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A STUDY OF DIFFERENT LOCAL ANAESTHETIC DRUGS USED IN THORACIC EPIDURAL ANAESTHESIA FOR BREAST SURGERIES IN TERTIARY CARE CENTRE IN TRIBAL AREA

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ABSTRACT

Background: Breast cancer is the second most common malignancy in females. Surgery is one of the mainstays of treatment. Thoracic Epidural Anaesthesia has demonstrated as a reasonable and safe alternative to GA for MRM where patients are found to have better preservation of pulmonary function and can ambulate early. Hence the present observational, analytical study was done at our tertiary care Centre to compare the effect of 0.75 % ropivacaine and 0.5% bupivacaine on hemodynamically stability, onset of action and postoperative analgesia in thoracic epidural anaesthesia in breast surgeries.

Methods: The observational, analytical study included 58 patients posted for elective breast surgeries under thoracic epidural anesthesia. Patients were allocated in two groups. One group is with 29 Patients were given Bupivacaine (0.5%)- Group A and in other group 29 patients were given Ropivacaine (0.75%)- Group B. The study done to compare the onset of action, hemodynamically stability and post-operative analgesia in thoracic epidural anaesthesia in breast surgeries.

Results:

The demographic characteristics (age, weight, BMI) and ASA Grading of our study is comparable between the two groups and not significant statistically. The onset of sensory block (18.24±2.79 mins vs. 13.52±3.31 mins; $p<0.05$) was significantly longer in Group A compared to Group B. The mean duration of sensory block (92.52±2.01 mins vs. 119.69±2.65 mins; $p<0.05$) was significantly prolonged in Group B compared to Group A. The heart rate, systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP) and SpO2 levels were comparable between the groups throughout the time interval. The time for requirement of first rescue analgesic was significantly longer in Group B compared to Group A as per Student t-test (546.28±72.44 mins vs 448.69±39.15 mins; $p<0.05$). The VAS score at post-operative time intervals (15 mins, 30 mins, 1 hour, 2 hours, 4 hours, 8 hours and 12 hours) was comparable between the groups ($p>0.05$).

Conclusion: Thoracic epidural anaesthesia comparing the effect of 0.75% ropivacaine and 0.5% bupivacaine is a safe and effective for breast surgery because it offers better hemodynamic stability and provides post operative analgesia. Time for requirement of first rescue analgesic was significantly longer in Group Ropivacaine compared to Group Bupivacaine. Hence thoracic epidural anaesthesia with 0.75% Ropivacaine is superior to 0.5% Bupivacaine in terms of intraoperative hemodynamic stability and postoperative analgesia.

Keywords: *Thoracic epidural anaesthesia, Bupivacaine (0.5%), Ropivacaine (0.75%).*

INTRODUCTION

Breast cancer is the most common cancer among Indian females with an age- adjusted rate as high as 25.8 per 100,000 women and mortality of 12.7 per 100,000 women[1]. It can occur at any age but the incidence rate in India begin to rise in the early thirties and peak at ages 50-64 years[2]. It is the second most common malignancy in females. Surgery is one of the mainstay treatments. Modified radical mastectomy (MRM) typically involves removal of the entire breast, including the skin, areola, nipple, and most axillary lymph nodes, but the pectoralis major muscle is spared. MRM is usually done under general anesthesia (GA).

In general, the infrequent use of Thoracic Epidural Anaesthesia for oncologic breast surgeries may be attributed to fear of potential complications like spinal cord injury, respiratory complications, spinal/epidural hematoma, and post-dural puncture headache. Thoracic Epidural Anaesthesia has demonstrated as a reasonable and safe alternative to GA for MRM where patients are found to have better preservation of pulmonary function and can ambulate early. Hence the present observational, analytical study was done at our tertiary care centre to compare the effect of 0.75 % ropivacaine and 0.5% bupivacaine on hemodynamically stability, onset of action and postoperative analgesia in thoracic epidural anaesthesia in breast surgeries.

