their efficacy and safety, as

Access this article online

www.ijss-sn.com

Month of Submission : 04-2022
Month of Peer Review : 05-2022
Month of Acceptance : 05-2022
Month of Publishing : 06-2022

Corresponding Author: Dr. A Arunsundar, Department of Anesthesiology and Critical Care, Government Villupuram Medical College, Viluppuram, Tamil Nadu, India.

both are long-acting local anesthetics.[3] The use of both the drugs is preservative free and approved by FDA and can be safely used in epidural anesthesia and analgesia technique. No additives were added in this study, and since they are long-acting, we have chosen the proposed anesthesia of choice for the procedure.[4]

Aim

The aim of the study was to compare the efficacy and safety between epidural bupivacaine and ropivacaine for lower extremities surgery.

MATERIALS AND METHODS

This prospective and randomized clinical trial comprised 60 patients who were scheduled to have lower extremity surgery at Government Villupuram Medical College. Patients were enrolled between December 2019 and August 2020 after written informed permission. The study was carried out after the Institutional Ethics Committee had approved it.

Inclusion Criteria

Patients of either sex, age between 18 and 65 years, weight 50–70 kg, patients with American Society of Anesthesiologists Physical Status Class I and II were included in the study.

Exclusion Criteria

Patient refusal, patients with American Society of Anesthesiologists Physical Status Class III and Class IV, patient age <18 years, clinical conditions contraindicated to regional anesthesia such as coagulopathy, patients taking anticoagulants therapy, neurological and musculoskeletal disorder, skin infection in the lumbar area, allergy or intolerance to local anesthetic para-aminobenzoic acid, and atypical plasma cholinesterase were excluded from the study.

The sample size is calculated as 30 patients in each group, a total of 60 patients to ensure the power of 90% and 0.05 alpha error with a confidence interval of 95% for detecting a difference of at least 20% in the duration of the blockade, and a contingency of 10% is also considered.

Patients were divided into two groups, Group R – 20 ml of 0.5% ropivacaine and Group B – 20 ml of 0.5% bupivacaine.

Pre-aesthetic Evaluation

History was noted, including associated comorbidities, previous surgeries, medication, and drug allergies. General and systemic examinations were performed. Height, weight, pulse rate, blood pressure, and oxygen saturation were recorded. In addition, routine baseline investigations such as complete blood count, blood urea nitrogen and serum creatinine, random blood sugar, electrocardiogram, and chest X-ray were carried out.

Pre-operative Preparation

Patients were instructed overnight fast for 6 h. Pre-medicated with tablet ranitidine 150 mg and tablet alprazolam 0.5 mg. Informed consent was obtained from all patients in written format. The sensory and motor assessment methods were well explained to the patient.

During surgery, the patient's blood pressure, electrocardiogram, and pulse oximetry were recorded every 3 min for the first 15 min, then every 5 min till 30 min, and every 15 min for 120 min. Hypotension was treated with Ephedrine 3 mg IV injection in incremental doses if systolic blood pressure (SBP) falls >20% from the baseline value. Bradycardia was treated as heart rate <50 beats/min with Atropine 0.6 mg IV injection. The observer was instructed to assess the sensory and motor blockade for every 3 min during the initial 15 min period and after the surgical procedure. Therefore, the time of completion of epidural drug injection was considered zero time. The time to readiness for surgery was assessed as the time interval between local anesthetic injection and the onset of complete loss of pinprick sensation in the anterior axillary line bilaterally at the T10 level. Other sensory blockade parameters observed were maximum sensory block height, time to reach maximum block height, time taken for regression to L1, and time taken for complete regression of sensory block.

After data collection, it will be entered in MS Excel. As a result, it will contain both categorical and continuous data; for categorical variables, the Chi-square test or Fischer test and for continuous variables Independent *t*-test will be used. The analysis shall be done using SPSS statistical software. $P < 0.05$ is considered significant.

