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Original Research Paper

Anaesthesiology

A STUDY ON COMPARISION OF 0.5%LEVOBUPIVACAINE AND 0.75% ROPIVACAINE IN THORACIC EPIDURAL FOR MODIFIED RADICAL MASTECTOMY

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KEYWORDS :

INTRODUCTION

Thoracic epidural anesthesia is increasingly being used for abdominal, major vascular and cardiothoracic & breast surgeries. The objective of thoracic block is not solely to block noxious afferent stimuli from the surgical site, but to impart a bilateral selective thoracic sympathectomy.

Provision of pain relief and sympatholysis of such magnitude that allows patients to cough, breathe deeply and mobilize can contribute to enhanced postoperative outcomes such as improved respiratory function, reduction in postoperative ileus, nausea and vomiting.

Levobupivacaine and ropivacaine both are newer long-acting local anesthetics like bupivacaine with less toxic effects. Both of these agents are pure left-isomers. Both drugs in three-dimensional structure are very less toxic effects on the central nervous system and the cardiovascular system.

Ropivacaine is "S" enantiomerwithlower lipid solubility, easier reversibility after inadvertent intravascular injection, significant reduction in central nervous system toxicity, lesser motor block and greater differentiation of sensory and motor block. Increasing concentrations caused quicker onset, greater intensity, slower regression and longer duration of motor blockade. Both are less lipophilic than bupivacaine andis less likely to penetrate large myelinated motor fibers resulting in a relatively reduced motor blockade. The reduced lipophilicity is also associated with decreased potential for central nervous system and cardiovascular system toxicity. So ropivacaine appears to be an important option for regional anesthesia and for the management.

Levobupivacaine the also isolated S(-) enantiomer of bupivacaine has been shown to be less cardiotoxic than bupivacaine in preclinical studies. Owing to the lower affinity of the S (-) isomer to the cardiac sodium channels compared to the R (+) isomer, it is associated with less cardiac side effects.

Both of these agents are pure left isomers. because of their three- dimensional structure they have less toxicity to both the central nervous system and the heart. The clinical profiles of levobupivacaine and ropivacaine are similar to that of racemic. bupivacaine and the minimal differences among the three agents are mainly related to the slightly different anesthetic potency. They produce effects similar to other local anesthetics. due to reversible inhibition of voltage gated sodium channels. Hence, in this study to compare the effects oflevobupivacaine 0.5% and ropivacaine 0.75%.in thoracic epidural anesthesia for modified radicalmastectomy.

AIM OF THE STUDY

The aim of the study is to compare 0.5%levobupivacaine and 0.75% ropivacaine in. thoracic epidural for modified radical mastectomy.

OBJECTIVES OF THE STUDY

- Time of onset.
- Duration of action.
- Monitoring vital parameters- electrocardiography, blood pressure, heart rate, saturation
- Conversion of general anesthesia.
- Patient comfort. (visual pain analogue scale at 1st and 2nd hour)
- Adverse effects. (hypotension, paresthesia)

ANATOMY OF THORACIC EPIDURAL SPACE

- The epidural space is the potential space between periosteum lining the vertebral canal.and spinal duramater.
- It extends from foraman.magnum to the sacral hiatus and surrounds the dura mater.anteriorly, .laterally .posteriorly.

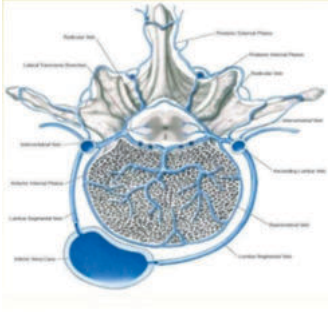
BOUNDARIES:

- Cranially by foraman magnum.
- Caudally by sacroccygealligament(sacral hiatus).
- Anteriorly by posterioirlongitiudinal ligament
- Laterally by vertebral pedicles & intervertebral foramina.
- Posteriorly by ligamentumflavum and laminae.