MATERIALS AND METHODOLOGY

Total 58 patients were included in the study after obtaining institutional ethical committee approval and written informed consent of patients. Patient undergoing Elective breast surgeries (phyllodes tumor, multiple and giant fibroadenomas, lipomas, antibioma, MRM Surgeries) under thoracic epidural anesthesia, Females patients age between 18-70 years, Weight 50-80 Kg, American Society of Anesthesiologists grade 1 and 2.

Group A: 29 patients were given Bupivacaine (0.5%)

Group B: 29 patients were given Ropivacaine (0.75%)

Patient's/ surgeon's refusal to participate in the study, Patient's with uncontrolled systemic diseases (e.g. diabetes mellitus, asthma and chronic obstructive lung disease), Vertebral deformities and coagulopathy disorders, cardiovascular disease, hepatic or renal disease, bronchospastic disease (ASA grade 3 or more) and pregnant females, Emergency surgeries were excluded from study.

Pre-anesthetic evaluation of the patients was performed by an anesthesiologist a day before the surgery. All patients were kept nil by mouth for 8 hours prior to surgery. A written informed valid consent was obtained from the patients who satisfy the inclusion criteria, after explaining about the procedure and technique. The patients satisfying the criteria were investigated preoperatively with a complete blood count, renal function tests, coagulation profile, 12 lead electrocardiogram, chest X-ray and echocardiogram. All patients were adequately explained and educated about the visual analog scale (VAS) (zero: no pain, ten: the worst pain experienced). In the pre operative room, a peripheral intravenous access will be secured using 18 Gauge cannula in the hand opposite to the side of surgery. The patients were premedicated with Tab. Alprazolam 0.5mg on the night before surgery, Tab. Pantoprazole 40 mg and Tab. Metoclopramide 10 mg in the morning one hour prior to surgery. In the operating room, monitors like an electrocardiogram, non-invasive blood pressure, and pulse oximetry were connected and the baseline parameters were recorded. Normal saline at 4ml/kg/hour was started.

With the patient in the sitting position, under all aseptic precautions, the thoracic epidural block was performed at T5-T6 intervertebral space. The epidural space identified by loss of resistance (LOR) technique using an 18G Tuohy needle. The epidural catheter was introduced 4-5 cm into the epidural space. Intravascular and intrathecal placement of the catheter was used to rule out by the standard test dose of 3ml of 2% lignocaine with adrenaline 1: 200000 after procedure. The catheter was secured to the skin. The patient was positioned supine and the hemodynamic parameters were noted. Five minutes after the test dose, 8 ml of the test drug administered through the epidural catheter for a period slowly, if the action did not come immediately below the clavicle, then 2 ml of the test drug is added. The patients in Group A received 8-10 ml of 0.5% bupivacaine whereas Group B received 8-10 ml of 0.75% ropivacaine. If action is not achieved by the test drug, those patients are excluded from the study.

The adequate level of anesthesia was confirmed from the inferior border of the clavicle to the inferior costal margin, using the pinprick method, then surgery will be initiated. The patients were sedated with midazolam 1.5 mg IV and oxygen at the rate of 6 L/min was administered via face mask. Intraoperative hemodynamics including heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP) and oxygen saturation (Spo2) were monitored every 5 minutes after the initial epidural dose till half an hour and thereafter every 15 minutes till the end of surgery. 60 minutes after the initial epidural dose, a top-up dose of 4 ml of the same drug i.e. 0.5% bupivacaine or 0.75% ropivacaine was administered, which was also repeated every 45 minutes till the end of surgery. Fluids were administered according to the maintenance requirements and blood loss. Any rise in MAP by more than 20 mmHg from the baseline was considered as hypertension, any increase in HR by more than 20% from the baseline was considered as tachycardia and was treated with incremental doses of IV Fentanyl 25 mcg and IV Midazolam 1mg. Hypotension was defined as a decrease in mean arterial pressure (MAP) of more than 20% from baseline and it was treated with 6 mg of mephentermine.

Bradycardia, defined as a heart rate of less than 60 beats per minute. It was treated with 0.6 mg of atropine intravenously (IV) as a stat dose, if Heart Rate less than 50 beats per minute or less than 60 beats per minute if patient is symptomatic.

