



## Original Research Article

## Comparison between bupivacaine and ropivacaine in thoracic epidural anaesthesia for modified radical mastectomy – A randomized controlled trial

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## ARTICLE INFO

## Article history:

Received 29-02-2020

Accepted 31-01-2020

Available online 08-09-2020

## Keywords:

Thoracic epidural

MRM

Bupivacaine

Ropivacaine

## ABSTRACT

**Background:** Modified radical mastectomies (MRM) is conventionally done under general anaesthesia. Various regional anesthetic techniques have also been used to provide effective analgesia in the perioperative period. This study was to compare the analgesia and hemodynamic effects of bupivacaine and ropivacaine when used in thoracic epidural for modified radical mastectomy.

**Methods:** 67 patients scheduled for MRM were enrolled in the study. They were randomized into two groups – Group R and Group B. Through an epidural catheter inserted at T5-T6, the patients in Group R received 12ml of 0.5% ropivacaine whereas those in group B received 12 ml of 0.5% bupivacaine. After one hour, 4 ml of the test drug was repeated every 30 minutes till the end of surgery. Intraoperative hemodynamic, side effects and postoperative VAS scores were recorded. 60 patients completed the study and their results were analyzed.

**Results:** Statistically significant differences were observed in heart rate and mean arterial pressure between the two groups at various time intervals. The mean time of onset of the analgesia was shorter in Ropivacaine group  $12.90 \pm 2.04$  mins,  $19.27 \pm 5.51$  in the Bupivacaine group. Post operative VAS scores were similar in both the groups. Patients in both groups were equally satisfied.

**Conclusion:** High thoracic epidural is a safe and reliable alternative to general anaesthesia in modified radical mastectomies. Ropivacaine 0.5% is preferred due to its faster onset, better hemodynamic stability and good analgesia.

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### 1. Introduction

Breast cancer is the most frequent cancer in women and is responsible for 20% of cancer deaths.<sup>1</sup> Modified radical mastectomy (MRM) done for breast cancers include total mastectomy and axillary clearance. The anesthetic technique chosen should be safe and optimal not only with regard to immediate perioperative outcomes but also for long-term outcomes.<sup>2</sup> Many factors in the perioperative period have been implicated in the increased risk of recurrence of cancer. These factors include anesthetic technique, use of opioids, inadequate pain control, hypoxia, hyperglycemia and intra operative hypothermia.<sup>3</sup> Regional anesthesia provides effective anesthesia and analgesia

in the perioperative period. Various regional anesthetic techniques have been used for breast surgeries, like local wound infiltration, cervical epidural,<sup>4</sup> thoracic epidural anesthesia,<sup>5</sup> thoracic paravertebral block,<sup>6</sup> thoracic spinal anesthesia,<sup>7</sup> interpleural block<sup>8</sup> etc.

This study is mainly intended to compare the analgesia and hemodynamic effects of two different local anesthetics – bupivacaine and ropivacaine when used in thoracic epidural for modified radical mastectomy.

### 2. Materials and Methods

This study was approved by the scientific advisory and Institutional Ethics Committee. After obtaining written informed consent, 67 patients were enrolled for the study [Figure 1]. The study was performed as a double blinded

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randomized controlled trial. Female patients of 18 to 70 years of age belonging to ASA physical status I, II were included in the study. Patients with known history of allergy to local anesthetics, those with local site infection, coagulopathy or bleeding disorders and with severe spinal deformity were excluded from the study.

Randomization was done by a computer-generated table of random numbers. The allocation list was generated and concealed in sealed envelopes. One envelope was opened for each eligible candidate and the patients were distributed in two groups namely, Group R and Group B. Based on the previous study,<sup>9</sup> sample size was taken as 30 patients in each group. The person performing the outcome assessments as well as the patients were blinded to the treatment allocation.

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. The patients were premedicated with Tab. Alprazolam 0.5mg on the night before surgery, Tab. Ranitidine 20 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. 18 G IV cannula was secured in the forearm opposite to the side of surgery. Normal saline at 4ml/kg/hr was started.

