

# Epidural Ropivacaine 0.75% vs Bupivacaine 0.5% for Surgical Anaesthesia, in Patients Undergoing Inguinal Hernioplasty

Jyoti Joshi<sup>1</sup>, Ahijit Banerjee<sup>1</sup>, Amita Jain<sup>2</sup>

<sup>1</sup>Anaesthesiologist, Department of Anaesthesiology,

<sup>2</sup>Trauma Surgeon, Department of Surgery, Base Hospital Delhi Cantt, Delhi, India

## Abstract

Bupivacaine first synthesized in 1957 has acceptance in virtually every area of local anesthetic practice like intrathecal, epidural, nerve blocks as well as post-op pain relief. Ropivacaine is a long-acting regional anaesthetic that is structurally related to Bupivacaine. It is a pure S (-) enantiomer, unlike Bupivacaine, which is a racemate, developed for the purpose of reducing its potential toxicity and improving relative sensory and motor block profiles. Both drugs are being used for epidural anesthesia. The aim of this study is to compare the efficacy of epidural ropivacaine 0.75% versus bupivacaine 0.5% for surgical anaesthesia. The objectives of the study were to compare the onset of anaesthesia, post-op pain, quality of sensory and motor blockade and side effects in the two groups after administering a single bolus epidural injection of the study drug. Study was carried out on 60 male patients who underwent inguinal hernioplasty. Both drugs produced similar sensory block profile. A faster onset of motor block was observed in the Bupivacaine group. Adverse effects in two groups were similar. Both drugs produced similar degree of post-operative pain relief.

**Key words:** Bupivacaine, Ropivacaine, Epidural Anaesthesia, Post-operative Analgesia, Inguinal Hernioplasty

## Introduction

Clinicians are primarily interested in local anaesthetics with a rapid onset of action, good penetration, a reasonable duration of action and a low potential for toxicity. In the surgical setting, one would prefer a local anaesthetic which had a rapid onset of action, good penetration, and a reasonable duration of action. If profound relaxation was required, a local anaesthetic which had a predilection for blocking motor fibres would be preferred. In most instances, the selection can be tailored to the needs of the individual patient.

Bupivacaine, was synthesized and introduced into clinical practice in 1963, and it has proved to be a very effective long-acting local anaesthetic agent. Bupivacaine had been used clinically for almost 20 years before Albright brought to notice the problem of its cardiotoxicity [1].

Ropivacaine, although structurally similar to bupivacaine and mepivacaine, is an isomer, the active ingredient of which is the (S) enantiomer of Iso propyl - 2', 6' pipercoloxylidine [2]. Its physical and chemical profile is similar to that of bupivacaine. In equipotent

concentrations the degree of motor blockade is less pronounced with ropivacaine and there is a greater propensity for blocking A $\sim$  and C fibres. So it may prove to be advantageous in obstetric patients in labour and in others suffering from acute and chronic pain. Moreover, it appears to have most of the blocking characteristics of bupivacaine without the cardiotoxic effects. Also, the potential for CNS toxicity appears to be less with Ropivacaine [3]. These purported safety profiles also provide justification for using ropivacaine in neuraxial anaesthesia.

## Material and Methods

The study was commenced after taking approval of the Ethics Committee of the institution. Written informed consent was obtained from all patients. Sixty male patients in ASA physical status I or II participated in this randomized, double-blind study. All were posted for mesh hernioplasty and were aged between 30 to 50 years. Their body weight ranged from 50 kg to 70 kg and height between 160 to 170 cm. Patients having contraindications to central neuraxial blocks, like spinal deformities, patient refusal etc, were excluded from the study. Those patients having communication difficulties were also excluded. Patients were fasted for 8 h prior to surgery. On the night before surgery, ranitidine 150 mg, and diazepam 5 mg were given by the oral route. They were preloaded with 10-15ml/kg of Ringer lactate solution half an hour before surgery in the pre-op room. They were then allocated randomly using a

## Address for Correspondence

Dr. Ahijit Banerjee, Anaesthesiologist, Department of Anaesthesiology,  
Base Hospital Delhi Cantt, Mobile No +919910492535  
E-Mail : hishighness.banerjee@gmail.com

Received: January 2021  
Accepted: February 2021

computer-generated random numbers table to receive epidural anaesthesia using either 15 ml of 0.75% ropivacaine (Group R) or 15 ml of 0.5% bupivacaine (Group B). An operating room assistant helped in preparation of the study drug. The anaesthesiologist, surgeon and other staff involved in the surgery and anaesthesia were blinded to the study group (Group 'B' / Group 'R').