Episodes of hypotension or hypertension, tachycardia or bradycardia during the procedure were noted in both the groups. Postoperatively patients were shifted to recovery room with continuous monitoring of vital parameters for 30 minutes. After anaesthesiologist clearance, the patient will be transferred to post-operative ward.

Based upon the Visual Analogue Scale, if the score is > 4, sensory top up of 0.125% (8cc) of Bupivacaine or 0.1875% (8cc) of Ropivacaine was given to the patients till 24 hours. After that the catheter is removed.

Onset time for the sensory block defined as the time interval between the end of local anesthetic administration and complete loss of pin prick sensation at the lower border of the clavicle.

Duration of the sensory block is defined as the time interval between the complete sensory block to complete recovery from pin prick sensation at the lower border of clavicle and cold sensation is tested by alcohol swab.

HR, SBP, DBP, MAP, SpO2 was recorded every 5 minutes till 30 minutes and every 15 minutes till end of surgery and Adverse events such as Hypotension, bradycardia, Nausea, vomiting were noted and treated accordingly.

STATISTICAL ANALYSIS

The data was collected and entered in Microsoft excel and analyzed using IBM SPSS

Statistics 20.0 The quantitative data was expressed in terms of mean and standard deviation. The qualitative data was expressed in terms of numbers and percentages. Independent t test was used to compare mean between two independent group. Fisher exact test was applied to determine the association between the two categorical variables. p value < 0.05 was considered significant.

OBSERVATIONS AND RESULTS

The demographic characteristics (age, weight, BMI) of our study is comparable between the two groups and not significant statistically as depicted in following table.

Table 1: Distribution of patients according to Age:

Age (years)	Group A		Group B		p Value
	N	%	N	%	
18-20 years	1	3.4%	1	3.4%	>0.05
2130 years	1	3.4%	2	6.8%	
31-40 years	3	10.2%	4	13.6%	
41-50 years	5	17.2%	4	13.6%	
51-60 years	8	27.6%	6	20.4%	
61-70 years	11	38.2%	12	42.2%	
Total	29	100%	29	100%	
Mean ± SD	53.62 ± 12.93		52.69 ± 14.27		

Table 2: Distribution of patients according to Weight and BMI:

Weight (kg)	Group A		Group B		p Value
	N	%	N	%	
51-60 kgs	7	24.1%	8	27.6%	>0.05
61-70 kgs	10	34.2%	11	38.2%	
71-80 kgs	12	41.7%	10	34.2%	
Total	29	100%	29	100%	
Mean BMI	66.83 ± 8.84		66.31 ± 8.15		

Table 3: Distribution of patients according to ASA Grading:

ASA Grading	Group A		Group B		p Value
	N	%	N	%	
I	16	55.2%	18	61.8%	>0.05
II	13	44.8%	11	38.2%	
Total	29	100%	29	100%	

The ASA Grading of the patients between two groups was comparable and statistically not significant as per Chi-Square test (p>0.05).