### 2.1. Methodology

With the patient in the sitting position, under all aseptic precautions, the thoracic epidural block was performed by the anesthesiologist at T5-T6 intervertebral space. The epidural space was 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 ruled out by the standard test dose of 3ml of 1.5% lignocaine with adrenaline 1: 200000. The catheter was secured to the skin. The patient was positioned supine and the hemodynamic parameters were noted. Five minutes after the test dose, 12 ml of 0.5% of the test drug was administered through the epidural catheter in 4 ml fractions. The patients in Group R received 12 cc of 0.5% ropivacaine whereas Group B received 0.5% bupivacaine.

The onset of analgesia was defined as the time taken from the administration of epidural dose to the loss of pinprick sensation in the patient. The adequate level of anesthesia was confirmed from the inferior border of the clavicle to the inferior costal margin, using the pinprick method. The patient was sedated with midazolam 1.5 mg IV and oxygen at the rate of 6 L/min was administered via face mask. Inadequate level of anesthesia was considered as block failure and general anesthesia was administered to that patient. Such patients were excluded from the study.

The surgery was then commenced.

Intraoperative hemodynamics including heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP) and oxygen saturation (Spo<sub>2</sub>) were monitored every 10 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 0.5% ropivacaine was administered, which was also repeated every 30 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. A fall in MAP less than 70 mmHg was considered as hypotension and was treated with Inj. Ephedrine 6mg IV bolus. A fall in HR less than 50/min was considered as bradycardia and was treated with inj. Atropine 0.6 mg IV bolus. Episodes of hypotension or hypertension, tachycardia or bradycardia during the procedure were noted in both the groups. If the patient experienced any pain or discomfort during axillary dissection, the surgeon was asked to infiltrate the area with 3-5 ml of lignocaine. Such patients were also excluded from the study. The total duration of surgery in both groups was noted.

After the surgery, the patients were shifted to the Post Anesthesia Care Unit (PACU). Post-operative pain was assessed using the Visual Analogue Scale (VAS) score every four hours till 24 hours. The epidural pump was connected and the patients in Group R received 5ml/hr of 0.125% ropivacaine plus 2mcg/ml fentanyl, whereas patients in Group B received 5ml/hr of 0.125% bupivacaine plus 2 mcg/ml fentanyl. Any intraoperative or postoperative complications were also noted.

### 2.2. Statistical analysis

Statistical Analysis was done by Statistical Package for Social Sciences (SPSS Version 17.0) statistical analysis software. The values were represented in number (%) and mean  $\pm$  standard deviation. Suitable statistical tests of comparison were done. Continuous variables were analyzed with the unpaired t-test. Categorical variables were analyzed with the Chi-Square Test and Fisher Exact Test. Statistical significance was taken as  $P < 0.05$ .

## 3. Results

A total of 67 patients, satisfying the criteria were recruited for the study. Out of the 67 patients, 7 patients were excluded from the study [Figure 1]. The remaining 60 patients completed the study and the results were statistically analyzed.

Descriptive statistics like age, weight, height, duration of surgery and ASA status were comparable in both groups [Table 1]. The patients' heart rates at baseline were equal in both groups. There was no statistically significant difference between the heart rates after five minutes of giving the test dose. Ten minutes after the epidural dose, there was a statistically significant difference between the two groups with a p value of 0.04. Similarly, a significant difference was observed at 90 minutes i.e. half an hour after the repeat dose. There was no significant difference in heart rate between the two groups at the time of shifting to PACU [Table 2].

The mean arterial pressure (MAP) at baseline was comparable between the two groups. There was a significant difference in MAP between the two groups at five minutes after the test dose. Also the difference in MAP was significant at ten minutes after the epidural dose with a p value of 0.001. The mean arterial pressure continued to remain significant between the two groups from 30 minutes to 120 minutes after the epidural dose [Table 3].

The mean time of onset of the analgesia was  $19.27 \pm 5.51$  minutes in group B as compared to  $12.9 \pm 2.04$  minutes in Group R. This difference was highly significant with a p value of 0.001. [Table 4] Postoperatively, the pain was assessed using VAS scores. In both groups, VAS scores up to 0, 1, and 2 were reported by the patients. There was no significance between the two groups. [Figure 2]

Patients in both groups were equally satisfied. The incidence of bradycardia was not statistically significant between the two groups, whereas hypotension was more pronounced in group B with a p value of 0.03 [Table 5]. Correspondingly, the need of vasopressors was higher in Group B when compared with Group R.