In the sitting position the patient was cleaned and draped. The interspinous space at L3 – L4 was identified by palpation method and local anaesthetic infiltration was given. Using all aseptic precautions, an 18 G Tuohy needle was inserted in the cephalad direction, and the epidural space was identified by loss of resistance to air. After confirming negative aspiration for CSF and blood, a 3 ml test dose of 2% lignocaine with adrenaline was given over 15 sec. if there were no untoward effects within three minutes, the main dose of 15 ml of the study drug was injected over two minutes.

Sensory block was assessed using sensation to cold stimulus with ice cube. Surgery was not started until anaesthesia to cold with ice cube was achieved bilaterally upto T<sub>10</sub> level.

Onset of sensory block was taken as the time taken after the injection of study drug till the block reached T<sub>10</sub> level. Sensory level was checked at 5-minute interval from the injection of study drug till block reached T<sub>10</sub> dermatomal level.

Additional 5 ml of the study drug was given if the sensory block did not reach T<sub>10</sub> level within 30 minutes. Beyond that if the surgical anaesthesia was still not achieved, then patient was withdrawn from the study and surgery was carried out using anaesthetic technique at the discretion of the anaesthesiologist.

Spo<sub>2</sub>, ECG, Respiratory rate, Temperature and Non-Invasive Blood Pressure were recorded at intervals of 5 minutes from the beginning of surgery till the surgery was completed.

A fall in the Mean Arterial Pressure by 20 percent or more of the baseline was identified as hypotension requiring intervention, for which a bolus of 3 mg mephentermine was given along with increase in rate of Ringers lactate infusion. A heart-rate below 50 per minute was considered as Bradycardia for which 0.6 mg inj atropine was given intravenously.

After giving main bolus of the study drug, sensory and motor block were checked at every 5 minute interval upto 30 minutes. Surgery was allowed to proceed once the sensory block reached T<sub>10</sub> level, which was taken as the time of onset of sensory anaesthesia for the purpose of this study.

Modified Bromage Scale as given below was used to assess motor block:

Extent of Weakness	Grade
No weakness	0
Unable to raise extended leg	1
Unable to flex knee	2
No movement at any joint in leg	3 (Significant block)

Grade 3 block was considered as significant block. Adverse events such as nausea, vomiting, shivering, bradycardia and hypotension were recorded.

Patient's post-operative pain status was assessed using Visual Analogue Scale (VAS) (0 - no pain to 10 -max pain). Patients were offered analgesic in the form of injection diclofenac when VAS score was more than 3. Duration of analgesia was taken from the time of onset of sensory block to the time when VAS score exceeded 3.

### Statistical Analysis

To estimate sample size we did a pilot study before starting the main study. A sample size of 27 subjects in each group was required at  $\alpha = 0.05$ , and power of 90%. Continuous variables were presented as the mean  $\pm$  SD and categorical variables were presented as frequencies (percentage of patients). Statistical analysis were performed using the SPSS software. Difference between groups were assessed by X<sup>2</sup> test. A t-test used to compare two groups. P value < 0.05 was considered as statistically significant.

### Result

A total number 30 patients each in Group were enrolled for the study. No patients needed to be withdrawn from this study in either of the groups. There was no incidence of any dural puncture.

Table 1 shows the demographic profile of patients in the two groups undergoing hernioplasty the two groups were comparable in terms of age, body weight and height. In the Bupivacaine group (group B) age of patients was between 30 to 45 years. Mean  $\pm$  SEM was 37.1  $\pm$  0.51 (95% confidence interval 36.0-38). In the Ropivacaine group (group R) age of patients was in the range of 30 to 45 years, with mean + SEM of was 38.0  $\pm$  0.54 and 95% confidence interval of 36-39.1. Students t test was used for statistical analysis which indicated that there was no difference between the two age groups (t=1.21, df=58).

Body weight of the patients in bupivacaine group (group B) and ropivacaine group (group R) was 65.16  $\pm$  0.59 (mean  $\pm$  SEM) (95% CI=63.96-66.37) and 66.43  $\pm$  0.60 (mean  $\pm$  SEM) (95% CI=65.20-67.69) respectively and did not differ statistically (t=1.5; p=0.14; df=58).

