DOI: 10.21088/ijaa.2349.8471.12325.2

Indian Journal of Anesthesia and Analgesia
Volume 12 Number 3 July - September 2025

ORIGINAL ARTICLE

Comparison Between Levobupivacaine vs Ropivacaine in Thoracic Epidural Anaesthesia for Modified Radical Mastectomy: A Randomised Controlled Trial

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How to cite this article:

S. Subramaniam, V. Haribabu. Comparison Between Levobupivacaine vs Ropivacaine in Thoracic Epidural Anaesthesia for Modified Radical Mastectomy: A Randomised Controlled Trial. Ind J Anesth Analg. 2025; 12(3): 171-175.

ABSTRACT

Objective: To compare the onset and duration of sensory and motor block, haemodynamic responses, side effects associated with administration of thoracic epidural Levobupivacaine (0.5%) and Ropivacaine (0.5%) for modified radical mastectomy.

Place and Duration of Study: Govt. Arignar Anna Memorial Cancer Hospital and Research Institute, Kanchipuram. 2023 - 24.

Study Design: Randomized controlled clinical trial.

Methodology: After obtaining approval from institutional ethics committee and written informed consent from all patients, a randomized controlled double blinded clinical trial was conducted on 30 ASA 3 carcinoma breast cases undergoing modified radical mastectomy. Patients were randomly allocated into two groups. Group L and Group R of 15 each. Patients in Group L were to receive Levobupivacaine 0.5% and Group R 0.5% Ropivacaine. Haemodynamic variables (heart rate, systolic and diastolic BP) and onset and duration of sensory and motor block, sensory regression time were recorded and compared using unpaired T-test.

Conclusion: Levobupivacaine is better suited thoracic epidural anaesthetic drug for modified radical mastectomy surgeries than Ropivacaine.

KEYWORDS

• Levobupivacaine • Ropivacaine • Unpaired T-test

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➢ **Received:** 21-03-2025 ➢ **Accepted:** 31-05-2025

INTRODUCTION

The introduction of thoracic epidural anaesthesia and analgesia has reduced the incidence of intraoperative and postoperative complications and provided early mobilisation and recovery. The newer drugs like levobupivacaine and ropivacaine with superior pharmacokinetic profile and less toxicity seems to provide an efficient alternative drug for thoracic epidural anaesthesia and analgesia[1] avoiding the risks associated with conventional general anaesthesia.

METHODOLOGY

The study population was randomly divided into two groups with 15 patients in each group. The study was carried out as a randomized double blinded study. The study drugs were prepared andnumbered and the register was maintained by another faculty member. Group L consisting of 15 patients were to receive 0.5% levobupivacaine. Group R consisting of 15 patients were to receive 0.5% Ropivacaine. A thorough preanaesthetic evaluation was done, all ASA 3 patients with systemic diseases (DM, SHT, CAD) were posted for surgery only after stabilisation with drugs.

Tab. Diazepam 10mg and Tab. Ranitidine 150mg were given on the night before surgery. Patients were maintained nil by mouth for a duration of 8 hours prior to the surgery. On the day of surgery patient was shifted to the operating room. Intravenous access was secured. A multichannel monitor consisting of pulseoximeter, electrocardiogram, heart rate, noninvasiveblood pressure was connected. The baseline heartrate, oxygen saturation, electrocardiogram, systolic, diastolic and mean arterial blood pressures were recorded. An observer new to the group assignments, recorded the evolution of sensory block(using the pin prick sensation test) and the motor block by Visual AnalogScale (VAS). VAS score for grading of pain consist of a 10 cm line with 10mm to each point of the scale and two end points representing no pain and worst possible pain, where 0 = no pain, 1-3 = mild pain, 4-6 = moderate and 7-10 = severe pain (quoted from Ghai et al, 2015).[11]

The C7 prominent spinous process, T3 scapular spine, T7 inferior border of scapula are useful landmarks to approximate the puncture site to the planned segments. T3 or T4 thoracic interspinous space is selected. With patient in sitting position using 18G, tuohy needle epidural space is identified by loss of resistance technique and then the thoracic epidural catheter is threaded 4-5cms in cephalic direction. A quantity of 3ml of 2% lidocaine with 1:20,000 epinephrine is used as a test dose of the technique. Any increase in the heart rate to rule out intravascular placement of catheter is noted. Then 12ml of 0.5% levobupivacaine or ropivacaine is given and the resultant effects of sensory and motor block were recorded and evaluated. At the end of the first hour, topup dose of 8ml of 0.5% levobupivacaine/ropivacaine was given in both the groups and the results were evaluated. It was planned to treat bradycardia (HR < 50/min) with inj. Atropine 0.01mg/kg and hypotension(decrease in systolic arterial BP 30% < baseline) with inj. Mephentramine (6-12mg). Patients were not sedated during surgery.