RESULTS

The majority of patients were between 30 and 50 years (43.3%). About 40% of patients were <30 years, and 16.7% of patients were >50 years. The mean and standard deviation of age in years is 36.4 ± 12.092. The median age in years is 36.5 and the range is 40 (19–59). The maximum numbers of patients were male 55% and 45% of patients were female. Out of 60 patients, the majority were in ropivacaine group 51.7% and 48.3% of patients were in the bupivacaine group [Table 1]. The mean age of Group B patients was 37.55 ± 12 years, and in Group R, 35.32 ± 12.28 years. There is no statistically significant difference in age between

groups $P = 0.480$. The mean height of Group B patients was 159.52 ± 7.36 cm and in Group R 160.65 ± 5.41 cm. There is no statistically significant difference in height between groups $P = 0.499$. The mean weight of Group B patients was 65.21 ± 7.35 kg and in Group R 64.61 ± 8.63 kg. There is no statistically significant difference in kgs between groups $P = 0.776$ [Table 2]. There is no significant difference in PR values between groups [Figure 1]. There is no significant difference in SBP values between groups [Figure 2]. There is no significant difference in diastolic blood pressure values between groups [Figure 3]. There is no significant difference in SPO_2 values between groups [Figure 4]. The hemodynamic parameters for both the groups interpreted are the variation in blood pressure significantly lowered in 10 min and 15 min which was effectively managed by vasopressors and fluids. This is seen more with the bupivacaine group than the ropivacaine group.

The mean duration of motor blockade concerning the group ($t = 2.194$, $P = 0.032$). The ropivacaine group shows lesser motor blockade with a mean of 217.419 min than bupivacaine. The mean duration of sensory blockade concerning the group ($t = 1.869$, $P = 0.067$). The ropivacaine group shows lesser sensory blockade with a mean of 240.968 min than bupivacaine. Mean of time for regression of blockade concerning the group ($t = 1.566$, $P = 0.123$). The comparison of both the groups showed that no major differences in regression of blockade though ropivacaine showed earlier regression than bupivacaine [Table 3]. Therefore, the requirement of rescue analgesia was not needed in both groups for the completion of the procedure. The intraoperative complication found is hypotension. That is more significant with the bupivacaine group, which is effectively managed by vasopressors. The ropivacaine group had less similar episodes of hypotension and was managed adequately with fluids.

Table 1: Distribution of patient characteristics

Patient characteristics	No. of Cases	Percentage
Age group		
<30	24	40
31–50	26	43.30
>51	10	16.70
Gender		
Male	33	55
Female	27	45
ASA		
I	30	50
II	30	50
Group		
Bupivacaine	29	48.30
Ropivacaine	31	51.70

Table 2: Comparison of patient characteristics

Patient characteristics	Bupivacaine		Ropivacaine		*P*-value
	Mean	SD	Mean	SD	
Age	37.55	12.00	35.32	12.28	0.480
Height	159.52	7.36	160.65	5.40	0.499
Weight	65.21	7.35	64.61	8.63	0.776

Table 3: Comparison of blockade between groups

Patient characteristics	Bupivacaine		Ropivacaine		*P*-value
	Mean	SD	Mean	SD	
Duration of Motor Blockade	234.66	32.68	217.42	28.13	0.032
Duration of Sensory Blockade	255.86	36.21	240.97	24.81	0.067
Regression of Blockade	206.72	29.53	194.52	30.75	0.123

DISCUSSION

Choosing epidural aims to have a wise knowledge about the technique and provide post-operative analgesia. This study was a prospective, randomized, controlled, and clinical study that evaluated the clinical efficacy and safety of 0.5% bupivacaine and 0.5% ropivacaine when given epidural anesthesia.

In our study, both the groups were comparable in age, sex, height, weight, ASA physical status, and type of surgery. In addition, there was no significant difference between the two groups.

This study uses both ropivacaine and bupivacaine at 0.5% of 20 ml to assess their efficacy in the epidural. Using both drugs in the same volume and concentration will produce effective results without affecting the statistical analysis. McGlade *et al.*[5] found that comparing both the drugs at the same concentration assessed their efficacy and safety.