Similarly, the height of patients in bupivacaine group (group B) and ropivacaine group (group R) was similar (t=0.61; p=0.54; df=58). In group B, the height was in the range of

**Table 1: Demographic profile of the patients undergoing hernioplasty (values expressed in mean±SEM)**

Parameter	Group R	Group B	P
Age (Yrs)	38±0.54	37.1±0.51	0.21
Weight (Kg)	66.4±0.60	65.2±0.59	0.14
Height(cms)	166.2±0.47	165.7±0.71	0.54

P= not significant

153-170 cm (mean± SEM) was 165.7±0.71(95% confidence interval=164.24-167.16), whereas in group R the height ranged from 161 to 170 cm (mean± SEM 166.23±0.47), 95% confidence interval 165.26-167.20. Therefore, in terms of age, body weight and height the patients enrolled in both the groups were comparable.

Table 2 shows base line vital parameters of the two groups undergoing hernioplasty. Mean+SEM for baseline blood pressure (systolic/diastolic) in the Bupivacaine group (group B) was 125.8±0.64/83.3±0.59, while in the Ropivacaine group (group R) it was 127.2±0.44/83.8±0.58.5.

Students t-test was used for statistical comparison, which indicated that the values in groups did not differ significantly for systolic and diastolic blood pressure (p = 1.84 for systolic, 0.57 for diastolic). Mean + SEM for heart rate in bupivacaine group was 69.5±0.64 while in

ropivacaine group (group R) it was 69.6±0.54. (p=0.84). Mean+SEM for SPO<sub>2</sub> for bupivacaine group (group B) was 99.1±0.15 and for ropivacaine group (group R) it was 99.1±0.14. (p=0.87). Hence in terms of baseline blood pressure, heart rate and SPO<sub>2</sub> the two groups undergoing hernioplasty were comparable.

Table 3 shows the sensory block profile of the two groups of patients undergoing hernioplasty. In bupivacaine group (group B) Mean + SEM for onset of sensory block was 19.1±0.93 while for ropivacaine group (group R) it was 18.83±1.0. 95% confidence intervals for bupivacaine and ropivacaine group were 17.23-21.03 and 16.71-20.95 respectively. Unpaired t test was used for statistical analysis. P value calculated was 0.83. No statistically significant difference was found in the onset time of sensory block between the two groups undergoing hernioplasty.

Table 4 shows motor block profile of the two groups undergoing hernioplasty at 10, 20 and 30 minutes after the injection of study drug. In bupivacaine group (group B) at 10 minutes no patient had developed grade 3 block.

Similarly, in the Ropivacaine group (group R) no patient developed grade 3 block at 10 minutes. At 20 minutes 11 patients in Bupivacaine group (36.67%) and 2 patients in ropivacaine group (6.67%) had developed grade 3 block. At 30 minutes 16 patients in bupivacaine group (53.33%) and 13 patients in ropivacaine group (43.33%) developed grade 3 motor block. Chi Square (x<sup>2</sup>) test with Yates correction was used for statistical analysis. 95% confidence

**Table 2: Hemodynamic profile of the patients (values expressed in mean±sem)**

Parameter	Group R	Group B	p
BP (mm Hg)	127.2±0.44/83.8±0.58	125.8±0.64/83.3±0.59	1.84/0.57
HEART RATE (per min)	69.6±0.54	69.5±0.64	0.84
SPO <sub>2</sub>	99.1±0.14	99.1±0.15	0.87

**Table 3: Time to onset of Sensory block in Hernioplasty (values expressed in mean±sem)**

Sensory blockage	Group R	Group B	p
Sensory Block of T10 (min)	18.83±1.0	19.1±0.93	0.83

**Table 4: Percentage of patients having Motor blockade at 10, 20 and 30 minute interval (Patients developing Modified Bromage scale 3 block)**

Time (min)	Group R (%)	Group B (%)	P
10	0	0	NA
20	6.67	36.67	0.01
30	43.33	53.33	0.61

interval was calculated using Katz approximation.

There was no difference in motor block profile between the two groups at 10 minutes. There was statistically significant difference in motor block profile between two groups at 20 minutes. ( $X^2=6.29$ , 95% CI 1.38-3.18,  $p=0.01$ ). At 20 minutes more patients in bupivacaine group developed grade 3 block in comparison to ropivacaine group. At 30 minutes, no significant difference in motor block profiles of the two groups was found ( $X^2=0.27$ , 95% CI= 0.72-2.11,  $p=0.6$ ).