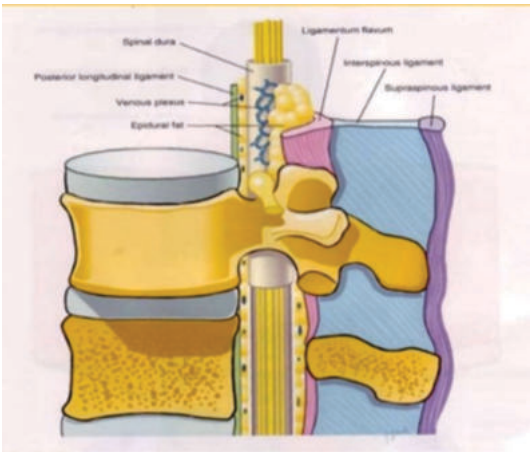
CONTENTS

- Areolar connective tissue
- Fat
- Spinal nerve roots with their dural sleeves
- Blood vessels-spinal arteries and venous plexus(Batson's plexus)
- Lymphatics

BLOOD VESSELS:

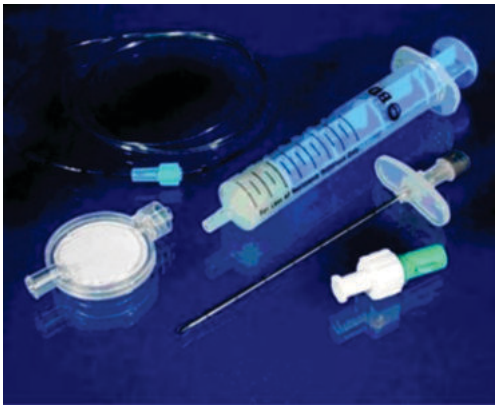


These veins communicate with the segmental veins of the neck, intercostal, azygos and lumbar veins. With the veins of bones of the vertebral column, the internal and external vertebral plexuses form **Batson's plexus.**These veins are predominantly in the antero-lateral part of the epidural space, and ultimately drain into the azygous system of veins.As the whole system is valveless, increased intrathoracic or intraabdominalpressure(e.g.ascites, pregnancy) can lead to major congestion and vessel enlargement within the spinal canal.



- The epidural arteries located in the lumbar region of the vertebral column are branches of the ilio-lumbar arteries.
- These arteries are found in the lateral region of the space and therefore not threatened by an advancing epidural needle

TECHNIQUE:

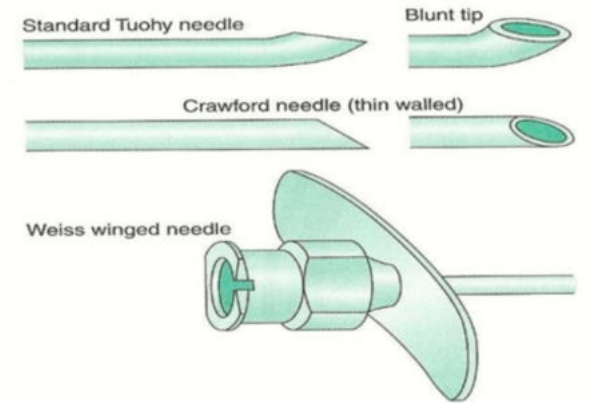


PREPARATION:

- Place patient in sitting or lateral position
- Prepare skin over a wide area with povidone iodine
- Fenestrated sterile drape
- Intervertebral space selection

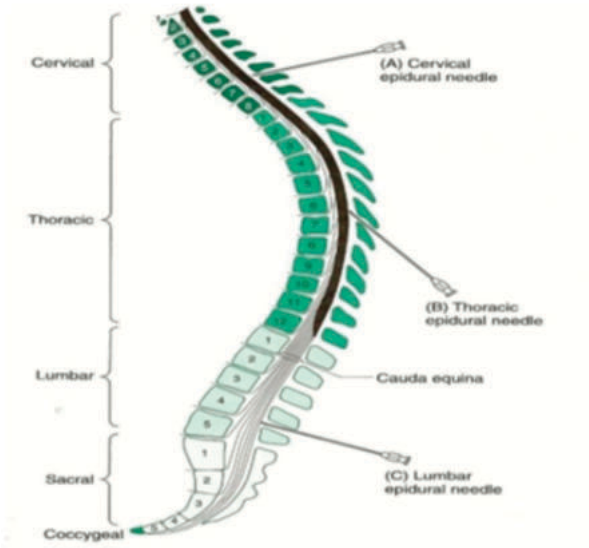
TECHNIQUE:

- Sitting or lateral position
- Local anesthetic is injected at the planned insertion site and a skin wheal is raised with an injection of 1to 2 ml of drug with 26gauge skin needle.
- The epidural is most often performed with 16 /17/18 gauge Tuhoy needle with a blunted tip designed to facilitate passage of a catheter into the epidural space.
- The blunted tip is also designed specially to avoid puncture of dura and if it comes contact with the dura.
- Epidural needle is placed bevel up and introduced into skin
- It is passed slowly through the supraspinous ligament and seated in the interspinous ligament before the stylet is removed.