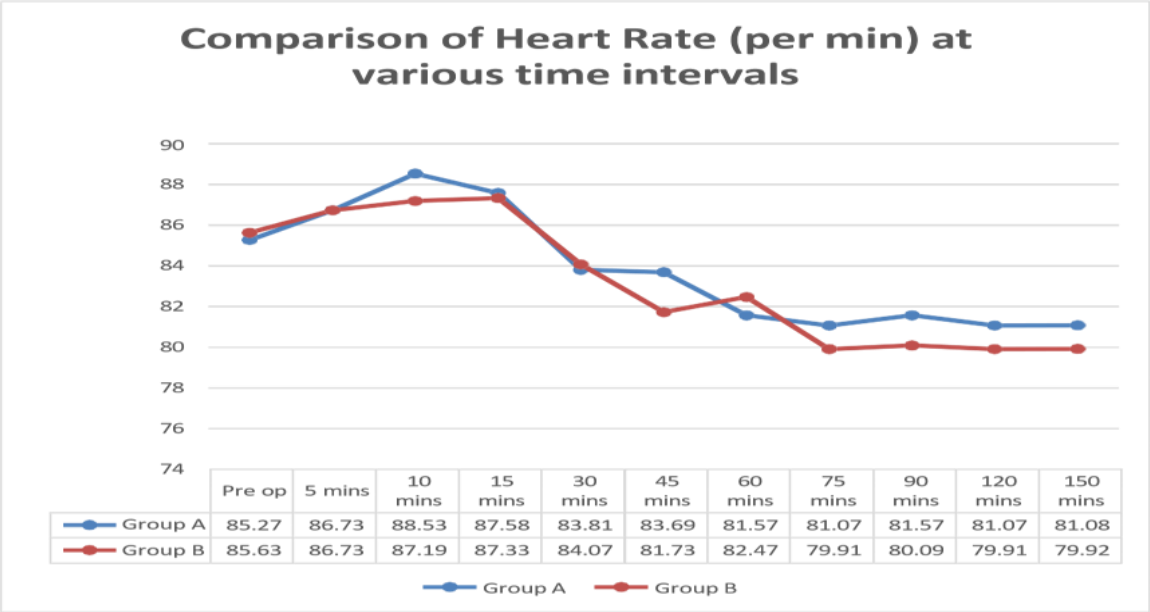
Table 4: Comparison of Onset of sensory block and Duration of sensory block between the groups:

Onset time	Group A		Group B		p Value
	Mean	SD	Mean	SD	
Sensory Block (mins)	18.24	2.79	13.52	3.31	**<0.05**
Mean duration of Sensory Block (mins)	92.52	2.01	119.69	2.65	**<0.05**

The onset of sensory block (18.24±2.79 mins vs. 13.52±3.31 mins; p<0.05) was significantly longer in Group A compared to Group B.

The mean duration of sensory block (92.52±2.01 mins vs. 119.69±2.65 mins; p<0.05) was significantly prolonged in Group B compared to Group A.

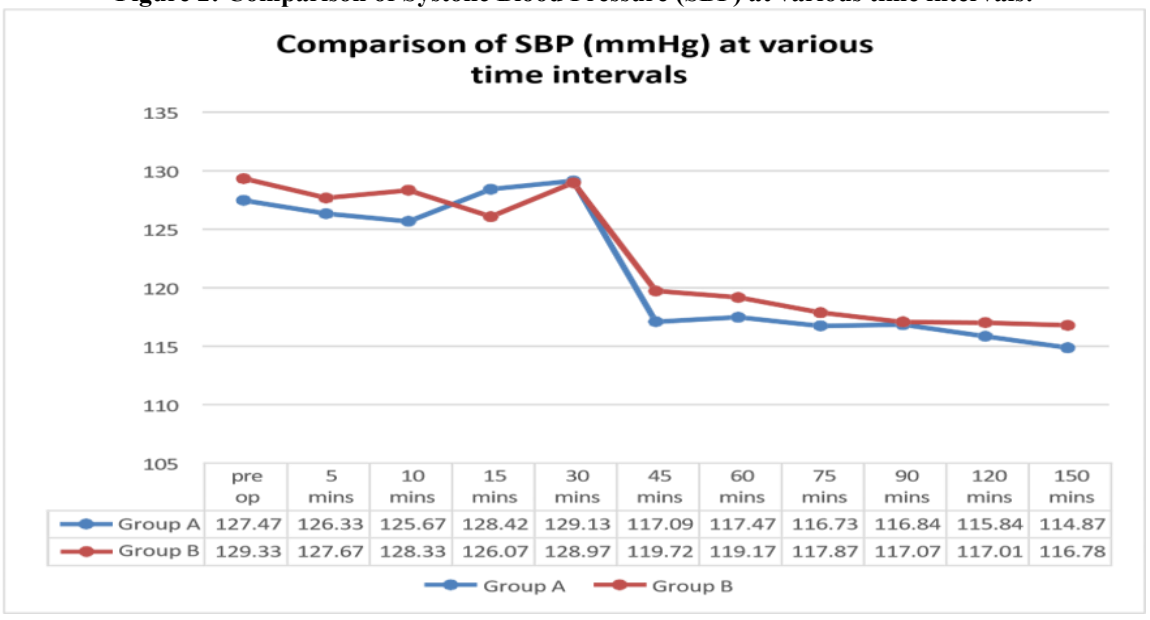
Figure 1: Comparison of Heart Rate (per min) at various time intervals between the groups:



	Pre op	5 mins	10 mins	15 mins	30 mins	45 mins	60 mins	75 mins	90 mins	120 mins	150 mins
Group A	85.27	86.73	88.53	87.58	83.81	83.69	81.57	81.07	81.57	81.07	81.08
Group B	85.63	86.73	87.19	87.33	84.07	81.73	82.47	79.91	80.09	79.91	79.92

The heart rate levels were comparable between the groups throughout the time intervals and not statistically significant.

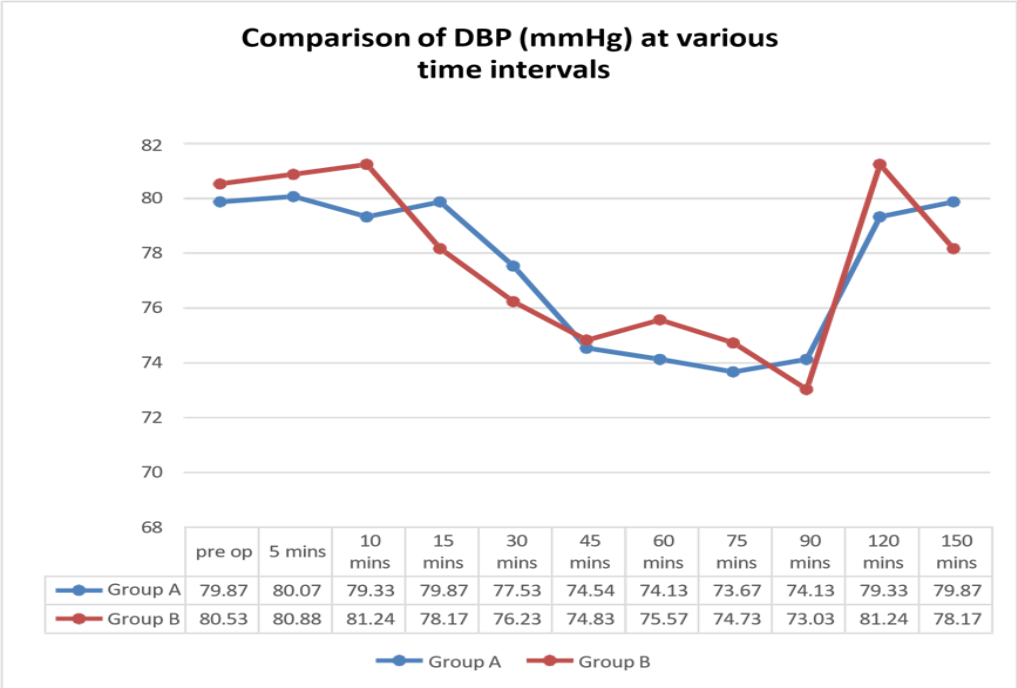
Figure 2: Comparison of Systolic Blood Pressure (SBP) at various time intervals:



	pre op	5 mins	10 mins	15 mins	30 mins	45 mins	60 mins	75 mins	90 mins	120 mins	150 mins
Group A	127.47	126.33	125.67	128.42	129.13	117.09	117.47	116.73	116.84	115.84	114.87
Group B	129.33	127.67	128.33	126.07	128.97	119.72	119.17	117.87	117.07	117.01	116.78

The systolic blood pressure (SBP) levels were comparable between the groups throughout the time interval as per Student t-test (p>0.05).

