

Original Research

To Compare The Efficacy Of Isobaric Levobupivacaine And Isobaric Ropivacaine In Patients Undergoing Breast Cancer Surgeries Under Thoracic Segmental Spinal Anaesthesia

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ABSTRACT:

Background- Breast cancer is the second most common cause of cancer deaths in women around the world and the main modality of its treatment is surgery, which is associated with postoperative nausea-vomiting (PONV) and pain. It is commonly performed under general anesthesia (GA), but can also be performed under regional anaesthesia such as thoracic segmental spinal anaesthesia (TSSA), which is an effective alternative to GA especially in patients who are at risk under GA. The aim of the study is to compare the efficacy of isobaric levobupivacaine and ropivacaine in patients undergoing breast cancer surgeries under TSSA. **Methods-** The study enrolled 60 patients scheduled for Modified Radical Mastectomy, divided randomly into two groups of 30 each (group L and R), belonging to the age group 18-60 years of ASA grade I and II. Group L received 1.8 ml 0.5% isobaric levobupivacaine and group R received 1.8 ml 0.5% isobaric ropivacaine. **Results-** The mean onset of sensory block of group R (7.18 ± 0.62 min) was more than group L (3.66 ± 0.51 min). The mean time to attain maximum sensory level in group R (7.91 ± 0.47 min) was more than group L (5.33 ± 0.63 min). Total duration of the sensory block was more in group L (180.83 ± 6.17 min) than group R (129.50 ± 6.47 min). Intraoperative and postoperative hemodynamics were stable and no PONV was seen in either group. The total number of rescue analgesia doses were more in group R (2.16 ± 0.83) than group L (1.46 ± 0.62). **Conclusion-** Isobaric levobupivacaine provides adequate subarachnoid block for breast cancer surgeries under thoracic segmental spinal anaesthesia than isobaric ropivacaine with longer duration of sensory block.

Keywords: Thoracic segmental spinal anaesthesia, isobaric levobupivacaine, isobaric ropivacaine, breast cancer surgery

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INTRODUCTION:

General anaesthesia is considered as the standard technique for breast cancer surgeries.¹ However, it is associated with higher stress response, higher incidences of postoperative nausea-vomiting and increase in length of hospital stay. Breast cancer surgeries are often painful as the breast receives innervations from T3-T6, pectoralis medial and lateral nerves, long thoracic nerve and thoracodorsal nerve. Regional anaesthesia techniques like thoracic segmental spinal anaesthesia can alleviate these side effects and is becoming a preferred alternative for these surgeries

nowadays. It is an effective alternative to GA especially in patients who have medical problems and are at risk under GA. The primary goal in patients undergoing breast surgery is to provide ambulatory anaesthesia with rapid recovery from anaesthesia that would lead to early discharge with early resumption of routine activities providing a higher level of satisfaction to the patients. In the present study, we used isobaric levobupivacaine and isobaric ropivacaine as isobaric drugs deposit close to the puncture site and produce sensory blockade in a limited number of dermatomes causing limited

sympathectomy with minimal vasodilatation and few hemodynamic changes.

MATERIALS AND METHODS:

After obtaining approval from Institutional Ethics and Thesis Committee (Reference Number: 10768/D-26/2021) along with written and informed consent of the patients enrolled, this prospective, randomized, double-blind study was conducted on 60 female patients belonging to American Society of Anaesthesiologists (ASA) grade I and II, 20–60 years of age, admitted in tertiary care hospital undergoing modified radical mastectomy under thoracic segmental spinal anaesthesia.

INCLUSION

RANDOMIZATION:

Randomization was performed using a random number table generated by Microsoft Excel.

AIMS and OBJECTIVES:

The primary aim:

1. Onset of block
2. Duration of sensory block
3. Maximum level of dermatomal block achieved
4. Hemodynamic changes intraoperatively- MAP, HR, SpO₂, RR
5. Surgeon satisfaction score

The secondary aim:

1. Postoperative complications like Postoperative nausea and vomiting, pruritus, hypotension
2. Adequacy of analgesia using Visual Analogue Scoring (VAS)
3. Rescue analgesia
4. Patients satisfaction score

PROCEDURE:

Pre anaesthetic assessment was done a day prior to surgery and written informed consent was obtained from all the patients after explaining the possible risks and benefits of the procedure. All the patients were kept nil per oral as per the fasting guidelines and were premedicated with oral Alprazolam 0.25 mg night before surgery. An intravenous line was secured in the preoperative room. Intravenous Inj. Midazolam 0.05 mg/Kg 20 minutes before surgery. Inj. Glycopyrrolate 0.01 mg/Kg intravenously and Inj. Butorphanol 0.02 mg/Kg i.v. was given just before the surgery.