#### 4. Discussion

Thoracic Epidural Anesthesia (TEA) is one of the regional anesthetic techniques that can be solely used for mastectomies with axillary lymph node clearance. TEA provides better post operative pain relief and less nausea and vomiting; facilitates post anesthesia recovery and gives greater patient satisfaction.<sup>10</sup> TEA decreases the need for parenteral analgesics and opioids and reduces the intraoperative blood loss. TEA offers additional benefits in hypertensives, diabetics and asthmatics.<sup>11</sup> TEA beneficially redistributes the coronary blood flow and improves the myocardial oxygen supply and demand ratio in patients with severe CAD and unstable angina.<sup>12</sup> TEA by providing good quality analgesia in the post operative period has found to enhance patient's compliance for chest physiotherapy and thus speeden the recovery in patients with lung diseases.<sup>13</sup> TEA has been used for MRM in a patient with cryptogenic fibrosing alveolitis.<sup>14</sup> Regional anesthetic techniques like TEA and paravertebral block have been found to reduce the incidence of cancer recurrence or metastasis by maintaining the perioperative immune function through

their opioid sparing effect.<sup>15</sup> O'Connor et al have reported the successful use of TEA for bilateral mammoplasty in a patient with Klippel feil syndrome and difficult airway.<sup>16</sup>

However, the use of TEA is limited due to the fear of its adverse effects which include hypotension, bradycardia, axillary sparing and neurological complications. Hypotension with TEA is common and has been reported in studies by Balzarena et al<sup>17</sup> and Vineetha et al.<sup>18</sup> The hypotension occurs partly due to its cardio depressant activity and partly due to the functional hypovolemia caused by the inhibition of vasoconstrictor sympathetic outflow.<sup>12</sup> In our study, patients in the bupivacaine group had more pronounced hypotension as compared to the subjects in the ropivacaine group. Only 15 out of 30 patients (53%) had a fall of MAP more than 20 mm Hg from the baseline in group R whereas 23 out of 30 patients (80%) had hypotension in group R. Similar finding has been reported by Svitlyk et al demonstrating that ropivacaine is characterized by less pronounced inhibition of sympathetic activity.<sup>19</sup> This might be due to less pronounced disorders of baroreflexive regulation of the heart under the influence of ropivacaine and thereby less pronounced clinical manifestations of sympathectomy.

Vasopressors are preferred for the treatment of hypotension after TEA.<sup>12</sup> In our study, hypotension in both groups responded to vasopressors. Vasopressors were used only when the MAP was less than 70 mmHg. In group R only one patient needed a single dose of vasopressor whereas 7 patients in group B needed two to three doses of vasopressors. Kevin Chan et al reported a case of severe bradycardia and asystole after segmental TEA in a healthy patient after breast surgery.<sup>20</sup> In our study, 3 out of 30 patients in group R had a heart rate of less than 60 beats per minute whereas 5 out of 30 patients in group B recorded bradycardia. Anticholinergics were used when the heart rate fell less than 50 beats per minute. Only one patient in Group B needed a single dose of atropine 0.6 mg. This can be explained by the fact that inhibition of sympathetic efferents during epidural neuraxial blockade decreases venous return to the heart, further activating the baroreceptor reflexes causing bradycardia. A high level of sympathetic blockade may alter the balance of autonomic input to the heart favoring the vagal tone, which can be augmented by sedation and hypercarbia.<sup>12</sup> Bradycardia also occurs due to the blockade of cardiac accelerator sympathetic fibers T1 to T4.