The mean maximum sensory level reached in the present study was T8 in both groups, with the volume administered. Finucane *et al.*[6] found that the onset time for the sensory block to T12 was shorter when compared to the 0.5% bupivacaine group.

This study had a longer duration of sensory blockade with bupivacaine than with ropivacaine. Both groups showed sensory blockade with a mean of 240.968 min. The time of onset of the sensory block between the two groups was not statistically significant ($t = 2.194$, $P = 0.032$). Kerkkamp and Brown *et al.*[3,7] found a longer duration of the sensory block with bupivacaine.

This study showed a slower onset of ropivacaine than other groups. The motor block's onset time between the two

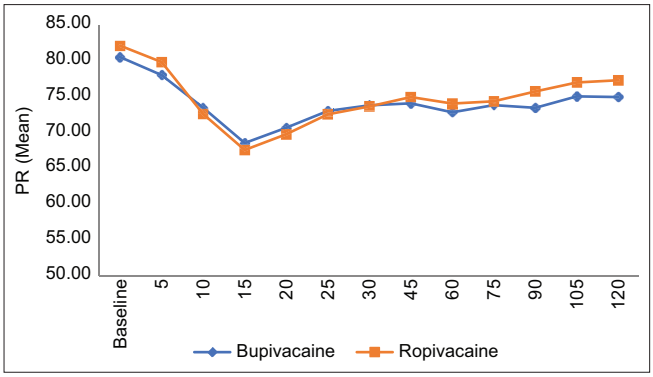

Figure 1: Comparison of PR between groups

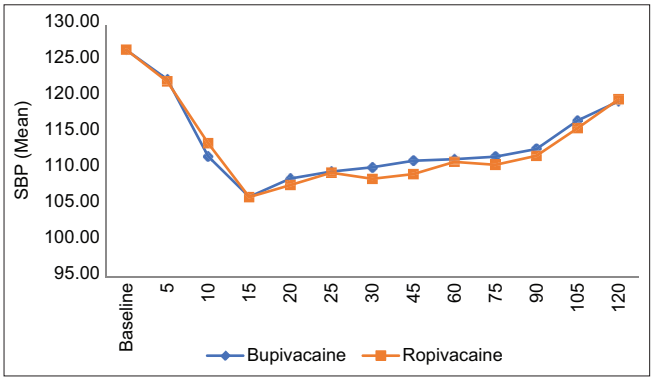

Figure 2: Comparison of systolic blood pressure between groups

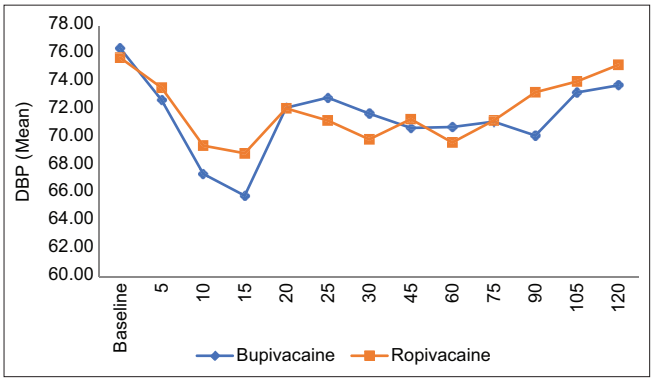

Figure 3: Comparison of diastolic blood pressure between groups

groups was statistically significant ($t = 2.194$, $P = 0.032$). The Ropivacaine group showed lesser motor blockade with a mean of 217.419 min than bupivacaine. Brockway *et al.*[8] showed that motor block produced by ropivacaine was slower in onset in the 0.75% ropivacaine group and also had a shorter duration of action.