After shifting patients to the operation theater, the monitors were attached to patient and baseline blood pressure (BP), pulse rate (PR), pulse oximetry (SPO₂), respiratory rate (RR) and electrocardiography (ECG) were noted.

The patients were made to sit with their head flexed. The upper back of the patient was cleaned with

povidone iodine solution and draped and the skin of the puncture site (T5-T6) was infiltrated with 2-3 ml of 2% Lignocaine. The subarachnoid space (SAS) puncture was performed at T5-T6 interspace with 26 G spinal needle. After introducing the spinal needle, stylet of the needle was removed and once free flow of CSF began, 0.5% of 1.8 ml of Isobaric Levobupivacaine (in group L) and 0.5% of 1.8 ml of Isobaric Ropivacaine (in group R) was injected. The patient was placed back to supine position.

The onset of sensory block was the time taken from injection of local anaesthetic in intrathecal space upto the time when the patient did not feel the pin prick sensations from the lower border of the clavicle (T2) to the inferior costal margin (T7). The patient was monitored intraoperatively and was followed postoperatively until discharged from the post anaesthesia care unit (PACU) and the data was recorded. The total duration of sensory blockade was considered as the time interval from intrathecal administration to regression of the sensory blockade.

Intra-operatively sensory block was checked only when the patient complained of discomfort or surgeon unsatisfied with level of anaesthesia. In case, the effect of the drug could not block the desired dermatomes required for surgery, GA was given and the patient was excluded from the study.

MONITORING:

Continuous multi-parameter hemodynamic monitoring (MAP, HR, RR, SpO₂, ECG) was done. Readings were recorded intra-operatively post giving thoracic spinal at 1, 3 and 5 minutes and then further every 5 minutes till the end of surgery in each group. Postoperatively readings were recorded every 1 hourly for 4th hour, then 2 hourly till 8 hour, then 4 hourly till 12th hour and then 6 hourly till 24th hour of study period.

Any side effects or complications were noted intra-operatively and managed accordingly: hypotension, bradycardia, nausea and vomiting, shivering, pruritus, headache, paresthesia during needle insertion, local anaesthetic toxicity, urinary retention, pain, neurological changes, backache and other complications.

RESCUE ANALGESIA:

Pain relief in the intraoperative & postoperative period was assessed by the Visual Analog Scale (VAS) till 24 hours. This was carried out with a 10 cm line. The first end mark '0' means 'no pain' and the end marked '10' means 'severe pain'. Time of 1st rescue analgesia was recorded which was given if the VAS >3. Drug preferred was Inj. Diclofenac (75 mg im). For breakthrough pain, inj. Paracetamol (1g iv) was given.

STATISTICAL ANALYSIS:

The above mentioned parameters and characteristics of the patients were compared using appropriate statistical tests. The results were analyzed and compared to the previous studies. Sample size was calculated keeping in view at most 5% risk, with minimum 80% power and 5% significance level (significant at 95% confidence interval). Data was recorded in a Microsoft excel spreadsheet and analyzed using Statistical Package for the IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp., Chicago.

Continuous data was presented as mean with standard deviation. Categorical data was expressed as numbers

and percentages. Power analysis was done to calculate the power of study which was 95% by taking α error 0.05. The p-value was then determined to evaluate level of significance.

The data from present study was systematically collected, compiled and statistically analyzed to draw relevant conclusions.

RESULTS:

Both the groups were comparable with respect to demographic parameters including mean age, ASA grade and mean weight as well as the duration of surgery. (Table-1)

