# **Original Research Paper**



## Anaesthesiology

# TO COMPARE THE EFFECTS, SAFETY AND EFFICACY OF ROPIVACAINE AND LEVOBUPIVACAINE IN PARAVERTEBRAL BLOCK

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ABSTRACT Introduction: A paravertebral block is essentially a unilateral block of the spinal nerve, including the dorsal and ventral rami, as well as the sympathetic chain ganglia. These blocks can be performed at any vertebral level. However, they are most commonly performed at the thoracic level because of anatomic considerations.

Aim: To compare the effects, safety and efficacy of ropivacaine (0.75%) and levobupivacaine (0.5%) in single injection thoracic paravertebral block Material and Methods: This single blind, prospective, randomized study was conducted in Department of Anaesthesiology and Critical Care, Maharani Laxmi Bai Medical College, Jhansi (UP). Following approval of ethical committee, patients admitted for breast surgery, between the age of 18 and 65 yrs., belonging to ASA grade 1 and 2 were taken as subjects of study. All the selected patients were subjected to a detailed history and clinical examination along with all routine investigations including Hb, T.L.C., D.L.C., Blood urea, serum creatinine, and urine examination. Specific investigations were prescribed as and when required.

Result: The patients who were accepted for study were in age group 18-65 years with reference to table 1 and 2, there is no significant difference in age in Group A (31.57±7.70) and Group B (31.87±10.12). The mean onset of complete sensory block during present study was found to be early with 0.75% Ropivacaine (Group A) (11.50±2.85 min) then 0.5% Levobupivacaine (Group B) (12.87±3.09 min) and comparison among than was found to be non significant [p value=0.0796]. Where as mean duration of sensory block was found longer with 0.5% Levobupivacaine (641.3±36.3 min) then 0.75% Ropivacaine (613±58.46 min) and comparison found to be significant [p value=0.0280]. Mean duration of post operative analgesia also found longer with 0.5% Levobupivacaine (680±35.13 min) then 0.75% Ropivacaine (652.±53.43 min) and comparison found to be significant [p value=0.0227]. After analyzing SBP, DBP and mean blood pressure variation and pulse oximetry for pulse rate and arterial oxygen saturation, it was found that both of the study group did not show hemodynamic instability. Only one patient in Levobupivacaine group developed complication, but overall hemodynamics remained fairly stable and comparable in both group. No any sign of drug toxicity or drug reaction was reported in any patients.

**Conclusion:** It can therefore be said that, Inj. Ropivacaine 0.75% is beneficial in respect to earlier onset and Inj. Levobupivacaine 0.05% have longer duration of sensory block and post operative analgesia but there were no much clinical difference in onset, duration, post operative analgesia among 0.75% Ropivacaine and 0.5% Levobupivacaine, when injected in equal volumes for PVB.

## **KEYWORDS**: Levobupivacaine, paravertebral block, ropivacaine

#### INTRODUCTION

A paravertebral block is essentially a unilateral block of the spinal nerve, including the dorsal and ventral rami, as well as the sympathetic chain ganglia. These blocks can be performed at any vertebral level. However, they are most commonly performed at the thoracic level because of anatomic considerations.

Thoracic paravertebral block involves injection of local anaesthetic at the site where the spinal nerve emerges from the intervertebral foramen. The paravertebral space contains dorsal and ventral rami and the synaptic chain. Hence, infiltration of this space results in unilateral sensory, motor and sympathetic blockade. Paravertebral block has been used to

- Relieve acute chest wall pain from rib fractures, herpes zoster, pleurisy
- b) To manage acute and chronic post thoracotomy pain and
- c) As an anaesthetic technique for surgery of chest wall

Comparison of PVB with other modalities of analgesia of chest wall: In comparing analgesia obtained from *epidural versus paravertebral*, side effects of postural hypotension, urinary retention are significant problems with epidural analgesia. Opioid requirements and related side effects are less in paravertebral group.

In comparing *intercostal block with paravertebral block*, intercostal block has inherent limitations of inadequate spread at multiple levels, inadequate analgesia and greater rates of complications of pleural or pulmonary damage.

Intrapleural analgesia leads to significantly worsened pulmonary

function in comparison to paravertebral block. Risk of pleural and pulmonary damage with intrapleural blocks is greater than paravertebral technique.

Chronic pain symptoms in the operated area and the ipsilateral arm are prevalent even one year after breast surgery. Unexpectedly, chronic pain has been found more after breast conserving than radical surgery. Good immediate postoperative analgesia is achieved by providing preincisional PVB in patients undergoing breast surgery for cancer. Good acute pain relief is associated with lower risk of development of chronic pain at operated area.