This study showed no significant difference in the mean time for regression of blockade concerning the group ($t = 1.566$, $P = 0.123$). Although this study has no statistical

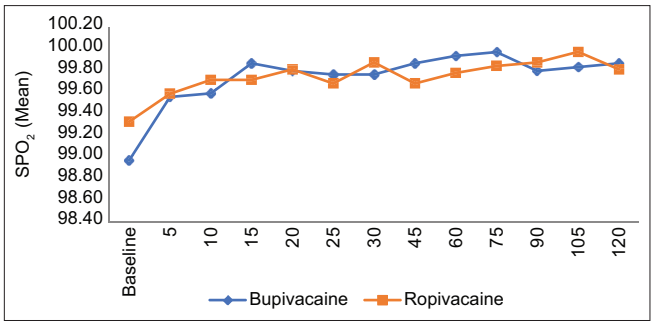

Figure 4: Comparison of SPO_2 between groups

difference, ropivacaine showed earlier regression than bupivacaine.

Our study concluded that both groups showed a fall in blood pressure at 10 min and it was lesser with the ropivacaine group, and there was no need for vasopressors in the bupivacaine group. Furthermore, the Chi-square test showed no significant difference between the groups ($P = 0.185$).

Zaric *et al.*[9] showed no significant changes in pulse rate, systolic and diastolic pressure, and mean arterial pressure between the two groups in the present study. In addition, there were no differences among groups in effective analgesia and patient satisfaction with analgesia in our study.

In our study, both groups showed no post-operative complications. Furthermore, Brockway *et al.*[8] showed no post-operative sequelae such as headache, backache, nausea, and vomiting for the next 24 h.

CONCLUSION

Our finding implies that comparing the efficacy of both drugs; ropivacaine has shown promising results of shorter duration of action, lesser hemodynamic effects on the cardiovascular system, and no significant change in the quality of anesthesia than bupivacaine.

REFERENCES

1. Hernandez AN, Singh P. Epidural Anesthesia. Treasure Island. FL: StatPearls Publishing; 2022.
2. Folino TB, Mahboobi SK. Regional Anesthetic Blocks. Treasure Island. FL: StatPearls Publishing; 2022.
3. Brown DL, Carpenter RL, Thompson GE. Comparison of 0.5% ropivacaine and 0.5% bupivacaine for epidural anesthesia in patients undergoing lower extremity surgery. Anesthesiology 1990;72:633-6.
4. Albright GA. Cardiac arrest following regional anesthesia with etidocaine or bupivacaine. Anesthesiology 1979;51:285-7.
5. McGlade JH. Ropivacaine. Br J Anaesth 1996;76:300-7.
6. Finucane BT, Sandler AN, McKenna J, Reid D, Milner AL, Friedlander M,

et al. A double blind comparison of ropivacaine 0.5%, 0.75%, 1% and bupivacaine 0.5%, injected epidurally, in patients undergoing abdominal hysterectomy. Can J Anaesth 1996;43:442-9.
7. Kerkkamp HE, Gielen MJ, Edstrom HH. Comparison of0.75% ropivacaine with epinephrine and 0.75% bupivacaine with epinephrine in lumbar epidural anesthesia. Reg Anesth 1990;15:204-7.
8. Brockway MS, Bannister J, McClure JH, McKeown D, Wildsmith JA. Comparison of extradural ropivacaine and bupivacaine. Br J Anaesth 1991;66:31-7.
9. Zaric D, Axelsson K, Nydahl PA, Philipsson L, Larsson P, Jansson JR. Sensory and motor blockade during epidural analgesia with 1%, 0.75%, and 0.5% ropivacaine-a double-blind study. Anesth Analg 1991;72:509-15.

How to cite this article: Venkatesan K, Nandhikaa R, Arunsundar A. Comparison of Efficacy and Safety of Epidural 0.5% Bupivacaine and 0.5% Ropivacaine in Lower Extremities Surgery: A Prospective and Randomized Study. Int J Sci Stud 2022;10(3):119-123.

Source of Support: Nil, **Conflicts of Interest:** None declared.