Pain was assessed using visual analogue score (0=no pain to 10=max pain). Time in minutes (from onset of sensory block to VAS>3) was taken as duration of analgesia. Table 5 shows the duration of analgesia. During hernioplasty minimum time to reach a VAS>3 was 165 minutes and maximum time was 225 minutes in Bupivacaine group (group B). In Ropivacaine group (group R) minimum and maximum time in minutes to reach a VAS>3 was 185 and 220 minutes respectively. Mean±SEM for group B was 199.66±3.03 and for group R was 200.96±2.46 whereas 95% CI for Bupivacaine and Ropivacaine groups were 193.53-205.81 and 195.93-206.0 respectively. Unpaired t-test was used for statistical analysis. (p value calculated was 0.739). Thus, no statistically significant difference was found in the pain scores of patients in the two groups.

**Table 5: Post-op pain (time to reach VAS>3 from onset of sensory block, values expressed in mean±SEM)**

Group R	Group B	p
200.96±2.46	199.66±3.03	0.74

Incidence of hypotension, bradycardia, nausea/vomiting and shivering was monitored during hernioplasty with both drugs as reflected in Table 6.

**Table 6: Major adverse effects in hernioplasty**

Adverse effects	Group R	Group B	P
Hypotension	20% (6)	16.67% (5)	0.74
Bradycardia	6.67% (2)	3.33% (1)	0.56
Shivering	10% (3)	6.67% (2)	0.64
Nausea And Vomiting	3.33% (1)	6.67% (2)	0.56

Patients of both groups were monitored for hypotension, bradycardia, shivering and nausea/vomiting. Chi Square test was used for statistical analysis. We found no significant difference in the incidence of these symptoms between the two groups.

## Discussion

The life-threatening toxicities of bupivacaine resulted in

the development of Ropivacaine in 1957. But ropivacaine was released for clinical use as late as 1996 [4,5]. This drug was fully evaluated only after a comment of Albright [1] on the difficult resuscitation and poor outcome consequent to accidental intravascular injection of Bupivacaine.

Ropivacaine is a long-acting amide local anaesthetic. Being less lipid soluble, ropivacaine is less likely to penetrate large, myelinated motor fibres than bupivacaine. Ropivacaine and bupivacaine both have been successfully used, and were found to be equally effective for subcutaneous infiltration, various neuraxial procedures as in surgery and obstetrics, upper and lower limb blocks, and also post-operative analgesia [6]. The pure S-enantiomer form of ropivacaine, makes it less cardiotoxic than Bupivacaine [7]. A number of studies comparing both these drugs have also concluded that Ropivacaine is less potent than bupivacaine. The degree of ropivacaine-induced sensory and motor block are dose and age-dependent, and equi-effective doses vis a vis bupivacaine has now been established.

The motor block produced by Ropivacaine was found to be less intense and shorter duration. Although preferred for epidural analgesia, the less intense and shorter motor block achieved with ropivacaine prevented it from becoming the local anaesthetic of choice for surgeries requiring good muscle relaxation lasting for longer duration [8]. This disadvantage of ropivacaine was somewhat ameliorated by increasing its concentration. Thus, a better quality of surgical anaesthesia could be possible due to the higher safety profile of ropivacaine [7,9,10].

In this study 0.5% bupivacaine and 0.75% ropivacaine have been compared for surgical anaesthesia and post-operative pain relief after a single bolus epidural injection in patients undergoing mesh hernioplasty.

The doses of bupivacaine and ropivacaine that have been compared in the study showed no significant difference in the profile of sensory block. During hernioplasty all patients achieved  $T_{10}$  level sensory block within 30 minutes. The results of our current study correlates well with the previous studies with regard to the duration and onset of sensory anaesthesia with 0.75% ropivacaine. The total duration found in our study was similar to a prior study by McGlade et al [8]. In a similar study with same concentrations of these drugs, Shalina et al [11] found that ropivacaine gave a relatively longer duration of analgesia, while observing the absence of any significant differences in other block parameters. However, in another study by Cekmen et al [12] where same concentration (0.5%) of both the drugs were used, the duration of sensory as well as motor block by ropivacaine was found to be significantly less than bupivacaine.

Casati et al conducted a study on 45 ASA I – III patients undergoing elective hip replacement surgery comprising epidural block with 10 ml of 0.5 % levo bupivacaine, 0.5% bupivacaine or 0.75% ropivacaine and found no difference in the time of onset of sensory and motor block.

As per a study by Brockway et al, the profiles of sensory block in case of ropivacaine and bupivacaine are similar for the same volume and concentration. However, motor block is slower in onset, less in intensity, and shorter in duration with ropivacaine [13]. In our study, although greater intensity of motor block was achieved at an earlier stage in the bupivacaine group, by about 30 minutes the difference was no more statistically significant. Motor block characteristics during hernioplasty in our study were similar to motor block characteristics found in previous studies [8].