Patients with uncontrolled systemic diseases, anatomical deformities of the spine, any bleeding disorders are excluded from the study.

RESULT

Adequate block to initiate the surgery was defined by sensory block height of T1 to T7 of mastectomy side which is assessed by pin prick and after confirming it, surgery is allowed to commence. The duration of surgery lasted for around 120 mins, the estimated blood loss was 350 ml and none of the patient required blood transfusion. Patient remained stable and comfortable throughout the surgery. 8 ml of 0.125% epidural bupivacaine 12th hourly was used for postoperative pain management.[6-8] Epidural catheter was removed on third postoperative day and patient got discharged on fifth postoperative day without any complications.

In the present study, the mean age (in yrs) in both group L and R is above 50 years.

The mean heart rate in group L is 75.76 and in group R is 78.64.

The preoperative mean systolic BP in group L is 137.8 and in group R is 144.2 and diastolic BP in group L 86, group R 89.6.

The intraoperative mean systolic BP in group L is 114.4 and in group R is 113.4 and diastolic BP in group L 77.6, group R 73.

The onset of sensory block is between 2-3 mins in group L and 4-5 mins in group R.

The onset of motor block is between 4-5 mins in group L and 5-7 mins in group R.

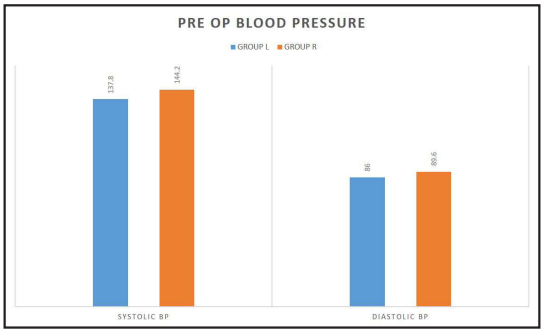
The total duration of analgesia in group L 179.6, group R 122.9.

Side effects like hypotension, nausea, vomiting and other adverse effects were not encountered in both the groups.

There is no significant change in age and height distribution between the two groups (Group L and Group R) and majority of patients are above 50 years in both groups.

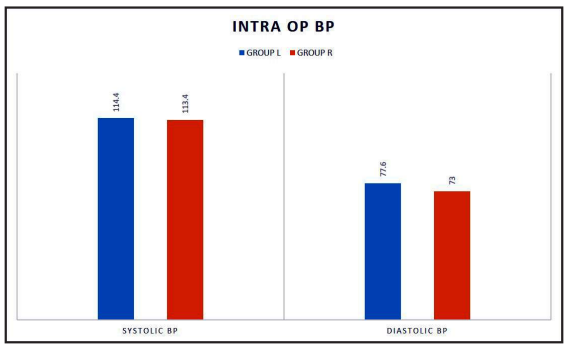
Pre OP Blood Pressure

Side	Systolic BP	Diastolic BP
Group L	137.8	86
Group R	144.2	89.6
P Value	0.136	0.391
T Value	1.60	1.48



Intra OP Blood Pressure

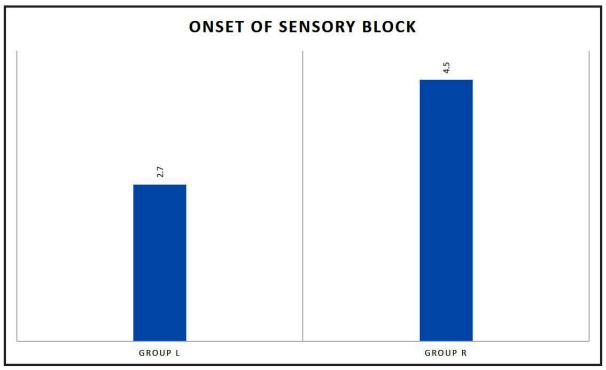
Side	Systolic BP	Diastolic BP
Group L	114.4	77.6
Group R	113.4	73
P Value	0.847	0.276
T Value	0.146	2.12



There is no significant change in blood pressure (preoperative and intraoperative, systolic and diastolic) between the groups L and R as shown in the 'P' value of unpaired T-test.

