Section: Anesthesia

Research

A COMPARATIVE STUDY OF EPIDURAL 0.5% LEVOBUPIVACAINE AND 0.75% ROPIVACAINE ANALGESIA FOR MODIFIED RADICAL MASTECTOMIES

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Abstract

Background: Modified radical mastectomies (MRM) are commonly performed under general anesthesia, which causes severe pain, blood loss, as well as postoperative complications. Regional anesthesia is a temporary block of pain fibres in particular parts of the body. There are a variety of regional anesthesia techniques. The present study is focused on the comparison of ropivacaine and levobupivacaine when used for the MRM in thoracic epidurals. **Materials and Methods:**66 patients participated in this study. They were divided into two groups, A and B, each with 33 patients. Patients were given thoracic epidural anesthesia at the T3-T4, T4-T5 intervertebral spaces. Group A receives 15 ml of 0.5% levobupivacaine and Group B receives 15 ml of 0.75% ropivacaine solution. A routine examination was performed before the study. Intraoperative and postoperative changes in onset of action, duration, visual pain analogue scale, heart rate, blood pressure, oxygen saturation, respiratory rate, conversion of general anesthesia, hypotension, and paresthesia were noted every 15 minutes. **Result:** Statistically significant differences were observed in groups A and B for the onset of action. The mean time to analgesia was 15.52 minutes for 0.75% ropivacaine and 17.36 minutes for 0.5% levobupivacaine. We have not observed any significant difference in other parameters. **Conclusion:** Thoracic epidural anesthesia is more reliable and safer over the general anesthesia. The post operative pain and complications such as vomiting, GI tract complications can be reduced by TEA. 0.75% ropivacaine showed faster onset of action than the levobupivacaine. Both groups show similar effects on heart rate, respiratory rate etc.

INTRODUCTION

Breast cancer is the most common type of cancer and the second leading cause of death in women. A number of breast cancer cases have been reported in developing countries in Africa, Southeast Asia, and South America.[1] Breast cancer is the most common diagnosed malignancy in women worldwide (22%), and in India (18.5%) it ranks second to cervical cancer.[2] The most common surgical procedure for treatment is a modified radical mastectomy, which removes a large amount of skin, the axillary muscles, and the entire breast but just not the pectoralis major tissue. The surgical procedure is typically performed under general anesthesia, with a 3-5 day hospital stay.[3] A high amount of tissue dissection in MRM causes nociception and sets off a chain of events that can increase pain perception and cause severe discomfort in the postoperative period. Another option is regional anaesthesia (RA), which is characterized by the temporary interruption of regular nerve function, which leads to loss of motor and sensory activity of a particular part of the body. There are a variety of RA techniques that have been used for breast surgeries, such as cervical epidural, intrapleural block, local wound infiltration, thoracic paravertebral block, thoracic spinal anesthesia, etc.[4] Thoracic epidural anaesthesia (TEA), which blocks selective pain fibers from the surgical site, is widely used for mastectomies with axillary lymph node clearance. This technique also helps patients recover faster by reducing post-operative pain and discomfort.[5] According to reports, 86% of patients in developed countries experienced discomfort and pain during the postoperative period.[6]Post-operative pain management is an essential component of anesthetic procedure. The goal of postoperative pain

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management is to minimise or nullify discomfort, pain, and adverse effects.

The current study compares the hemodynamic effects and analgesia of two long-acting local anesthetics, 0.5% levobupivacaine and 0.75 % ropivacaine, which have fewer toxic effects on the central nervous system. These agents were used in the study in the thoracic epidural anesthesia for the MRM.

MATERIALS AND METHODS

This study is a prospective randomized control trial. Cases with spinal deformities, allergies or sensitivity to local anesthesia, coagulation disorders, communication disorders, neurological disorders, and thoracic epidural contraindications were excluded from the study. After providing written informed consent, 66 patients participated in this study. The study included female patients aged 30 to 60 years old with ASA physical status I or II. Patients were divided into two groups, A and B, with 33 patients selected at random by a computer. In this study, 15 ml of each anesthetic were used, with group A receiving 0.5 percent levobupivacaine and group B receiving 0.75 percent ropivacaine solution. All patients were carefully investigated before the surgery. Routine examinations of patients were performed by monitoring pulse oximetry, ECG, and blood pressure. Thoracic epidural anesthesia was administered to patients in strict septic conditions while they were sitting or lying on their right side, especially at T3-T4, T4 T5 intervertebral space. The epidural space was identified using the loss of resistance technique

A catheter was inserted into the epidural space using an 18 or 16-gauge tuohy epidural needle to ensure no blood or fluid is aspirated. No aspiration confirmation was done by administering a test dose of 3ml of 2% lignocaine with adrenaline (1:2,00,000) dilution. Twenty minutes before the incision, 15 ml of epidural drug administration were given in both the groups. Both groups' patients were sedated with Fentanyl citrate 100mcg. For the maintenance of patients, drugs were given as per the need and time. The assessment criteria include onset of action, duration, visual pain analogue scale, heart rate, blood pressure, oxygen saturation, respiratory rate, conversion to general anesthesia, hypotension, and paresthesia. After each 15 minutes, these criteria were noted. The top-up epidural dose in both groups was 8 ml.