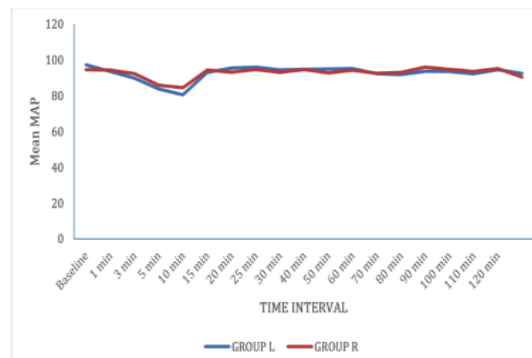
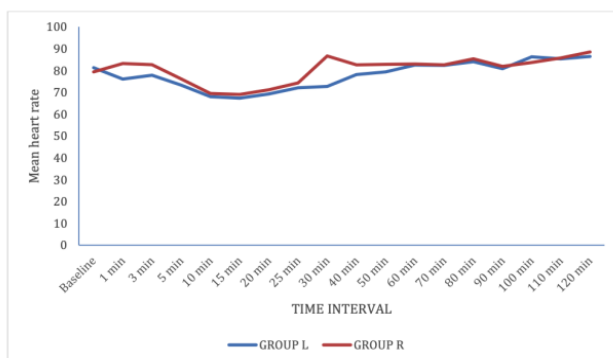
Table-1

Variable	Group L	Group R	p-value
Age	47.40±9.62	49.40±9.36	0.418
ASA grade I/II	9/21 (30/70)	7/23 (23.33/76.67)	0.559
Weight (Kg)	66.30±5.14	65.30±4.94	0.419
Duration of surgery (in minutes)	94.33±10.88	93.16±8.25	0.642

The onset of sensory block and the mean time to attain the maximum sensory level was faster, and the duration of sensory block was prolonged in group L. (Table-2)

Table-2

Parameters	Group L	Group R	p-value
Onset of sensory block (in min)	3.66±0.51	7.18±0.62	0.001*
Time to attain maximum sensory block (in min)	5.33±0.63	7.91±0.47	<0.001*
Total duration of sensory block (in min)	180±6.17	129.50±6.47	0.001*

**Fig 2: Intraoperative Heart Rate**

Intraoperatively, there was no significant difference as regards to MAP (Fig.1), HR (Fig.2), or oxygen saturation. However, hypotension developed in 6 (20%) patients in group L and in 3 (10%) patients in group R for which injection ephedrine was given i.v. Bradycardia was observed in 3 (10%) patients in group L and in 2 (6.66%)

patients in group R which was successfully managed with injection atropine sulfate 0.6 mg i.v. The incidence of nausea was observed in 2 (6.66%) patients in group L and 1 (3.33%) patient in group R. 5 (16.67%) patients experienced paresthesia during needle insertion in group L and 4 (13.33%) patients in group R. (Table-3).

Table-3

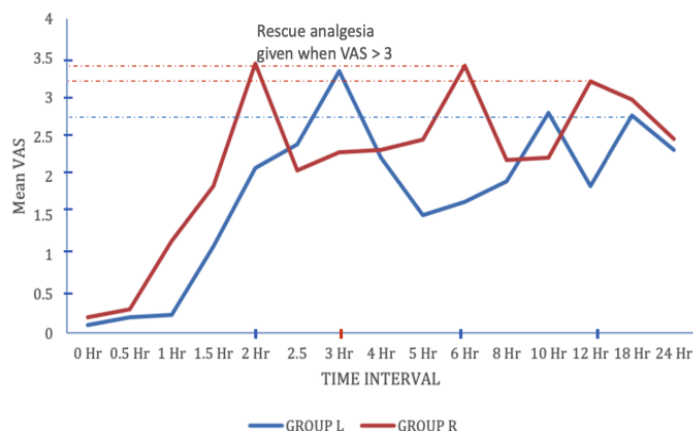
Complications	Group L	Group R	p-value
Hypotension	6 (20%)	3 (10%)	0.278
Bradycardia	3 (10%)	2 (6.66%)	0.640
Nausea	2 (6.66%)	1 (3.33%)	0.640
Vomiting	-	-	-
Paresthesia during needle insertion	5 (16.67%)	4 (13.33%)	0.553
Pruritus	-	-	-
High Spinal	-	-	-

The surgeon satisfaction score was higher in group L (4.06 ± 0.45) than group R (3.53 ± 0.50). Also the patient satisfaction score was significantly better in group L (4.10 ± 0.48) as compared to group R (3.40 ± 0.45). The total number of rescue analgesia doses were higher in group R (2.16 ± 0.83) than group L (1.46 ± 0.62). (Table-4)

Table-4

Parameters	Group L	Group R	p-value
Surgeon satisfaction score	4.06 ± 0.45	3.53 ± 0.50	$<0.001^*$
Patient satisfaction score	4.10 ± 0.48	3.40 ± 0.45	$<0.001^*$
Total number of rescue analgesia doses	1.46 ± 0.62	2.16 ± 0.83	0.001^*