Patients in both groups were equally satisfied with the anesthetic technique. No additional doses of analgesics or sedatives were needed in our study. The patients reported a VAS score of 0, 1, and 2 till two hours post operatively, which indicated only minimal or no pain. After two hours all patients reported no pain. This is in congruence with the studies by Macias et al where epidural ropivacaine with fentanyl offered no clinical advantage over bupivacaine

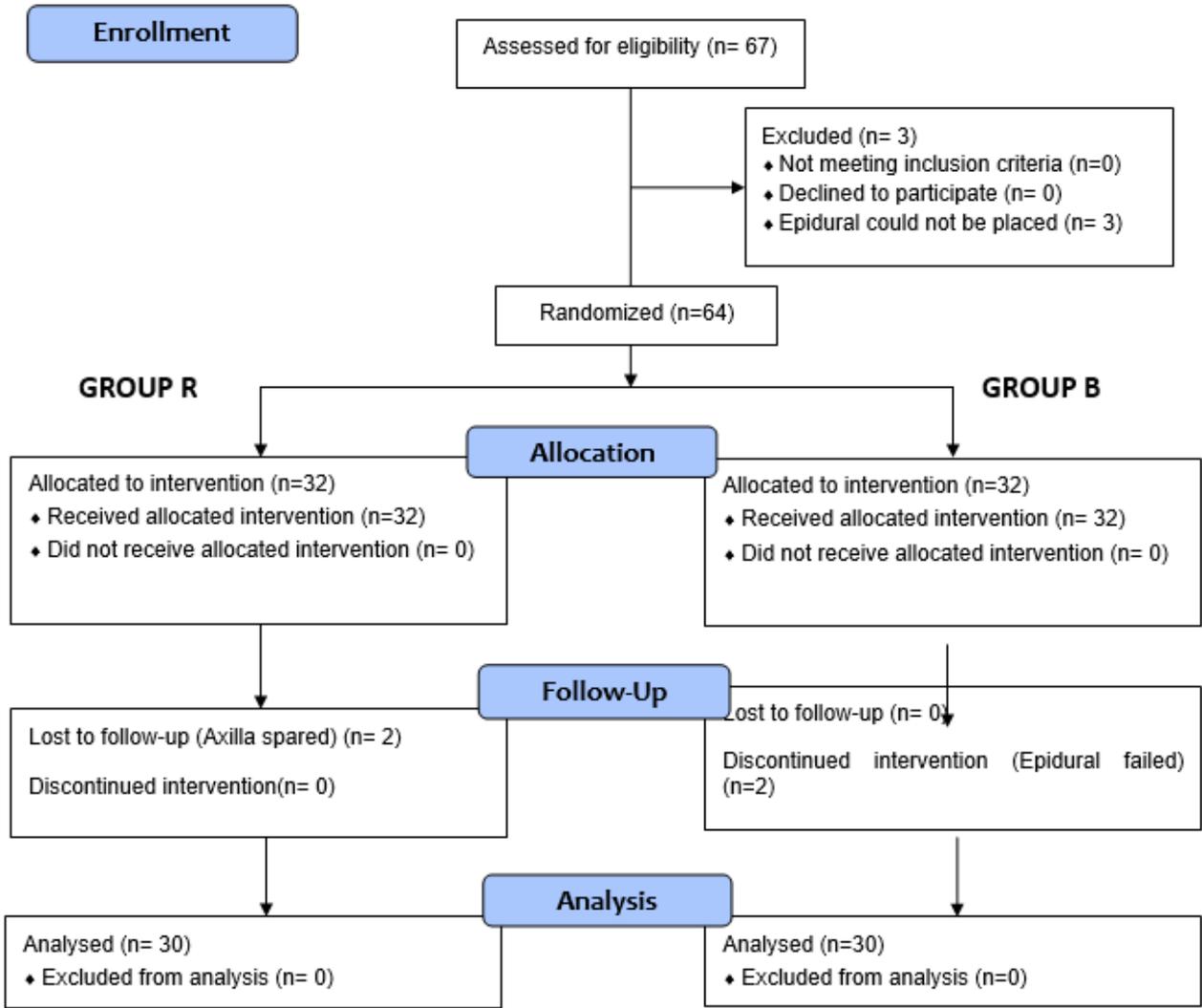


Fig. 1: Consort flow diagram

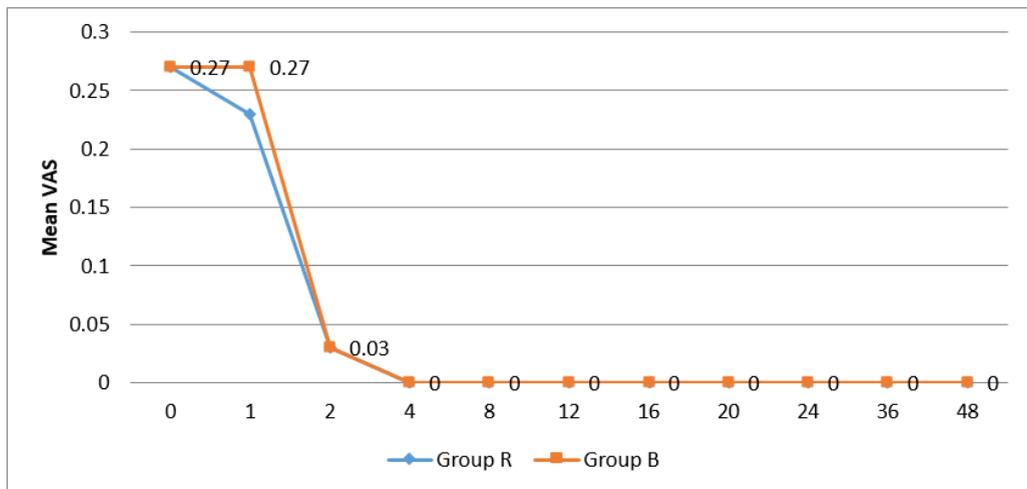


Fig. 2: VAS score between the two groups

**Table 1:** Descriptive statistics for two groups

Variables		Group R (N = 30)	Group B (N = 30)	P value
Age (in years)		59.27 ± 7.84	58.63 ± 4.87	0.71
Weight (in kg)		56.33 ± 6.15	57.77 ± 7.74	0.43
Height (in cm)		152.33 ± 5.50	153.53 ± 6.77	0.45
ASA status	I	15 (50%)	16 (53%)	0.80
	II	15 (50%)	14 (47%)	
Duration of surgery (in minutes)		138.0 ± 9.97	136.33 ± 9.64	0.51