SITE AND ANGLE OF NEEDLE ENTRY:

- Lumbar- exactly centre and directed perpendicular
- Thoracic:
- T2-T6 - angulated to 40 degrees T7-T12:upper border of lower spine
  Advanced 1 – 2 centimeters.
- Angulated to 70 degrees.
- Cervical – C7-T1 perpendicular



INSERTION:

- Stylet is removed and wall lubricated with loss of resistance syringe.
- Needle and syringe is advanced slowly with the left hand, while the thumb of right hand keeps constant pressure over plunger of the syringe.
- When the needle bevel passes through ligamentumflavum and enters the epidural space sudden loss of resistance to injection occurs.

CONFIRMATION:

- Sudden disappearance of resistance
- Sudden ease of injection of air
- Hanging drop sign
- Capillary tube method (movement of air bubble in a capillary tube attached to hub)

LEVELS OF AREA TO BE BLOCKED:

- Dermatomes that will have to be anaesthetized for a particular surgery are decided.
- The catheter tip to be placed in the center of the dermatomes to be blocked.
- Site of needle entry should be 1 or 2 vertebral spines away from intended site of catheter placement.
- Catheter length of 3-5 centimeters inside the space.
- Determines the spread of the anesthetic agent.

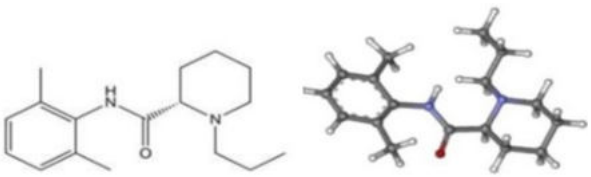
- >5 centimeters
- Kinking and knotting
- Entry into inter vertebral foramen
- <3 centimeters
- Chance of accidental exit
- Threaded cephalic or caudal direction
- Firmly fixed with plaster to skin
- Filters used for high performance anti-bacterial protection
- Epidural test dose used to identify that catheters have entered an epidural vein or the subarachnoid space.
- Commonly used test dose is 3ml of local anesthetic 2% lignocaine containing 5microgram/ml of epinephrine.
- Intravenous injection of this dose of epinephrine typically produces an average 30 beats per minute heart rate increase between 20 and 40 seconds after injection.

ROPIVACAINE:

Introduction:

- Long acting amide local anesthesia with both anesthetic and analgesic effects.
- Similar to bupivacaine &etidocaine in duration of activity.
- Structurally similar to mapivacaine& bupivacaine.
- Decreased cardiotoxicity
- Used for regional nerve block.
- At high doses it produces surgical anesthesia and at lower doses it produces analgesia (sensory block) with limited motor block.

STRUCTURE:

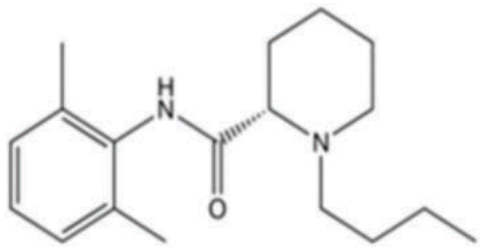


Levobupivacaine

Introduction:

Levobupivacaine pureS- enantiomer of bupivacaine. emerged as a safer alternative for regional anesthesia than its racemic parent. It demonstrated less affinity and central nervous vital centers inpharmacodynamic.status. Clinically, levopubivacaineis well tolerated in a variety of regional anesthesia techniques both after bolus administration and continuous postoperative infusion.

STRUCTURE:



- Levobupivacaine 2,6-dimethylphenyl piperidine -2-carboxamide
- It is pure s-enantiomer of bupivacaine

MECHANISM OF ACTION:

- Reversible blockade of sodium and minimally potassium channels
- Drug binds to intracellular portion of sodium channels.and blocks sodium influx into nerve cells which prevents depolarization.

MATERIALS

Source of Data.

Patients planned for modified radical mastectomy done at Hitech medical college and hospital , Bhubaneswar between February 2021 and June 2021 will be assessed for inclusion and exclusion criteria and will be included in the study after obtaining written informed consent.

STUDY

Comparison of ropivacaine with levobupivacaine under epidural anesthesia in the lower limb orthopedic surgeries: A randomized study

Anesth Essays Res. 2016 Sep-Dec; 10(3): 624–630.