The analysis of the distribution of mean VAS score between group L and group R was statistically significant at 1st, 2nd, 3rd, 5th, 6th 10th and 12th hour post segmental spinal anaesthesia ($p < 0.05$). Rescue analgesia was given primarily as injection diclofenac 75 mg im. For breakthrough pain, second rescue analgesia injection paracetamol 1 g iv was given. (Fig.3)

**Fig.3: Intraoperative and Postoperative VAS**

DISCUSSION:

With the advancement in the anaesthesia techniques, the trend of outpatient or short stay surgeries is increasing. Advantages like early mobilization, early discharge, cost effectiveness, patient comfort, safer anaesthetic techniques, decrease in the incidence of nosocomial infections etc. Spinal anaesthesia is the most commonly used technique for outpatient surgery due to its rapid onset and offset, easy administration, minimal expenses, effective analgesia and prolonged postoperative analgesia.

In our study, both groups were similar with regard to patient characteristics i.e. age, sex, ASA grade and duration of surgery.

MEAN TIME TO ONSET OF SENSORY BLOCK

(IN MINUTES): The mean time taken from the end of injection to loss of pin prick sensation from T2-T7 dermatome (onset of sensory block) in groups L & R was 3.66 ± 0.51 minutes and 7.18 ± 0.62 minutes respectively. Difference between 2 groups was statistically highly significant ($p=0.001$).

The results of group L of our study are in concordance with study done by Kour L. et al., using 0.5% isobaric levobupivacaine 2 ml + (25 µg) Fentanyl 0.5 ml for laparoscopic cholecystectomies under thoracic segmental spinal anaesthesia, with subarachnoid space puncture performed at T9-T10 or T10-T11. Onset of the sensory block was 2.03 minutes in group levobupivacaine. Duration of onset in this study was faster than in our study, which may be because of the higher dose of their study drug and addition of fentanyl as an adjunct.

Results of group R of our study are similar to the study done by Tarkase et al, using 0.5% hyperbaric Ropivacaine 3 ml in patients scheduled for infraumbilical surgeries. Lumbar puncture was performed at L3-4 or L4-5 with extensive cephalic spread upto T6. The mean time to onset of the sensory block was 7.26 ± 2.25 minutes in the Ropivacaine group..

MEAN TIME TO ATTAIN MAXIMUM SENSORY LEVEL (IN MINUTES):

In our study, the mean time to achieve maximum sensory block in groups L was 5.33 ± 0.63 minutes and 7.91 ± 0.47 minutes in group R. Drugs being isobaric, show segmental block with drug deposition proximal to punctured or target site with limited dermatomal spread.

Oraon P et al., conducted a study comparing intrathecal 0.5% hypobaric Levobupivacaine 2.5 ml and 0.5% hypobaric Ropivacaine 2.5 ml for lower segment cesarean sections. The mean time to maximum cephalic spread of the group L of their study was 5.2 ± 0.76 minutes and of group R was 5.33 ± 0.60 minutes, which is in line with results of our study.

In a study done by Kour L. et al., using 0.5% isobaric levobupivacaine 2.5 ml + Fentanyl 25µg for laparoscopic cholecystectomies under thoracic segmental spinal anaesthesia given at T9-T10 or T10-T11. The mean time to achieve peak sensory block height was 4.8 minutes, which was much earlier than our group L. The difference of time to achieve maximum height from our study could be because of the higher dose of the study drugs being used and the addition of Fentanyl to the study drug.

MEAN TOTAL DURATION OF SENSORY BLOCK (IN MINUTES):

Mean duration of sensory blockade in group L was 180.83 ± 6.17 minutes and in group R was 129.50 ± 6.47 minutes. The difference between the groups L and R was highly significant ($p=0.001$).

The results of the Levobupivacaine group of our study are comparable to the results of group L of the study conducted by Kour L. et al., using isobaric levobupivacaine 2.5 ml + Fentanyl 25 µg for laparoscopic cholecystectomies under thoracic segmental spinal anaesthesia given at T9-T10 or T10-T11, where the total duration (in minutes) of the sensory block was 180.03 minutes.

A study conducted by Chandra R et al., using isobaric Levobupivacaine 1.5 ml + 5 µg Dexmedetomidine in thoracic segmental spinal anaesthesia given at T5-T6 or T6-T7 for modified radical mastectomies, where they observed that the duration (in minutes) of the sensory block was between 122-154 minutes. The results of this study are in contrast to our study. This could be due to the fact that they used less doses of the study drug.