RESULTS

Total 66 patients were satisfying the inclusion criteria and included in this study. The results were statistically analyzed. Distribution of age, weight and onset of action in both groups were compared descriptively [Table 1]. The mean time of onset of the ropivacaine (15.52 minutes) and levobupivacaine (17.36 minutes) groups has shown a significant difference (<0.001). The ropivacaine group treated patients had a mean VAS score of 0.45±0.51, 8.00± 0.00, 5.21 ±3.50 and 0.79± 0.70 at 1 hour, second dose after 45 min, third dose after 45 min, 2 hr post operative respectively. The levobupivacaine group treated patients had mean score 0.52±0.67,8.18±0.58, 7.03± 2.35, and 0.88± 0.82 after 1 hrs, 2nd dose after 45 min, 3rd dose after 45 min, 2 hr post operative respectively [Table 2]. Prior to blocking, the patients' heart rates in both groups were the same. From baseline to 2 hours after surgery, there was no significant difference in mean heart rate between ropivacaine (74.78 bpm) and levobupivacaine (74.64 bpm) patients [Table 3]. According to the mean arterial pressure distribution table, there was no significant association between ropivacaine (74.49 mm Hg) and levobupivacaine (74.64 mm Hg) patients from baseline to 2 hours after surgery [Table 4]. Similarly, no significant association was found for the blood oxygen saturation distribution in either group or intervention. From before block to 2 hours postoperative, the ropivacaine group subjects had a mean respiratory rate of 14.41 breaths/min and the levobupivacaine group subjects had a mean respiratory rate of 14.60 breaths/min [Table 5]. According to respiratory rate distribution table, there was no significant difference between the two groups of analgesia [Table 6]. It is evident from the hypotension status table that most of the ropivacaine group subjects had no hypotensive episodes (84.85%) and in the levobupivacaine group majority had no hypotensive episodes (87.88%) (p= >0.999). The paresthesia status table shows that the majority of the ropivacaine group subjects had no paresthesia (100%) and the majority of the levobupivacaine group subjects had no paresthesia (96.97%) (p= >0.999) [Table 7].

Table 1: Showing the distribution of age, weight and onset action of distribution.

	Group A	Group B	P value
Age distribution	54.52± 4.79	53.45± 6.33	0.445
Weight	61.58± 6.05	63.0± 6.38	0.356
Onset of Action Distribution (mins)	15.52±2.17	17.36±4.76	<0.001

Table 2: Showing the VAS score at different time during surgery and post surgery

	Introperatiove - 1 hour	Introperatiove - Second Dose - After 45 mins	Introperatiove - Third Dose - After 45 mins	Postoperative - 2 hours
Group A	0.45±0.51	8.00± 0.00	5.21 ±3.50	0.79± 0.70
Group B	0.52±0.67	8.18±0.58	7.03± 2.35	0.88± 0.82
P value	0.679	0.078	0.016	0.629

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Table 3: shows heart rate distribution was measured prior to the block and every 15 minutes during surgery, as well as 60 and 120 minutes after surgery.

Heart Rate Distribution	Group A(R)(Mean± SD)	Group B(L)(Mean± SD)	P value
Before Block	90.21± 7.33	90.33± 8.83	0.952
15 mins	78.94± 6.35	79.55± 5.77	0.686
30 mins	76.15± 6.17	76.70± 5.98	0.716
45 mins	74.09± 5.58	74.45± 5.56	0.792
60 mins	73.42± 5.04	73.55± 5.15	0.923
75 mins	73.55±5.13	73.59±5.30	0.970
90 mins	76.82± 4.64	76.97± 4.81	0.900
105 mins	79.65± 4.37	80.36± 3.87	0.545
120 mins	80.21± 5.12	80.76± 4.99	0.704
1 hr Post operative	80.72± 5.08	81.09± 5.13	0.770
2 hr Postoperative	80.00± 6.64	79.67± 6.96	0.843

Table 4 shows mean arterial pressure distribution was measured prior to the block and every 15 minutes during surgery, as well as 60 and 120 minutes after surgery.

Mean Arterial Pressure Distribution	Group A (Mean± SD)	Group B (Mean± SD)	P value
Before Block	92.85± 5.17	93.36± 5.38	0.693
15 mins	76.27± 4.86	76.88± 4.83	0.613
30 mins	74.36± 4.94	74.79± 4.90	0.727
45 mins	72.42± 9.09	72.52± 9.13	0.968
60 mins	74.06± 4.56	74.30± 4.74	0.833
75 mins	74.52± 4.54	74.84± 4.50	0.771
90 mins	75.91± 4.90	76.39± 5.58	0.717
105 mins	76.38± 5.12	76.56±5.93	0.910
120 mins	76.79± 4.76	77.92± 4.65	0.405
1 hr Post operative	82.91± 3.66	82.76± 3.68	0.871
2 hr Postoperative	82.61± 3.53	82.61± 3.53	1.000

Table 5: shows Blood Oxygen Saturation Distribution was measured prior to the block and every 15 minutes during surgery, as well as 60 and 120 minutes after surgery.