Onset of Sensory Block

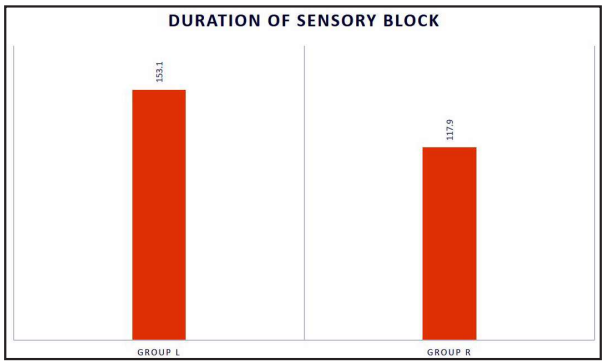
Onset of Sensory Block	Mean	SD
Group L	2.7	0.43
Group R	4.5	0.42
P Value - 0.001* , T Value -9.469		



Group L has a quicker onset of sensory block as compared to group R as shown in the graph and 'P' value of 0.001 in T-test. The mean duration of sensory block is 153.1 mins in group L and 117.9 mins in group R.

Duration of Sensory Block

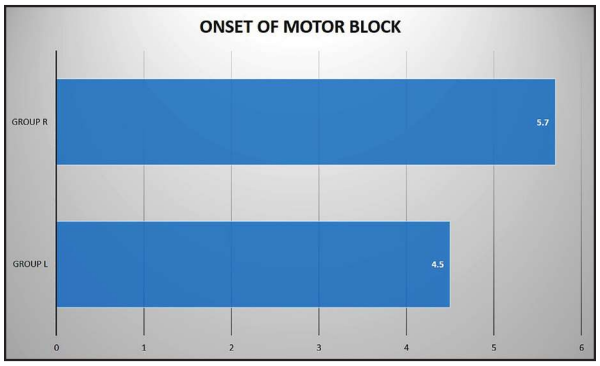
Duration of Sensory Block	Mean	SD
Group L	153.1	10.69
Group R	117.9	5.12
P Value - 0.001*, T Value -9.49		



Group L has longer duration of sensory block as compared to group R as seen in graph and 'P' value of 0.001 in T-test.

Onset of Motor Block

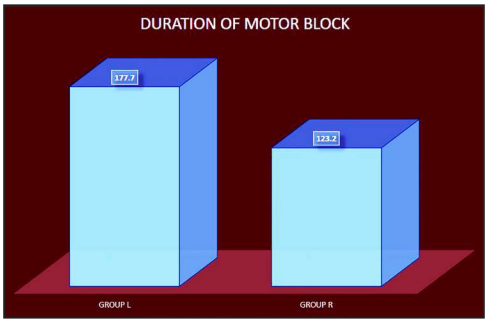
Onset of Motor Block	Mean	SD
Group L	4.5	0.4
Group R	5.7	0.51
P Value - 0.001*, T Value – 5.68		



Group L has quicker onset of motor block as compared to group R as depicted in the graph and 'P' value of 0.001 in T-test. The mean duration of motor block in group L is 177.7 mins and 123.2 mins in group R.

Duration of Motor Block

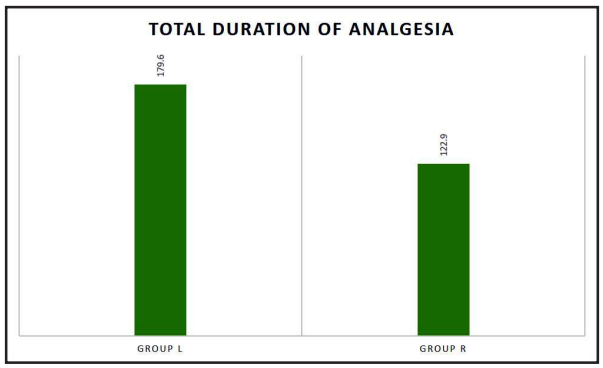
Duration of Motor Block	Mean	SD
Group L	177.7	5.76
Group R	123.2	5.09
P Value - 0.001* T Value – 20.87		



Group L has significant longer duration of motor block as compared to group R as proved by graph and 'P' value of 0.001 in T-test.