In this study, sensory onset and motor onset were significantly lower in Group II (17.86 ± 2.51 and 23.14 ± 2.73) as compared to Group I (26.14 ± 2.45 and 31.43 ± 2.59) (11% reduction difference)

DESCRIPTION:

- The confidence.level is estimated at 95% With a z value of 1.96.
- The confidence interval.or margin of error is estimated at +/-12.
- Assuming p% =11.and q%=89n = p% x q% x [z/e%] ^{2}n= 11 x 89 x [1.96/12]^{2}n= 27 per group

Adding attrition 10% = 27+3=30 per group

Therefore 60 is the minimum sample size required (30 per group) for the study.

In my study I plan to recruit a minimum of 66 subjects (33 per intervention arm)

STUDY TYPE:

A prospective,.Non–RandomizeddoubleArmand Single-Blind, Controlled study

Inclusion Criteria:

- Patients planned for elective modified radical mastectomy under thoracic epidural anesthesia.
- Age between 30 to 60 years.
- Females.
- ASA class 1 and 2.
- Patients who have given valid informed consent.

Exclusion Criteria:

- Patients not satisfying.inclusion criteria.
- Patients with an allergy.or sensitivity to opioid group of drugs and local anesthetics.
- Patients having spinal deformities.
- Any contraindication. to epidural anesthesia
- Patients with neurological disorders.
- Impaired ability to communicate.
- Patients who are unconscious or severely ill.
- Patients with Coagulation disorders.

METHODOLOGY

Patients in the above mentioned inclusion criteria selected andcounseled about the risks.and also the benefits involved

in the study. After getting consent, .patients who are willing to be included in the study will be enrolled and analyzed.

A total of 60 patients will be included in the study. Patients will be divided into two groups of 30 in each based on computerized random number into group A and group B.The patients in Group A will be receiving 0.5% levobupivacaine, the patients in Group B will receive solution containing 0.75% ropivacaine.The total volume of drug in either group will be 15ml.

This study is a prospective randomized control study. Patients will be preoperatively evaluated, clinically examined.and proper investigations will be done prior to the assessment. Procedures will be explained in detail.and written consent will be obtained.The procedure will be carried out in the theatre. Routine monitoring included ECG, Pulse Oximetry and blood pressure. Intravenous cannulation done with 18G venflon.

Under strict aseptic precautions patient in right lateral position or sitting position midline or paramedian approach at the level of T3-T4,T4-T5 intervertebral space, after subcutaneous infiltration of 2ml of 2% lignocaine, using 18 or 16 Gauge Tuhoyepidural needle, epidural space is identified by loss of resistance technique and catheter is threaded in via the needle. After ensuring that blood or cerebrospinal fluid was not aspirated via catheter, 3ml of 2% lignocaine with adrenaline(1:2,00,000) dilution was administered as a test dose.

The epidural drug administration is given 15 ml in both groups before 20 minutes of incision and sedation with inj.fentanyl 100mcg for both groups and for maintenance drugs given according to the duration.

METHOD OF COLLECTION OF DATA

66 patients added in the study. who undergo elective modified radical mastectomy under thoracic epidural anesthesia will be assessed individually. The parameters mentioned above. in the table will be recorded at every 15 minutes. throughout the surgery. The epidural top up dose will be 8ml of 0.5% levobupivacaine in group A , 8ml of 0.75% ropivacaine in group B.

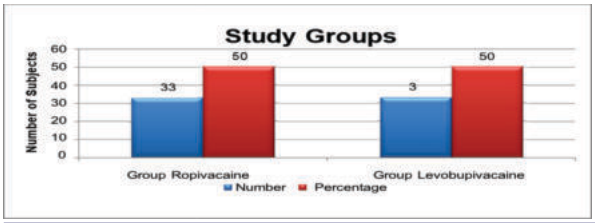
Statistical Analysis:

Descriptive statistics was done.for all data and were reported in terms of mean values and percentages. Suitable statistical tests of comparison were done. Continuous variables. wereanalyzed with the unpaired t test and ANOVA.

Categorical variables were analyzed with the Chi-Square Test and Fisher Exact Test. Statistical significance was taken as $P < 0.05$. The data was analyzed using SPSS.version 16 and Microsoft Excel 2007.