Besides, PVB are relatively easy to learn, have fewer contraindications and require no additional nursing surveillance. They are applicable to large number of patients and because of their low side effect profile they contribute to early post operative mobilization.

PVB provide excellent pain relief and inhibit the neuro endocrine stress response to surgical trauma which suggests that a very high quality afferent block can be effective.

Abolition of Somato sensory evoked potentials (SSEP) at multiple level indicates that cortical response to thoracic dermatomal stimulation can be completely abolished by thoracic paravertebral nerve blockade. Total blockade would remove the stimulus for central sensitization and hence the augmentation of nociception, which is thought to be responsible for postoperative and chronic pain. In addition, profound afferent block reduces neuro endocrine stress response to surgery as well.

Paravertebral nerve block was a popular technique in the early 20th

century. However, for some reason, paravertebral nerve block lost popularity and was almost extinct until the late 1970s, when there was a renewed interest in the technique. Recently, this technique was reviewed and found to be safe and efficacious for motor blockade as well as purpose of analgesia.

Regional anesthesia using paravertebral block has been suggested as an ideal adjunct to general anesthesia for modified radical mastectomy. Paravertebral block is an effective management of peri-operative pain for Modified radical mastectomy, however, there are no established guidelines regarding what is the most suitable strategy when varying drugs and dosages between different groups.

Paravertebral blocks (PVBs) were first performed in 1905 and became a popular technique for the provision of analgesia in the early part of the twentieth century. However, their use declined over the years until a publication by Eason and Wyatt in 1979 began a renaissance. Since then, a considerable number of good quality studies have been published on PVB and it is now an established regional anaesthetic technique.

Pain when experienced after thoracotomy is considered the most intense acute postoperative pain. This can adversely affect coughing and deep breathing, resulting in respiratory complications such as hypoxia, atelectasis, chest infection, and respiratory failure that may delay recovery and, if severe, could be life-threatening. It may also contribute to the development of chronic pain syndrome.

Paravertebral block is an effective alternative to epidural analgesia in the management of post-thoracotomy pain, however, there are no established guidelines regarding what is the most suitable strategy when varying drugs and dosages between different groups.

Thoracic epidural analgesia carries the risk of dural puncture, epidural hernatoma, epidural abscess, and side effects such as hypotension, bradycardia, and urinary retention and these commonly occur. Regional anesthesia by thoracic paravertebral block (TPVB) could be a good alternative for post-thoracotomy pain.

Ropivacaine is a new local anesthetic that could be a useful alternative to bupivacaine for TPVB. It is considered less cardiotoxic and neurotoxic than bupivacaine at equipotent doses and also less potent than bupivacaine at equal milligram doses. These properties could be important because higher concentrations and volumes of local anesthetics are needed for this technique.

Levobupivacaine is a local anaesthetic drug belonging to the amino amide group. It is the S-enantiomer of bupivacaine.

Levobupivacaine hydrochloride seems to have a lesser negative inotropic effect and, at intravenous doses >75 mg, produced less prolongation of the QTc interval than bupivacaine. Fewer changes indicative of CNS depression on EEG were evident with levobupivacaine. Levobupivacaine is long acting with a dose-dependent duration of anaesthesia.

### AIM AND OBJECTIVES

#### Aim:

To compare the effects, safety and efficacy of ropivacaine (0.75%) and levobupivacaine (0.5%) in single injection thoracic paravertebral block

#### **Objectives:**

- 1. Onset, time and duration of sensory block.
- Duration of post operative analgesia and rescue analgesic demand.
- 3. Overall quality of block.
- 4. Perioperative hemodynamic stability
- 5. Adverse effects if any.

#### **MATERIALAND METHODS:**

This single blind, prospective, randomized study was conducted in Department of Anaesthesiology and Critical Care, Maharani Laxmi Bai Medical College, Jhansi (UP). Following approval of ethical committee, patients admitted for breast surgery, between the age of 18 and 65 yrs., belonging to ASA grade 1 and 2 were taken as subjects of study. All the selected patients were subjected to a detailed history and clinical examination along with all routine investigations including Hb, T.L.C., D.L.C., Blood urea, serum creatinine, and urine examination. Specific investigations were prescribed as and when required.

#### **Exclusion criteria:**

- Patients aged <18yrs. or >65yrs.
- Patients having BMI < 18.5 & BMI > 30kg
- Patients having ASA grade III, IV, and V
- · Patients having peripheral neuropathy
- · Patients having hypersensitivity to local anaesthetic agents.
- Patients having history of seizures.
- · Patients having bleeding disorders
- Patients having receiving anti coagulation.
- Hepatic or renal failure

All patients were subjected to a detailed history and clinical examination.