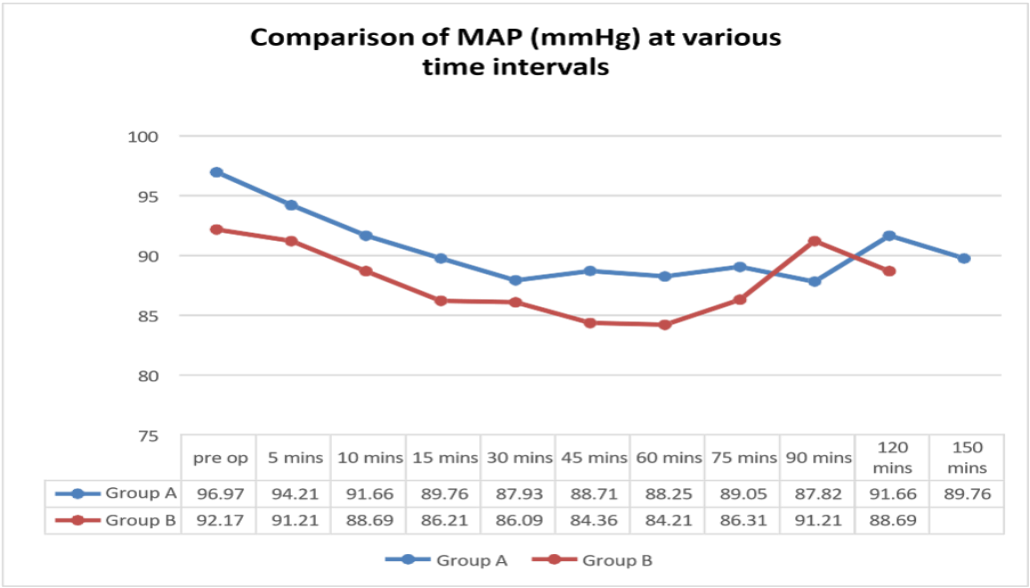
Figure 3: Comparison of Diastolic Blood Pressure (DBP) at various time intervals:



	pre op	5 mins	10 mins	15 mins	30 mins	45 mins	60 mins	75 mins	90 mins	120 mins	150 mins
Group A	79.87	80.07	79.33	79.87	77.53	74.54	74.13	73.67	74.13	79.33	79.87
Group B	80.53	80.88	81.24	78.17	76.23	74.83	75.57	74.73	73.03	81.24	78.17

The diastolic blood pressure (DBP) levels were comparable between the groups throughout the time interval and statistically not significant(p>0.05).

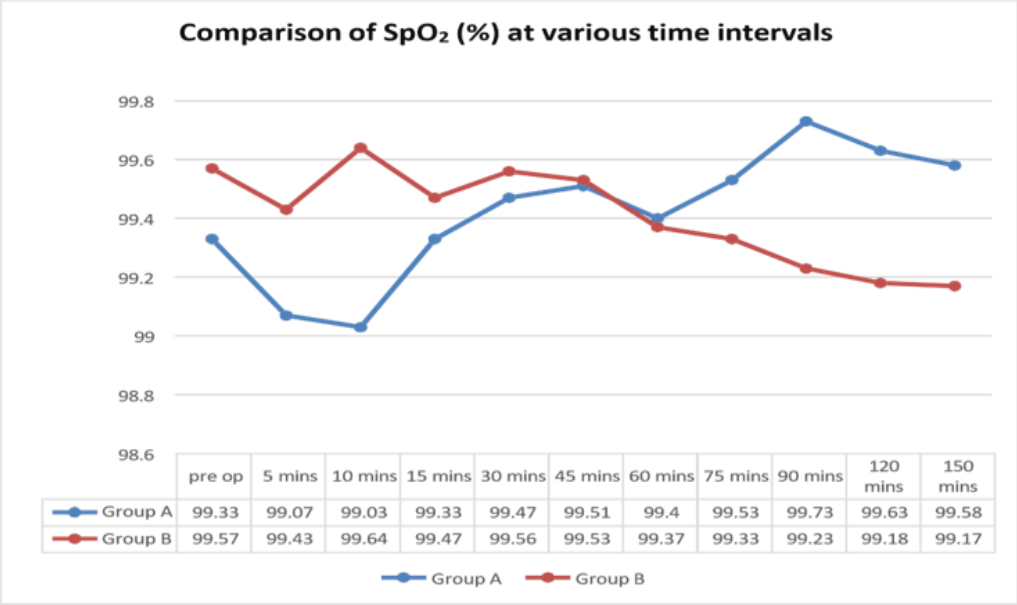
Figure 4: Comparison of Mean Arterial Pressure (MAP) at various time intervals:



	pre op	5 mins	10 mins	15 mins	30 mins	45 mins	60 mins	75 mins	90 mins	120 mins	150 mins
Group A	96.97	94.21	91.66	89.76	87.93	88.71	88.25	89.05	87.82	91.66	89.76
Group B	92.17	91.21	88.69	86.21	86.09	84.36	84.21	86.31	91.21	88.69	

The mean arterial pressure (MAP) levels were comparable between the groups throughout the time interval as per Student t-test (p>0.05).

Figure 5: Comparison of Saturation (Spo2) at various time intervals:



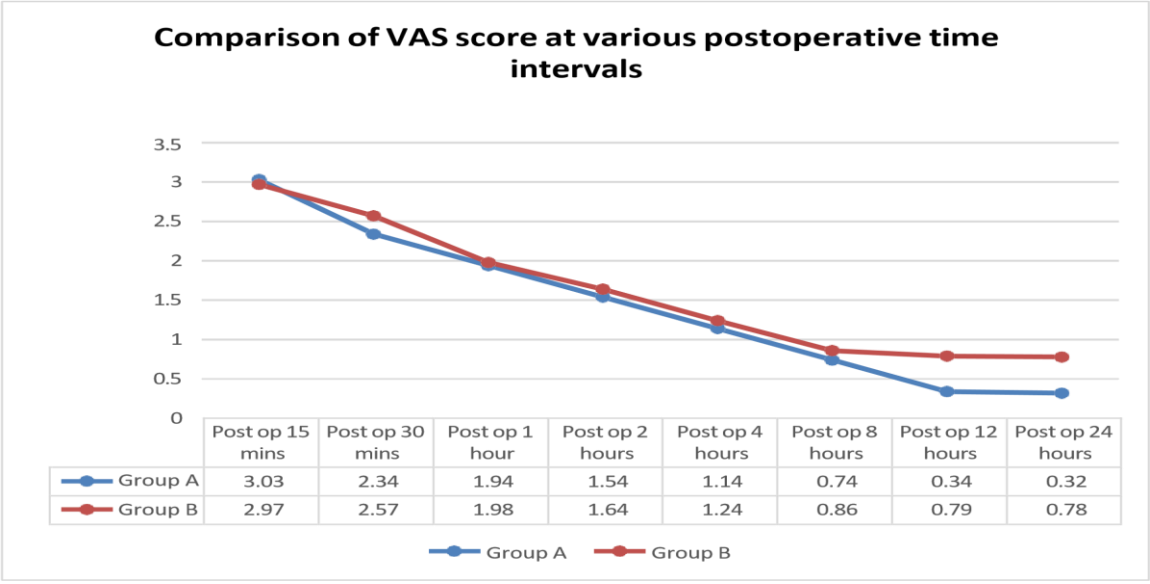
The SpO2 levels were comparable between the groups throughout the time interval as per Student t-test ($p>0.05$).

Table 5: Distribution of patients according to Time for rescue analgesic:

Parameter	Group A		Group B		p Value
	Mean	SD	Mean	SD	
Time for first rescue analgesic (mins)	448.69	39.15	546.28	72.44	**<0.05**

The time for requirement of first rescue analgesic was significantly longer in Group B compared to Group A as per Student t-test (546.28±72.44 mins vs. 448.69±39.15 mins; $p<0.05$).

Figure 6: Comparison of VAS score at various postoperative time Intervals:



The VAS score at post-operative time intervals (15 mins, 30 mins, 1 hour 2 hours, 4 hours, 8 hours and 12 hours) was comparable between the groups as per Student t-test (p>0.05).