Blood Oxygen Saturation Distribution	Group A (Mean± SD)	Group B (Mean± SD)	P value
Before Block	.38± 1.23	99.32± 1.14	0.113
15 mins	98.33±1.14	99.29± 1.00	0.231
30 mins	98.26 ±1.12	99.35± 0.88	0.341
45 mins	98.41± 1.27	99.40± 0.94	0.582
60 mins	99.00± 0.40	99.15± 0.37	0.120
75 mins	99.05± 0.39	99.08± 0.48	0.804
90 mins	99.90± 0.30	99.95± 0.22	0.402
105 mins	99.88± 0.33	99.93± 0.27	0.462
120 mins	99.80± 0.52	99.90± 0.30	0.294
1 hr Post operative	99.95± 0.22	99.95± 0.22	>0.999
2 hr Postoperative	99.06 ±0.43	99.06± 0.43	>0.999

Table 6: showing distribution of respiratory rate in both group of patients.

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

Table 7: showing the status of hypotension and paresthesia.

	Group A		Group B		P value
	Yes	No	Yes	No	
Hypotension Status	5 (15.15%)	28 (84.85%)	4 (12.12%)	29 (87.88%)	>0.5
Paresthesia Status	0	33 (100%)	1 (3.03%)	32 (96.97%)	>0.5

DISCUSSION

The choice of surgery and anaesthesia depends on the type and severity of breast cancer, age, weight, the patient's health condition, etc. These factors in this study were considered in both groups for the comparison of 0.5% levobupivacaine and 0.75 % ropivacaine. Thoracic epidural anesthesia (TEA) is a

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type of RA that is especially used in mastectomies with the excision of axillary lymph nodes. TEA gives a satisfactory result by reducing vomiting, postoperative pains, and other complications, such as impaired GI functions.[7] This procedure reduces the requirement for opioids and parenteral analgesics, which include buprenorphine, pethidine, morphine, fentanyl, and blood loss during surgery. The improved TEA outcome was primarily due to better pain control and improved respiratory function.[8] It also reduces the central sympathetic stimulation as well as provides a better effect on the homeostasis, coagulation, immune system, and metabolic system. In 9 Patients who had Cryptogenic fibrosing alveolitis, it has been found that MRM with TEA was helpful for the speedy recovery of patients. TEA reduces the prevalence of cancer recurrence by positively boosting the patient's immune system through their opioid-sparing effect.[9,10] Stress caused by surgery and anesthesia can induce catecholamine levels, increase the heart rate and other cardiac complications, TEA reduces adverse cardiac events as well as morbidity and mortality rate.[9] The mean time to block pain fibers with 0.5% levobupivacaine was 17.36 minutes and 15.52 minutes with 0.75% ropivacaine. Similarly, R Mageswaran et al have observed a significant difference between 0.5% ropivacaine (13.5 minutes) and 0.5% levobupivacaine (11.1 minutes) for the sensory block for infraclavicular brachial plexus block.[11] In a double-blind, randomized, crossover trial, Jonathan Stewart et al. compared the cardiovascular and CNS effects of levobupivacaine and ropivacaine in healthy volunteers at equal concentrations, and infusion rates.[12] There was no significant difference observed between levobupivacaine and ropivacaine for cardiovascular and CNS effects. We discovered similar results in our research. Mean arterial pressure distribution was measured every 15 minutes, including 15, 30, 45, 60, 75, 90, 105, and 120 minutes during surgery and 60 and 120 minutes after surgery. No significant difference was observed between the two groups, which was consistent with other findings.[13,14] Lacassie et al. discovered that bupivacaine is more potent than levobupivacaine (levobupivacaine/bupivacaine ratio 0.87). Similarly, another study has confirmed this finding as there is a less intense motor block of levobupivacaine and ropivacaine than bupivacaine. In our study, there were no differences in hypotension and paresthesia observed between groups.[15,16] Radiating pain or paresthesia is typically caused by needle-related nerve injury during the process of catheter placement and epidural process.

CONCLUSION

On comparison of 0.75% ropivacaine and 0.5% levobupivacaine in thoracic epidural anaesthesia for modified radical mastectomy, we conclude that ropivacaine group had faster onset of action and lower mean VAS score when compared with levobupivacaine group.

Limitation

In this study, we have not included the data on the duration of sensory blockade and patient's satisfaction regarding their treatment. Patients' personal experiences and their emotional status should also be considered.

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