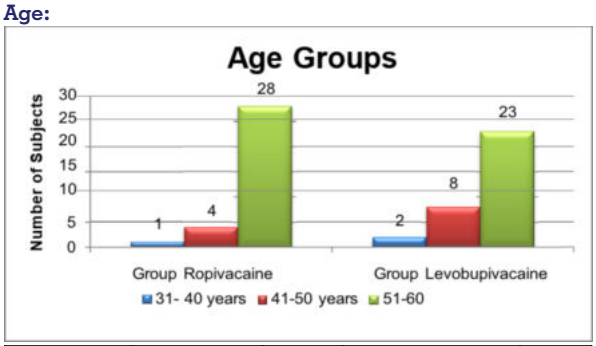
In this study, an analytical approach was adopted to assess the effectiveness of 0.5%levobupivacaine and 0.75% ropivacaine in thoracic epidural for modified radical mastectomy.

Data collected from 66 selected subjects were internally compared, tabulated, analyzed and interpreted by using descriptive and inferential statistics based on the formulated objectives of the study



Study Groups	Intervention	Number	%
Group Ropivacaine	0.75% ropivacaine in thoracic epidural for modified radical mastectomy	33	50.00
Group Levobupivacaine	0.5%levobupivacaine in thoracic epidural for modified radical mastectomy	33	50.00
Total		100	100.00

Age:



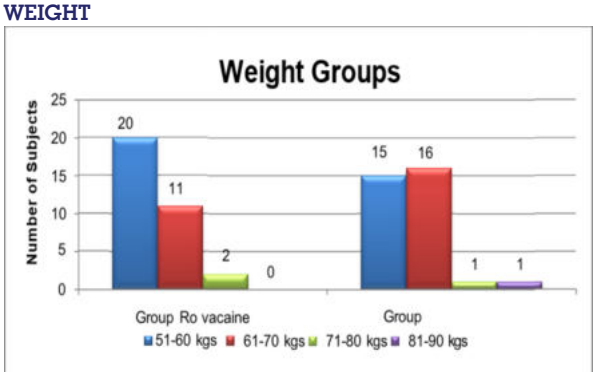
Age Groups	Group Ropivacaine	%	Group Levobupivacaine	%
31- 40 years	1	3.03	2	6.06
41-50 years	4	12.12	8	24.24
51-60 years	28	84.85	23	69.70
Total	33	100.00	33	100.00

Age Distribution	Group Ropivacaine	Group Levobupivacaine
Mean	54.52	53.45
SD	4.79	6.33
P value Unpaired t Test		0.445

Conclusion:

It is evident from the age distribution table.that most of the ropivacaine group subjects were in 51-60 years age group (84.85%) with a mean age of 54.52 years. In levobupivacaine group majority too were in 51-60 years age group (69.70%) with a mean age of 53.45 years.($p = 0.445$) .The data subjected to unpaired t test reveals the existence of statistically non-significant association between age distribution and intervention groups ($p > 0.05$)

WEIGHT



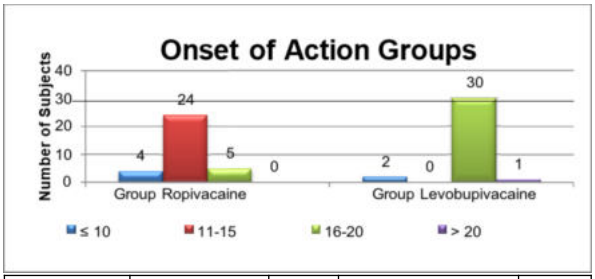
Weight Groups	Group Ropivacaine	%	Group Levobupivacaine	%
51-60 kilograms	20	60.61	15	45.45
61-70 kilograms	11	33.33	16	48.48
71-80 kilograms	2	6.06	1	3.03
81-90 kilograms	0	0.00	1	3.03
Total	33	100.00	33	100.00

Weight Distribution	Group Ropivacaine	Group Levobupivacaine
Mean	61.58	63.00
SD	6.05	6.38
P value Unpaired t Test		0.356

Conclusion:

On analysing the weight distribution table, it was observed that most of the ropivacaine group.subjects were in 51-60 kilograms weight group (60.61%) with a mean weight of 61.58 kilograms. In levobupivacaine group majority were in 61-70 kilograms weight group (48.48%) with a mean weight of 63.00 years. .(p= 0.356). The data subjected to unpaired t test reveals the existence of statistically .non-significant association between weight distribution and intervention in both groups (p > 0.05).