There was no difference in the incidence of adverse effects in the two groups during hernioplasty. Hypotension with both drugs was transient and resolved quickly after giving bolus of Ringer's lactate and 3 mg of mephenteramine. Quality and degree of pain relief was similar with both the drugs in concentrations used in this study.

## Conclusion

0.5% bupivacaine and 0.75% ropivacaine both can be used for epidural anaesthesia for inguinal mesh hernioplasty.

Surgical anaesthesia provided by single epidural injection of 15 ml of 0.5% bupivacaine and 15 ml of 0.75% ropivacaine provide similar and satisfactory surgical anaesthesia in terms of sensory and motor block profile, pain relief and adverse effects and can be used for surgeries like inguinal mesh hernioplasty. Although motor block with bupivacaine 0.5% was achieved slightly earlier than 0.75% ropivacaine, still both the study drugs in their given concentrations provided similar quality of epidural anaesthesia in terms of sensory and motor block profile, pain relief and adverse effects for inguinal mesh hernioplasty.

<b>Conflict of interest:</b>	All authors declare no COI
<b>Ethics:</b>	There is no ethical violation as it is based on voluntary anonymous interviews
<b>Funding:</b>	No external funding
<b>Guarantor:</b>	Dr. Ahijit Banerjee will act as guarantor of this article on behalf of all co-authors.

## References

1. Albright GA. What is the place of bupivacaine in obstetric epidural analgesia? *Can Anaesth Soc J.* 1985;32(4):392–4.
2. Kuthiala G, Chaudhary G. Ropivacaine: A review of its pharmacology and clinical use. *Indian J Anaesth.* 2011;55(2):104–10.
3. Knudsen K, Beckman Suurküla M, Blomberg S, Sjövall J, Edvardsson N. Central nervous and cardiovascular effects of i.v. infusions of ropivacaine, bupivacaine and placebo in volunteers. *Br J Anaesth.* 1997;78(5):507–14.
4. McClure JH. Ropivacaine. *Br J Anaesth.* 1996;76(2):300–7.
5. Åberg G. Toxicological and Local Anaesthetic Effects of Optically Active Isomers of Two Local Anaesthetic Compounds. *Acta Pharmacol Toxicol (Copenh).* 1972;31(4):273–86.
6. Simpson D, Curran MP, Oldfield V, Keating GM. Ropivacaine: A review of its use in regional anaesthesia and acute pain management. *Drugs.* 2005;65(18):2675–717.
7. Graf BM, Abraham I, Eberbach N, Kunst G, Stowe DF, Martin E. Differences in cardiotoxicity of bupivacaine and ropivacaine are the result of physicochemical and stereoselective properties. *Anesthesiology.* 2002; 96(6):1427-34.
8. McGlade DP, Kalpokas M V., Mooney PH, Buckland MR, Vallipuram SK, Hendrata M V., et al. Comparison of 0.5% ropivacaine and 0.5% bupivacaine in lumbar epidural anaesthesia for lower limb orthopaedic surgery. *Anaesth Intensive Care.* 1997;25(3):262–6.
9. Dony P, Dewinde V, Vanderick B, Cuignet O, Gautier P, Legrand E, et al. The comparative toxicity of ropivacaine and bupivacaine at equipotent doses in rats. *Anesth Analg.* 2000;91(6):1489-92.
10. Knudsen K, Beckman Suurküla M, Blomberg S, Sjövall J, Edvardsson N. Central nervous and cardiovascular effects of i.v. infusions of ropivacaine, bupivacaine and placebo in volunteers. *Br J Anaesth.* 1997;78(5):507–14.
11. Shalina Chandran SH, Viswanathan P. Comparison of 0.75% ropivacaine and 0.5% bupivacaine for epidural anaesthesia in lower extremity orthopaedic surgeries INTRODUCTION. *Indian J Anaesth.* 2014;58(3):334–6.
12. Cekmen N, Arslan M, Musdal Y, Babacan A. Comparison of the effects of a single dose of epidural ropivacaine and bupivacaine in arthroscopic operations. *Res J Med Sci.* 2008;2(3):109-115.
13. Brockway MS, Bannister J, McClure JH, Mckeown D, Wildsmith JAW. Comparison of extradural ropivacaine and bupivacaine. *Br J Anaesth.* 1991;66(1):31-7.