Table 6: Distribution of patients according to Adverse Events:

Adverse Events	Group A		Group B		p Value
	N	%	N	%	
Hypotension	13	44.8%	9	31.1%	>0.05
Nausea & Vomiting	5	17.2%	4	13.6%	
Bradycardia	1	3.4%	0	-	
Hypertension/ Tachycardia	0	0.0%	0	0.0%	
Dura Puncture	0	0.0%	0	0.0%	

DISCUSSION

An observational, analytical study was conducted with 58 patients to compare the effect of 0.75% ropivacaine and 0.5% bupivacaine in context of onset of action, hemodynamically stability and postoperative analgesia in thoracic epidural anaesthesia in breast surgeries. The patients were allocated into following two groups:

Group A: 29 patients were given Bupivacaine (0.5%)

Group B: 29 patients were given Ropivacaine (0.75%)

Thoracic epidural anesthesia has traditionally been considered the gold standard for regional anesthesia following breast and thoracic procedures. It has been documented to contribute to a reduction in hospital stay, provide markedly improved pain relief.

In the present study, there was no significant difference in the age, mean weight and ASA grading of patients between the groups. These findings are similar to the studies done by Kumar S et al[3], Parameswari RD et al[7], Vishwanath S et al[6] and Aswini L et al[5].

It was observed in our study that the onset of sensory block (18.24±2.79 mins vs. 13.52±3.31 mins; p<0.05) was significantly longer in Group A compared to Group B. The mean duration of sensory block (92.52±2.01 mins vs. 119.69±2.65 mins; p<0.05) was significantly prolonged in Group B compared to Group. This is comparable to the study of Vishwanath S et al[6].

In the present study, the heart rate levels were comparable between the groups throughout the time interval. There was no statistically significant difference between the heart rates. In our study, the systolic blood pressure (SBP) and diastolic blood pressure (DBP) levels were comparable between the groups throughout the time interval which is statistically not significant (p>0.05). These findings are similar to the studies done by Parameswari RD et al[7].

It was observed in the present study that the mean arterial pressure (MAP) levels were comparable between the groups throughout the time interval which is not statistically significant (p>0.05). This is concordant to the studies of Vishwanath S et al[6] and Aswini L et al[5].

In our study, the time for requirement of first rescue analgesic was significantly longer in Group B compared to Group A as per Student t-test (546.28±72.44 mins vs. 448.69±39.15 mins; p<0.05). Similar observations were noted in the studies of Kumar S et al[3] and Parameswari RD et al[7].

It was observed in the present study that the VAS score at post-operative time intervals (15 mins, 30 mins, 1 hour 2 hours, 4 hours, 8 hours and 12 hours) was comparable between the groups as per Student t-test (p>0.05). This is similar to the studies of Kumar S et al[3], Parameswari RD et al[7], Aswini L et al[5] and Geetha C et al[4].

It was observed in our study that in Group A, 13 (44.8%) patients had hypotension while 5 (17.2%) and 1 (3.4%) patient had nausea & vomiting and bradycardia respectively. In Group B, 9 (31.1%) patients had hypotension while 4 (13.6%) patients had nausea & vomiting. There was no significant difference between the groups as per Chi square test (p>0.05). Hypotension occurs partly due to its cardiodepressant activity and partly due to the functional hypovolemia caused by the inhibition of vasoconstrictor sympathetic outflow and patients in the bupivacaine group had more pronounced hypotension as compared to the subjects in the ropivacaine group. This is comparable to the studies of Kumar S et al[3], Parameswari RD

et al[7] and Vishwanath S et al[6].

CONCLUSION

Thoracic epidural anaesthesia comparing the effect of 0.75% ropivacaine and 0.5% bupivacaine is a safe and effective for breast surgery because it offers better hemodynamic stability and provides post operative analgesia. Time for requirement of first rescue analgesic was significantly longer in Group Ropivacaine compared to Group Bupivacaine. Adverse effects like hypotension, bradycardia, nausea and vomiting are less in Ropivacaine group. Hence thoracic epidural anaesthesia with 0.75% Ropivacaine is superior to 0.5% Bupivacaine in terms of intraoperative hemodynamic stability and postoperative analgesia.

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