The results of the group R of the present study are in concordance to the study conducted by Oraon P et al., the mean total duration (in minutes) of sensory block of the group R was 126.67 ± 15.55 minutes. And the mean total duration (in minutes) of sensory block of group L was 137.67 ± 16.95 minutes.

Similarly, the results of group Ropivacaine of our study are in accordance with study done by Vincenzi P et al., in 4 patients undergoing breast and axillary surgery under opioid free thoracic segmental anaesthesia with intrathecal sedation. The thoracic segmental spinal anaesthesia was given at T6-T7 or T7-8 using preservative free Midazolam 2 mg, preservative free Ketamine 20 mg and 3.2 ml of 0.25% Isobaric Ropivacaine (8 mg). The duration (in minutes) of the sensory block of 4 patients ranged between 120-165 minutes.

HEMODYNAMIC PARAMETERS:

Respiratory rate and Oxygen saturation-

The mean baseline respiratory rate and the mean baseline oxygen saturation (SPO2) in group L and group R was found to be comparable in the two groups

with p -value >0.05 at all measured intervals in intraoperative and postoperative periods.

Heart Rate-

The mean baseline heart rate in group L was 81.20 ± 6.25 per minute and 79.33 ± 6.22 per minute in group R, which was comparable between the two groups ($p > 0.05$). In the present study, 3 patients (10%) of group L had a significant fall in heart rate during the 5-15 minutes interval as compared to 2 patients (6.66%) of group R.

MEAN ARTERIAL BLOOD PRESSURE (MAP)-

The mean baseline MAP was 97.23 ± 8.46 mmHg in group L and 94.53 ± 9.00 mmHg in group R. Blood pressure recordings were recorded at a 5 minute interval in the two groups in both intraoperative and postoperative period. The difference was statistically significant ($p = 0.03$) at 10 minute post giving spinal but remained non-significant at all other measured intervals ($p > 0.05$). Hypotension was observed in 6 patients (20%) in group L and 3 patients (10%) in group R.

VAS SCORE & DURATION OF ANALGESIA:

VAS score was evaluated with 0 hour taken as time of injection of 0.5% Isobaric Levobupivacaine and injection 0.5% Isobaric Ropivacaine intrathecally in both the groups respectively. VAS was measured from time of the onset of the sensory block every half hourly till 3 hours, then one hourly till 6th hour, then 2 hourly till 12th hour and then every six hourly till 24 hours and was given rescue analgesia when the VAS was >3 in both the groups. The time to first rescue analgesia was longest in group L which was demanded at 3rd hour than group R which was demanded at 2nd hour.

The results of the Levobupivacaine group of our study are in accordance with the study done by Kour L et al., using 0.5% isobaric bupivacaine 2.5 ml + 25 μ g Fentanyl in thoracic segmental spinal anaesthesia (at T9-T10 or T10-T11) for laparoscopic cholecystectomies, where the 1st dose of the rescue analgesia was given at 180.03 minutes (~3 hours).

Paliwal NW et al., conducted a study using 0.5% isobaric Levobupivacaine 2 ml + 25 μ g Fentanyl for thoracic segmental spinal anaesthesia in patients undergoing laparoscopic cholecystectomy with subarachnoid space puncture at T9-T10, also documented the increase in VAS and the 1st rescue analgesia dose given at the 3rd hour post giving spinal, which was comparable to the Levobupivacaine group our study.

In the Ropivacaine group of our study, VAS started increasing at 1.5 hours and the patient demanded the 1st rescue analgesia dose at 2nd hour. This is in accordance with the study done by Chung CJ et al, using 18 mg (3.5 ml) of 0.5% hyperbaric Ropivacaine for LSCS, with

lumbar puncture done at L2-3 or L3-4, where the 1st rescue analgesia dose was given at 129.2 ± 28.5 minutes.

DOSES OF RESCUE ANALGESIA

The patients in group Levobupivacaine required less doses of rescue analgesia as compared to group Ropivacaine. Number of rescue analgesia doses required in group L were 1.46 ± 0.62 and in group R were 2.16 ± 0.86 . Difference between the 2 groups was statistically highly significant ($p = 0.002$).