Data expressed as Mean ± SD or as number (proportion). P value < 0.05 was considered significant.

**Table 2:** Comparison of heart rate (beats per minute) between the two groups

Time	Group R (N=30)	Group B (N=30)	P Value
Baseline	86.90 ± 10.87	88.07 ± 10.38	0.67
5 min after test dose	77.13 ± 7.38	72.97 ± 9.50	0.06
10 min after epidural	74.00 ± 7.06	69.43 ± 9.82	0.04*
After 20 min	73.27 ± 6.77	69.30 ± 9.34	0.07
After 30 min	71.90 ± 7.99	68.90 ± 9.39	0.19
After 45 min	71.50 ± 9.01	68.87 ± 9.13	0.27
After 60 min	71.03 ± 9.12	68.63 ± 8.40	0.29
After 75 min	73.70 ± 9.44	69.30 ± 8.26	0.06
After 90 min	74.17 ± 8.40	69.03 ± 8.29	0.02*
After 105 min	75.00 ± 9.44	74.37 ± 7.51	0.95
After 120 min	73.69 ± 9.07	69.37 ± 8.11	0.06
After 135 min	74.07 ± 8.27	68.67 ± 7.51	0.01*
After 150 min	73.50 ± 7.13	68.50 ± 7.92	0.01*
At the time of discharge from PACU	72.00 ± 8.50	68.33 ± 6.68	0.07

Data expressed as Mean ± SD. (beats per minute). \*P value < 0.05 was considered significant.