Total Duration of Analgesia

Total Duration	Mean	SD
Group L	179.6	5.97
Group R	122.9	3.86
P Value - 0.001* , T Value – 19.32		



DISCUSSSION

Ropivacaine is an 'S' enantiomer of bupivacaine with low lipid solubility it provides hemodynamic stability with shorter duration motor block which is desirable for early ambulation, voiding and physiotherapy.[8,12]

Levobupivacaine is a pure 'S' enantiomer of bupivacaine, which has clinical profile of racemic bupivacaine but with less toxicity because of its three dimensional structure. With greater margin of safety and long duration of action levobupivacaine finds its wide application in thoracic epidural anaesthesia.[9,12]

The quality of sensory and motor blockade and the duration of anaesthesia determines the choice of local anaesthetic for thoracic epidural anaesthesia.[6] With the advent of levobupivacaine the need of an ideal local anaesthetic with minimal cardiovascular and neurological toxicity has been satisfied.[2,3] Thoracic epidural anaesthesia provides superior post operative analgesia with reduced pulmonary complications and decreased duration of post operative ileus and reduced mortality.[5] In cardiac patients[1] it provides earlier mobilization, improved pulmonary function, fewer cardiac arrhythmias and decreased pain scores, thus eliminating the risks associated with general anaesthesia.[6-8]

CONCLUSION

Haemodynamically both the drug groups (L and R) showed comparable and stable results. Thoracic epidural anaesthesia has emerged as a safe and reliable alternative to general anaesthesia for radical mastectomy surgeries and we conclude that Levobupivacaine with its hemodynamics stability and long duration of action is better suited for thoracic epidural anaesthesia in modified radical mastectomy surgeries for carcinoma of breast cases.

REFERENCES

1. W.S. Beattie, N.H. Babner, P. Choi, Epidural analgesia reduces postoperative myocardial infarction: a meta-analysis, AnesthAnalg, 93(2001), pp. 853-858, view record in scopus Google Scholar.
2. Grewal S., Hocking G., Wildsmith JA: Epidural abcesses. Br J Anaesth 2006; 96: 292-302.
3. Perkins F.M., Kehlet H.: Chronic pain as an outcome of surgery. A review of predictive factors. Anesthesiology 2000; 93: 1123-33.
4. Bong C.L., Samuel M., Ng J.M., lp-Yam C: Effects of preemptive epidural analgesia on post-thoracotomy pain. J CardiothoracVascAnesth 2005; 19: 786-93
5. Amr Y.M., Yousef A.A., Alzeftawy A.E., Messbah W.I., saber A.M.: Effect of preincisional epidural fentanyl and bupivacaine on postthoracotomy pain and pulmonary function. Ann ThoracSurg; 89:381-5.
6. F. McLeod, F. Cumming, Thoracic epidural anaesthesia and analgesia. randomized controlled trial. Volume 4 (2004), Google Scholar.
7. G. Consani, A. Nunziata, G. Amorese, U. Boggi, Thoracic epidural anaesthesia in awake upper abdominal surgery; safety/ validity of bromage's formula, J Anesthclin Res, 5(2014), p. 391, Google Scholar.
8. Giebler R.M., Scherer R.U., Peters J. Incidence of neurological complications related to thoracic epidural catheterization. Anesthesiology 1997; 86: 55-63.
9. Gould T.H., Grace K., Thorne G., Thomas M. Effect of thoracic epidural anaesthesia on colonic blood flow. Br J Anaesth 2002; 89: 446-51
10. Hogan Q. Distribution of solution in the epidural space: examination by cryomicrotome section. RegAnesth Pain Med 2002; 27: 150-6.
11. Ghai *et al.,* 2015
12. K. Knudsen *et al.,* Cental nervous system and cardiovascular effects of ropivacaine, bupivacaine, IV infusions and placebo in volunteers. Br. J. Anaesth (1997).