After a thorough preoperative screening, and obtaining written and informed consent, Patients were randomly assigned using "slips in a box technique" to one of the following groups with each group consisting of 30 patients.

**Group A:** Patients were given 20m1 lnj. Ropivacaine (0.75%)

**Group B:** Patients were given 20 ml lnj. Levobupivacaine (0.5%)

**Advice to patient:** Patients were fasted for 6-8 hrs and received no medication preoperatively.

#### **Armamentarium:**

- Multichannel monitor for NIBP, Sp02 and pulse rate monitoring.
- Autoclaved sponge holding forceps, gauze piece, apron, gloves.
- Disposable syringe (20ml).
- Inj. Ropivacaine 0. 75%
- Inj. Levobupivacaine 0.5%
- Emergency drugs inj. Atropine, Inj Adrenaline, InjHydrocortisone, Inj. Deriphyllin,
- All resuscitation equipments,

#### Pre-anaesthetic evaluation:

All patients will undergo pre-anaesthetic check up one day prior to the day of operation. The purpose and nature of study will be fully explained to all patients and a written and informed consent will be obtained.

Patients will be instructed on the use of VAS, Visual Analogue Scale (0-10) for assessment of pain (0 for no pain to 10 for worst pain imaginable).

Besides a long and thorough clinical examination like history, general examination and systemic examination the following investigations will be done to exclude any systemic illness and also for ASA grading.

- a. Blood Hemoglobin
- b. Total count and differential count of WBC
- c. ESR
- d. ECG
- e. X-Ray chest PA view
- f. Blood sugar fasting and postprandial
- g. Blood urea, serum creatinine

#### Anaesthetic technique:

After shifting to the operation theatre, the monitors were applied and baseline pulse rate, blood pressure, respiratory rate and Sp0<sub>2</sub> were recorded. IV line was established with 18 Guaze cannula, patient-were started infusion of Ringer's lactate solution.

## **Needle Insertion Point:**

2.5 cm lateral to the tip of spinous process at the level of T3 on the side of surgery.



Needle Insertion Point

#### **Procedure**

Part was cleaned and painted with antiseptic solution. Sterile drape was placed. Planned needle insertion point was infiltrated with local anaesthetic. A 16 G needle was inserted perpendicular to the skin to contact transverse process at 2-4 cm depth. Then the needle was manipulated to walk off the superior aspect of transverse process until loss of resistance was felt. Insertion was limited to <2 cm past the transverse process. 20 ml of 0.5 % Levobupivacaine or 0.75% Ropivacaine was injected. Dose to be used is 3-4 ml/dermatome. Patient was made to lie down supine. Onset of sensory anaesthesia was checked 5 min after the injection by needle prick technique. If the patient has lack of sensory blockade in 10-15 min it was considered as failed Paravertebral Block and the patient was excluded from the study.

**Monitoring:** NIBP, ECG, Sp02 **Patient position:** Sitting

#### **Equipment:**

- 20 ml syringe
- 5 ml syringe with 25 gauge needle for skin infiltration
- · A 16 gauge needle
- Local anaesthetic agents Inj. Ropivacaine 0.75% and Inj. Levobupivacaine 0.5%
- · Sterile towels and gauze packs
- · Sterile gloves
- · Antiseptic solution for cleaning and painting of part
- · Distilled water for dilution.

#### Statistical analysis:

The data were summarized as mean values with standard deviations (SD). The statistic analysis was performed using Student's t-test. The SPSS 11.0 for Windows computer software (SPSS Inc., Chicago, IL) was used for statistic analysis. P value less than 0.05 was considered significant.

RESULT: Table 1: Age distribution in study group

Age	Group		Grou	ір В
(in years)	(Ropivae	caine)	(Levobup	ivacaine)
	Number of	Percentage	Number of	Percentage
	patients		patients	
18-30	16	53.33%	17	56.66%
31-40	08	26.66%	09	30.00%
41-50	06	20.00%	01	3.33%
51-60	00	0.00%	03	10.00%
>60	00	0.00%	00	0.00%

Table 2: Mean age distribution in study group

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Age (in years)	Group A (Ropiva caine)		p value
Mean±SD	31.57 ±7.709	$31.87 \pm 10.129$	0.9813