The results of the Levobupivacaine group of the present study are comparable to the study conducted by Paliwal N et al., using 0.5% isobaric Levobupivacaine 1 ml with 20 mcg Fentanyl for breast cancer surgeries under thoracic segmental spinal anaesthesia, where the mean total opioid consumption was 70.00 ± 27.38 and only 5 out of 28 patients (17.85%) required the rescue analgesia.

SURGEON SATISFACTION SCORE-

Surgeon satisfaction score was recorded intraoperatively in both the groups. Score range varied from minimum 1 (very dissatisfied) to maximum 5 (very satisfied). Difference between the mean of Surgeon satisfaction score in the two groups was significant ($p < 0.0001$), suggesting that surgeons in group L were more satisfied than those in group R. The mean surgeon satisfaction score was more in group L (4.06 ± 0.45) than in group R (3.53 ± 0.50).

In the group Levobupivacaine of the present study, the Surgeon satisfaction scores were 3 in 2 patients (6.67%), 4 in 24 patients (80%) and 5 in 4 patients (13.33%). The outcome of Levobupivacaine group of our study was comparable to the outcome of the study conducted by Paliwal N. et al., using 0.5% isobaric Levobupivacaine 1 ml with 20 mcg Fentanyl in thoracic segmental spinal anaesthesia for breast cancer surgeries at T5-T6, where the median surgeon satisfaction score was 5 with interquartile range (IQR) of 1.

In Group Ropivacaine of the present study, the Surgeon satisfaction scores were 3 in 14 patients (46.67%) & 4 in 16 patients (53.33%). The outcome of group R of our study are in contrast to the study done by Chung CJ et al, using 18 mg (3.5 ml) of 0.5% hyperbaric Ropivacaine for LSCS, where 27 patients (90%) experienced excellent (score 5) muscle relaxation intraoperatively and 3 patients (10%) described satisfactory (score 4) intraoperative muscle relaxation.

PATIENT SATISFACTION SCORE-

Patient satisfaction scores were recorded in both intraoperative and postoperative periods in both the groups. Score range varied from minimum 1 (very dissatisfied) to maximum 5 (very satisfied). Difference of the patient satisfaction score between the 2 groups was statistically significant ($p < 0.001$) in our study,

suggesting that patients in group L were more satisfied than those in group R.

In group L, the patient satisfaction score was 3 in 2 patients (6.67%), 4 in 23 patients (76.67%) and 5 in 5 patients (16.66%). The outcome of Levobupivacaine group of our study were comparable to the outcome of the study conducted by Paliwal N et al., using 0.5% isobaric Levobupivacaine 1 ml with 20 mcg Fentanyl in thoracic segmental spinal anaesthesia for breast cancer surgeries at T5-T6, where the median patient satisfaction score was 5 with interquartile range (IQR) of 1.

In group R, 18 patients (60%) had a patient satisfaction score of 3 & 12 patients (40%) had a score of 4. No patient had a patient satisfaction score of 5. The results of group Ropivacaine of our study were in contrast to the study done by Chung CJ et al, using 18 mg (3.5 ml) of 0.5% hyperbaric Ropivacaine for LSCS, where 26 (86.87%) patients experienced excellent (score 5) analgesia, 1 (3.3%) patient experienced good analgesia (score 4) and 3 (10%) patients described that the intraoperative analgesia was fair (score 3).

LIMITATIONS

1. The sample size of the study was small. Though the results of our study were conclusive, we feel that larger sample size would have been more beneficial and would have added more strength to our findings.
2. Only ASA grade I & II patients were included in the study.
3. Very limited literature was available on Isobaric levobupivacaine and Isobaric Ropivacaine for thoracic segmental spinal for thoracic surgeries. Had the literature been available, it would have added more strength to our findings.
4. The anaesthesiologist performing the block was also monitoring the block parameters. Hence, double blinding was not possible.

CONCLUSION

It is concluded from our study that Isobaric Levobupivacaine provides adequate subarachnoid block for breast cancer surgeries under Thoracic Segmental Spinal Anaesthesia than Isobaric Ropivacaine. Both the groups were effective in providing adequate surgical anaesthesia and analgesia with good hemodynamic stability but Isobaric Levobupivacaine is better than Isobaric Ropivacaine as regard to:

Early onset of the sensory block
Extended duration of the sensory block
Prolonged postoperative pain analgesia
Lesser number of doses of rescue analgesia
Higher Surgeon and Patient satisfaction scores

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