**Table 3:** Comparison of Mean Arterial Pressure (MAP) (mm Hg) between the two groups

Time	Group R (N=30)	Group B	P Value
Baseline	102.60 ± 8.60	99.57 ± 8.22	0.17
5 min after test dose	85.98 ± 6.18	80.23 ± 10.04	0.010*
10 min after epidural	85.49 ± 4.13	79.71 ± 7.00	0.001*
After 20 min	84.64 ± 4.65	79.61 ± 8.20	0.005*
After 30 min	86.26 ± 5.47	80.16 ± 8.69	0.002*
After 45min	86.19 ± 6.52	79.36 ± 7.01	0.001*
After 60 min	86.30 ± 6.84	77.13 ± 5.17	0.001*
After 75 min	85.10 ± 5.37	78.00 ± 5.28	0.001*
After 90 min	85.62 ± 5.70	77.56 ± 5.58	0.001*
After 105 min	86.60 ± 6.81	77.39 ± 7.56	0.001*
After 120 min	87.07 ± 5.60	80.07 ± 5.74	0.001*
After 135 min	82.90 ± 5.52	80.76 ± 6.67	0.180*
After 150 min	82.86 ± 5.15	80.13 ± 6.17	0.069*
At the time of discharge from PACU	83.07 ± 5.53	78.80 ± 5.79	0.005*

Data expressed as Mean ± SD (mm hg). \*P value < 0.05 was considered significant.

**Table 4:** Comparison of onset of analgesia between the two groups

Onset of sensory block (min)	Mean	SD	p value
Group R	12.90	2.04	0.001*
Group B	19.27	5.51	

Data expressed as Mean ± SD. \*P < 0.05 considered significant.

**Table 5:** Comparison of patients' satisfaction and side effects between the two groups.

Parameters	Response	Group R		Group B		P value
		N	Percentage	N	Percentage	
Patient satisfaction	Yes	29	96.7%	27	90%	0.305
	No	1	3.3%	2	10%	
Bradycardia	Yes	0	0%	1	3.3%	0.317
	No	30	100%	29	96.7%	
Hypotension	Yes	16	53.3%	24	80%	0.03*
	No	14	46.7%	6	20%	
Vasopressor use	Yes	1	3.3%	4	13.3%	0.165
	No	29	96.7%	26	86.7%	

Data expressed as number (proportion). P < 0.05 was considered significant.

with fentanyl for post thoracotomy analgesia.<sup>21</sup> Continuous epidural infusion has been found to provide superior post operative analgesia with early patient mobilization.<sup>22</sup>

The mean time for onset of analgesia was shorter in the ropivacaine group as compared to that in the bupivacaine group. This finding is supported by Umbrin et al where ropivacaine provided faster onset of sensory and motor blockade and equal post operative analgesia as compared to bupivacaine when used in brachial plexus block.<sup>23</sup> The level of analgesia attained was from C7 to T7 in most patients.

Another fear of TEA in MRM surgeries includes sparing of axilla and the need for supplementary analgesics. This is due to the innervations of axilla by the medial brachial cutaneous (C8, T1) and intercostobrachial nerves (T1, T2). We had two patients of axillary sparing during the procedure, general anesthesia was administered to these patients and they were excluded from the study. To combat this, TEA in combination with the ipsilateral brachial plexus block<sup>24</sup> and ipsilateral interscalene block<sup>25</sup> has been used as an alternative to general anesthesia in MRM. The deep angulation of the thoracic spine poses a challenge in identifying the epidural space especially in obese individuals. We could not identify the epidural space in three patients. The level of analgesia was inadequate after the placement of the catheter in two of the patients. These patients were administered general anesthesia and were excluded from the study.

TEA reduces the incidence of PONV after mastectomies.<sup>22</sup> Only two patients in our study complained of nausea intraoperatively and were treated with inj. Ondansetron i.v. No complaints of pruritus were noted in our study. No incidence of respiratory depression, Horner's syndrome, neurological or catheter related complications occurred in our study.

## 5. Conclusion

High thoracic epidural is a safe and reliable alternative to general anesthesia in modified radical mastectomies. Ropivacaine in a concentration of 0.5% is preferred due to its faster onset, better hemodynamic stability and good analgesia.

## 6. Limitations

We did not assess the degree and duration of the motor blockade in the patients. The anxiety of the patients regarding the procedure and pain relief needs to be addressed and the patients have to be counseled preoperatively.

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**Cite this article:** Aswini L, Chavan S, Ganesan I, Radhika K, Uma R. Comparison between bupivacaine and ropivacaine in thoracic epidural anaesthesia for modified radical mastectomy – A randomized controlled trial. *Indian J Clin Anaesth* 2020;7(3):409-415.