ONSET OF ACTION



Onset of Action Groups	Group Ropivacaine	%	Group Levobupivacaine	%
≤ 10 minutes	4	12.12	2	6.06
11-15 minutes	24	72.73	0	0.00
16-20 minutes	5	15.15	30	90.91
>20 minutes	0	0.00	1	3.03
Total	33	100.00	33	100.00

Onset of Action Distribution (minutes)	Group Ropivacaine	Group Levobupivacaine
Mean	12.52	17.36
SD	2.17	4.76
P value Unpaired t Test		<0.001

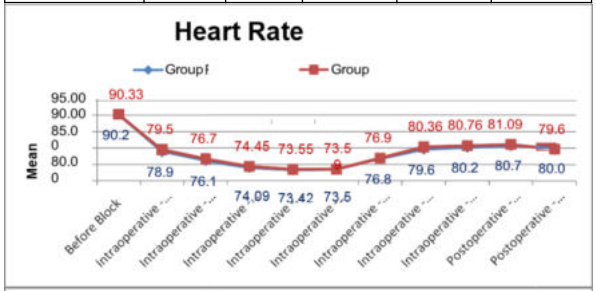
Observations in the onset of action distribution table revealed that most of the ropivacaine group subjects were in 11-15 minutes onset of action group .(72.73%) with a mean onset of action of 15.52 minutes. In levobupivacaine group majority were in 16-20 minutes onset of action group (90.91%) with a mean onset of action of 17.36 minutes..(p= <0.001). The data subjected to unpaired t test reveals the existence of statistically significant association between onset of action distribution and intervention groups for both drugs. (p< 0.05)

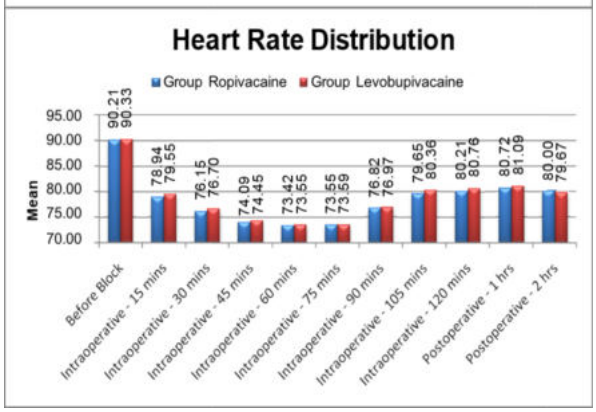
DISCUSSION:

In our study the onset of action status.between the ropivacaine group and levobupivacaine group was meaningfully significant. . This is evident by the decreased onset of action in ropivacaine group.compared to levobupivacaine group (mean difference of 4.85 minutes, 28% shorter).

HEART RATE:

Heart Rate Distribution	Group Ropivacaine		Group Levobupivacaine		P value Unpaired t Test
	Mean	SD	Mean	SD	
Before Block	90.21	7.33	90.33	8.83	0.952
Intra operative - 15 minutes	78.94	6.35	79.55	5.77	0.686
Intra operative - 30 minutes	76.15	6.17	76.70	5.98	0.716
Intra operative - 45 minutes	74.09	5.58	74.45	5.56	0.792
Intra operative - 60 minutes	73.42	5.04	73.55	5.15	0.923
Intra operative - 75 minutes	73.55	5.13	73.59	5.30	0.970
Intra operative - 90 minutes	76.82	4.64	76.97	4.81	0.900
Intra operative - 105 minutes	79.65	4.37	80.36	3.87	0.545
Intra operative - 120 minutes	80.21	5.12	80.76	4.99	0.704
Postoperative - 1 hrs	80.72	5.08	81.09	5.13	0.770
Postoperative - 2 hrs	80.00	6.64	79.67	6.96	0.843



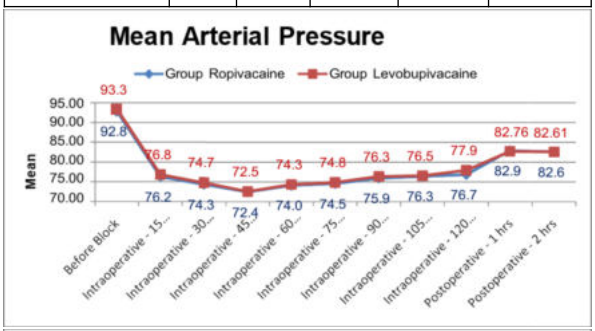


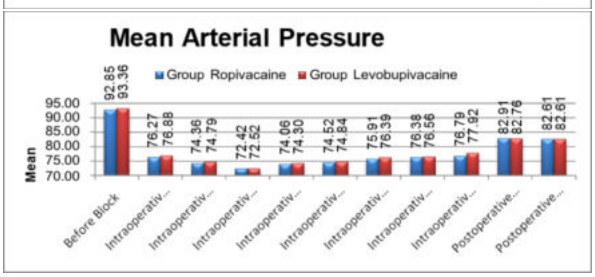
Mean Arterial Pressure:

In the mean arterial pressure distribution table, it was observed that ropivacaine group subjects had a mean MAP of 74.49mm Hg overall from before block to 2 hours postoperative period. Similarly in levobupivacaine group subjects had a mean MAP of 74.42mm Hg overall from before block to 2 hours postoperative period. All data collected from the patients. Subjected to unpaired t test shows non-significant association between mean arterial pressure distribution and intervention groups (p > 0.05.)

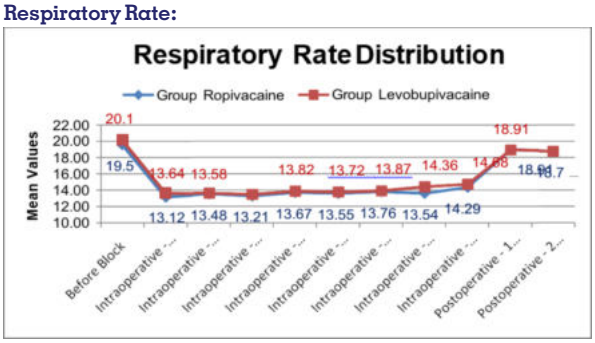
Mean Arterial Pressure Distribution	Group Ropivacaine		Group Levobupivacaine		P value Unpaired t Test
	Mean	SD	Mean	SD	
Before Block	92.85	5.17	93.36	5.38	0.693
Intra operative - 15 minutes	76.27	4.86	76.88	4.83	0.613

Intra operative -30 minutes	74.36	4.94	74.79	4.90	0.727
Intra operative - 45 minutes	72.42	9.09	72.52	9.13	0.968
Intra operative -60 minutes	74.06	4.56	74.30	4.74	0.833
Intra operative - 75 minutes	74.52	4.54	74.84	4.50	0.771
Intra operative - 90 minutes	75.91	4.90	76.39	5.58	0.717
Intra operative - 105 minutes	76.38	5.12	76.56	5.93	0.910
Intra operative - 120 minutes	76.79	4.76	77.92	4.65	0.405
Postoperative - 1 hrs	82.91	3.66	82.76	3.68	0.871
Postoperative - 2 hrs	82.61	3.53	82.61	3.53	1.000

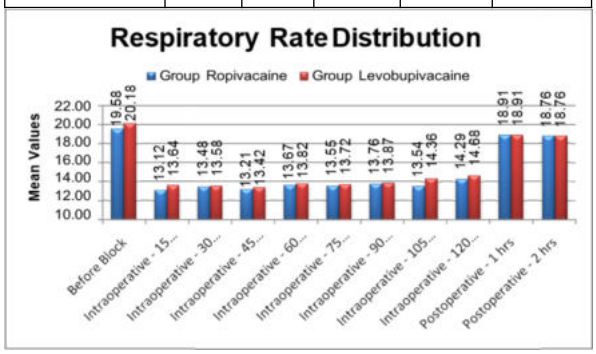




Respiratory Rate:



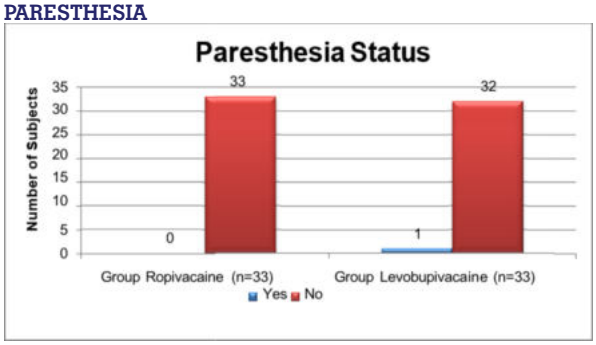
Respiratory Rate Distribution	Group Ropivacaine		Group Levobupivacaine		P value Unpaired t Test
	Mean	SD	Mean	SD	
Before Block	19.58	1.73	20.18	1.57	0.141
Intra operative - 15 minutes	13.12	1.14	13.64	0.96	0.051
Intra operative - 30 minutes	13.48	0.83	13.58	0.83	0.659
Intra operative - 45 minutes	13.21	0.93	13.42	0.87	0.341
Intra operative - 60 minutes	13.67	0.99	13.82	0.88	0.514
Intra operative - 75 minutes	13.55	1.03	13.72	0.96	0.486
Intra operative - 90 minutes	13.76	0.61	13.87	0.50	0.422
Intra operative - 105 minutes	13.54	1.24	14.36	1.29	0.074
Intra operative - 120 minutes	14.29	1.52	14.68	1.55	0.380
Postoperative - 1 hrs	18.91	1.15	18.91	1.28	0.993
Postoperative - 2 hrs	18.76	0.97	18.76	0.97	1.000