Table 3: Mean weight (kg) distribution in study group

Mean weight (Kg)	Group A (Ropivacaine)	Group B (Levobupivacaine)	p value
Mean±SD	55.37±5.904	56.80±7.607	0.3957

Table 4: Diagnosis distribution in study group

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Diagnosis	Group A		Group B		
	(Ropivacaine)		(Levobup	ivacaine)	
	Number of	Percentage	Number of	Percentage	
	patients		patients		
Antibioma	04	13.33%	05	16.66%	
Fibroadenoma	26	86.66%	25	82.33%	

Table 5: Proposed surgery distribution in study group

Proposed	Group A			up B	
Surgery	(Ropivacaine)		rgery (Ropivacaine) (Levobupivac		ivacaine)
	Number of	Percentage	Number of	Percentage	
	patients		patients		
Excision	30	100%	30	1000%	

Table 6: Mean systolic bp (mmhg) distribution in study group

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Mean Systolic BP (mmHg)		Group B (Levo- bupivacaine)	p value
Basal	119.67 ±7.009	118.47 ±7.440	0.5227
5 Minutes	119.67 ±6.583	118.53 ±7.181	0.5241

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10 Minutes	119.53 ±6.922	118.17 ±7.566	0.4705
20 Minutes	119.47 ±5.406	118.40 ±8.066	0.5485
30 Minutes	118.73 ±5.132	117.73 ±5.866	0.4850
60 Minutes	117.27 ±5.546	117.27 ±7.037	1.0000

Table 7: Mean diastolic BP (MMHG) distribution in study group

Mean Diastolic BP	Group A	Group B	p value
(mmHg)	(Ropi-vacaine)	(Levo- bupivacaine)	
Basal	$78.47 \pm 5.029$	77.00 ±5.350	0.2774
5 Minutes	$78.67 \pm 4.373$	77.80 ±4.310	0.4408
10 Minutes	77.73 ±4.891	76.40 ±4.797	0.2920
20 Minutes	77.67 ±4.611	76.40 ±4.591	0.2895
30 Minutes	77.67 ±4.205	76.40 ±4.591	0.2685
60 Minutes	$76.80 \pm 4.413$	75.60 ±4.822	0.3188

Table: 8 Mean BP (MMHG) distribution in study group

Mean BP	Group A	Group B	p value	
(mmHg)	(Ropivacaine)	(Levo-bupivacaine)		
Basal	92.13±5.588	90.77±5.544	0.3479	
5 Minutes	92.40±4.875	91.43±4.768	0.4391	
10 Minutes	91.63±5.359	90.73±5.010	0.5043	
20 Minutes	91.77±4.783	90.23±4.569	0.2073	
30 Minutes	91.30±4.504	90.23±4.621	0.3675	
60 Minutes	90.27±4.842	89.10±4.901	0.3561	

Table 9: Mean pulse rate (beats per minute) distribution in study group

Mean Pulse Rate	Group A	Group B	р
(beats per minute)	(Ropivacaine)	(Levo- bupivacaine)	value
Basal	77.87±6.101	77.40±5.123	0.7478
5 Minutes	78.27±3.769	77.77±4.812	0.6558
10 Minutes	78.67±4.795	76.40±3.979	0.0507
20 Minutes	78.00±4.785	76.33±3.367	0.1234
30 Minutes	79.13±5.673	76.27±5.819	0.0588
60 Minutes	77.93±6.203	76.33±4.611	0.2615

Table 10: Mean SPO2 distribution in study group

Group A	Group B	p value
(Ropivacaine)	(Levo- bupivacaine)	
98.27±0828	98.43±0.504	0.9992
99.37±0.765	99.03±0.718	0.0811
99.30±0.651	98.90±0.845	0.0445
99.47±0.571	99.17±0.592	0.0504
99.30±0.702	99.03±0.669	0.1327
99.30±0.596	98.63±0.718	0.0779
	(Ropivacaine) 98.27±0828 99.37±0.765 99.30±0.651 99.47±0.571 99.30±0.702	(Ropivacaine)         (Levo- bupivacaine)           98.27±0828         98.43±0.504           99.37±0.765         99.03±0.718           99.30±0.651         98.90±0.845           99.47±0.571         99.17±0.592           99.30±0.702         99.03±0.669

Table 11: Mean time of complete sensory block (in mins) distribution in study group

Mean time of Complete Sensory Block (in mins)	Group A (Ropi-vacaine)	Group B (Levo- bupivacaine)	p value
Mean±SD	$11.50 \pm 2.850$	$12.87 \pm 3.093$	0.0796

Table 12: Mean duration of sensory block (in mins) distribution in study group

Duration of Sensory		Group B	p
Block (in mins)		(Levo-bupivacaine)	value
Mean±SD	613 ±58,462	641.33 ±36.363	0.0280

Table 13: Mean duration of analgesia (in mins) distribution in study group

Mean Duration of Analgesia (in Mins)		Group B (Levo- bupivacaine)	p value
Mean±SD	652.67 ±53.430	680.00 ±35.135	0.0227

Table 14: Adverse effects distribution in study group

Adverse effects	Group A (Ropivacaine)		Group B (Levobupivacaine)	
	Number of patients	%	Number of patients	%
Drug reaction	0	0%	0	0%
Hypotension (fall in MAP<20% of baseline)	0	0%	1	3.33%
Bradycardia (pulse rate<60/min)	0	0%	1	3.33%

Nausea	2	6.67%	1	3.33%
Vomiting	0	0%	0	0%
Sedation	0	0%	0	0%

#### DISCUSSION:

The present prospective randomized comparative study was conducted in the department of anaesthesia, Maharani Laxmi Bai Medical College, Jhansi, carried out during the study period from April 2018 to October 2019, with principle aim to evaluate the comparative effects of Levobupivacaine and Ropivacaine for effects, safety and efficacy in Paravertebral block.

To compare the time of complete onset and duration of sensory block, as well as duration of analgesia among the Levobupivacaine and Ropivacaine.

The hemodynamic stability and any adverse effects was watched for.

Total 60 patient were included in the study out of these 30 patients received 20ml of Inj. 0.75% Ropivacaine (Group A), other 30 patients were given 20ml of 0.5% Inj. Levobupivacaine (Group B).

Total of 8 patient during the study period have incomplete block and required general anaesthesis for operative procedure were excluded from both the study group.

On present study observation and results are tabled and are being discussed to draw a final conclusion.

Demographic variation in present study are coincidently identical in each group (Table 1, 2 and 3)

The patients who were accepted for study were in age group 18-65 years with reference to table 1 and 2, there is no significant difference in age in Group A (31.57±7.70) and Group B (31.87±10.12).

The mean onset of complete sensory block during present study was found to be early with 0.75% Ropivacaine (Group A) (11.50±2.85 min) then 0.5% Levobupivacaine (Group B) (12.87±3.09 min) and comparison among than was found to be non significant [p value=0.07961

Where as mean duration of sensory block was found longer with 0.5% Levobupivacaine (641.3±36.3 min) then 0.75% Ropivacaine (613±58.46 min) and comparison found to be significant [p value=0.0280].

Mean duration of post operative analgesia also found longer with 0.5% Levobupivacaine (680±35.13 min) then 0.75% Ropivacaine (652.±53.43 min) and comparison found to be significant [p value=0.0227].

After analyzing SBP, DBP and mean blood pressure variation and pulse oximetry for pulse rate and arterial oxygen saturation, it was found that both of the study group did not show hemodynamic

Only one patient in Levobupivacaine group developed complication, but overall hemodynamics remained fairly stable and comparable in both group.

No any sign of drug toxicity or drug reaction was reported in any patients.

#### Limitation of my study:

- Further studied can be done on a longer group of patient for better verification of the effectiveness of the block and its implication. Due to limited patient input, study group is limited to 30 each.
- Blind studies are more accurate and preferred for scientific researches.
- USG guided PVB would further reduce the complication rate and would increase the efficacy and precision of the block.
- Addition of adjuvants to local anaesthetics might further increase onset and duration of block.

#### **CONCLUSION:**

After completion of study and analysis of data following conclusion were derived at

- Onset of sensory block was early with Ropivacaine 0.75% than Levobupivacaine 0.5% but difference is not significant (p value >0.5)
- Duration of sensory block was significantly prolonged with

- Levobupivacaine 0.5% in comparison of Ropivacaine 0.75% (p value 0.05)
- Duration of post operative analgesia was longer with 0.5% Levobupivacaine in comparison to 0.75% Ropivacaine.
- SBP, DBP, mean arterial blood pressure and mean pulse rate did not show any significant change at any point of time in both
- Adverse effects in both group is insignificant. Only one patient in Levobupivacaine group shows nausea, hypotension, bradycardia.

It can therefore be said that, Inj. Ropivacaine 0.75% is beneficial in respect to earlier onset and Inj. Levobupivacaine 0.05% have longer duration of sensory block and post operative analgesia but there were no much clinical difference in onset, duration, post operative analgesia among 0.75% Ropivacaine and 0.5% Levobupivacaine, when injected in equal volumes for PVB.

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