In the respiratory rate distribution table, it was observed that ropivacaine group subjects had a mean respiratory rate of 14.41 breaths/min overall from before block to 2 hours postoperative period. Similarly in levobupivacaine group subjects had a mean respiratory rate of 14.60 breaths/min overall from before block to 2 hours postoperative period.

The data subjected to unpaired t test shows. The existence of statistically non-significant association between respiratory rate distribution and intervention groups. (p> 0.05)

PARESTHESIA



Paresthesia Status	Group Ropivacaine (n=33)	%	Group Levobupivacaine (n=33)	%
Yes	0	0.00	1	3.03
No	33	100.00	32	96.97
Total	33	100.00	33	100.00
P value Fishers Exact Test	>0.999			

It is evident from the paresthesia status table that most of the ropivacaine group subjects had no paresthesia (100%) and in levobupivacaine group majority had no paresthesia (96.97%) (p= >0.999).

The data from the patients subjected to fishers exact test shows the existence of statistically non-significant. association between paresthesia status and intervention groups (p >0.05)

DISCUSSION

In this prospective, randomized study, the efficacy of 0.75% ropivacaine and 0.5% levobupivacaine was compared in patients undergoing modified radical mastectomy for breast cancer. 66 patients, satisfying the inclusion criteria were chosen and divided into two groups of 33 each. One group received 0.75% ropivacaine 15ml as starting dose followed by

8 ml topup for every 45 min. Another b group received 0.5% levobupivacaine 15ml as initial dosage followed by 8 ml every 45 min.

It is evident from the age distribution table.that most of the ropivacaine group subjects were in 51-60 years age group (84.85%) with a mean age of 54.52 years. In levobupivacaine group majority too were in 51-60 years age group (69.70%) with a mean age of 53.45 years.(p= 0.445). The data is statistically non-significant association between age distribution and intervention groups ($p > 0.05$)

On analysing the weight distribution table, it was observed that most of the ropivacaine group subjects were in 51-60 kilograms weight group (60.61%) with a mean weight of 61.58 kilograms. In levobupivacaine group majority were in 61-70 kilograms weight group (48.48%) with a mean weight of 63.00 years.(p= 0.356). The data collected from the patients. subjected to unpaired t test reveals the existence ofstatistically.non-significant association between weight distribution and intervention groups ($p > 0.05$)

Observations in the onset of action distribution table revealed that most of the ropivacaine group subjects were in 11-15 minutes onset of action group (72.73%) with a mean onset of action of 15.52 minutes. In levobupivacaine group majority were in 16-20 minutes onset of action group (90.91%) with a mean onset of action of 17.36 minutes.(p= <0.001). The data shoesexistence of statistically significant. association between onset of action distribution and intervention groups ($p < 0.05$).

CONCLUSION

Age, weight, VAS score during Intra operative - 1 hour, Intra operative - Second Dose - After 45 minutesand Postoperative - 2 hours periods,heart rate, MAP, BLOOD OXYGEN SATURATION, respiratory rate, hypotension status and paresthesia statushad no statistically significant role to play on comparison of 0.5%levobupivacaine and 0.75% ropivacaine in thoracic epidural for modified radical mastectomy.

On internal comparison of 0.5%levobupivacaine and 0.75% ropivacaine in thoracic epidural for modified radical mastectomy the following conclusions were observed

- Faster onset of actionin ropivacaine group compared to levobupivacaine group
- Lowered mean VAS scores in ropivacaine group compared to levobupivacaine group during Intra operative - Third Dose - After 45 minutes period leading to better analgesic status

This study is a hypothesis proving study. Hence results have high clinical significance.

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