

## A RANDOMISED PROSPECTIVE COMPARATIVE STUDY BETWEEN THORACIC EPIDURAL BLOCK AND GENERAL ANESTHESIA FOR MODIFIED RADICAL MASTECTOMY SURGERY

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### ABSTRACT

A popular surgical technique for treating breast cancer is modified radical mastectomy (MRM). The choice of anesthetic technique significantly influences perioperative hemodynamic stability, postoperative pain control, recovery profile, and postoperative complications. Thoracic epidural anesthesia (TEA) has arisen as a potential substitute to general anesthesia (GA) because of its analgesic and opioid-sparing benefits. To compare TEA and GA with respect to intraoperative hemodynamic parameters, postoperative unfavorable effects and pain scores in patients having MRM surgery. The prospective randomization comparative study was done in the Department of Anaesthesiology, J.K. Cancer Institute, Kanpur. Forty patients receiving unilateral modified radical mastectomy were fragmented into two random groups: GA group (n=20) and TEA group (n=20). Postoperative nausea and vomiting (PONV), hemodynamic parameters, and postoperative pain scores using the Numerical Rating Scale (NRS) were evaluated. For statistical analysis, the Independent Student's t-test and the Chi-square test were employed. The TEA group demonstrated significantly better attenuation of perioperative sympathetic response with reduced heart rate and blood pressure (BP) during surgery readings related to the GA group. The TEA group had significantly decreased postoperative pain levels at 2, 6, and 12 hours ( $p < 0.001$ ). Additionally, the TEA group had a significantly lower prevalence of PONV than the GA group (20% vs. 80%;  $p = 0.0005$ ). TEA provided superior postoperative analgesia, improved perioperative hemodynamic modulation, and reduced PONV compared with GA, supporting its effectiveness as an substitute anesthetic method for MRM surgery.

## INTRODUCTION

Breast cancer is a major cause of cancer-related illness and death rate and is one of the most prevalent diseases among women. Modified radical mastectomy (MRM) is often used as the definitive breast cancer surgery and especially advised in cases where a large amount of tissue needs to be removed and clearance of the axillary lymph nodes is desired. The decision of using anesthetic modalities is a key factor to consider in order to achieve a stable, balanced hemodynamics, pain management and patient satisfaction after breast cancer surgery. For MRM, general anesthesia (GA) has historically been recommended procedures; but as enhanced recovery strategies and opioid-sparing become more important, techniques for localized anesthesia have

received more attention. The different regional blocks namely paravertebral block, erector spinae plane block, serratus anterior plane block and thoracic epidural anesthesia (TEA) have shown encouraging results for breast surgery analgesia.<sup>[1]</sup> Regional ultrasound guided techniques has been reported to have a better perioperative analgesic effect and decrease postoperative discomfort in MRM patients.<sup>[2]</sup> Likewise, serratus anterior plane block and erector spinae plane block have shown to be associated with improved postoperative analgesia and decreased consumption of analgesics in breast cancer surgery.<sup>[3]</sup> Of these regional techniques, thoracic epidural anesthesia (TEA) has become a valuable alternative due to the effective sympathetic blockade, improved perioperative analgesia and reduced opioid requirement. Additionally, TEA has been used in conjunction with other regional

techniques as a safe and effective anaesthetic choice for high-risk breast surgery patients.<sup>[4]</sup> Additionally, regional anesthesia techniques have shown positive impact on acute and chronic post-mastectomy pain, which has also helped in the overall post-operative recovery.<sup>[5]</sup> Hemodynamic control and postoperative analgesia have been found to be better in patients receiving thoracic epidural anesthesia compared to general anesthesia in previous comparative studies in patients undergoing modified radical mastectomy.<sup>[6]</sup> Adjunctive regional analgesic techniques with thoracic paravertebral approaches have also been demonstrated to decrease the perioperative analgesic requirement and pain severity after surgery.<sup>[7]</sup> In addition, it has been demonstrated that the use of regional anesthesia is associated with better perioperative outcomes after the surgery for breast cancer in recent superiority trials involving new interfascial plane blocks.<sup>[8]</sup> Although there is a gradual improvement in regional anesthesia techniques, there is not sufficient Indian data that specifically assessment thoracic epidural anesthesia with GA in modified radical mastectomy. Studies in the literature have mainly focussed on newer regional techniques like serratus anterior plane block and thoracic paravertebral block under general anesthesia not in comparison with thoracic epidural anesthesia.<sup>[9]</sup> Other newer methods like thoracic segmental spinal anesthesia (TSSA) have also shown a potential trend of better perioperative outcomes in the surgery of breast cancer, but these methods are technically demanding and have risks of severe hypotension and neurologic complications.<sup>[10]</sup> Comparative observational studies have shed light on the necessity for more evidence in the areas of perioperative safety, analgesic efficacy, and recovery outcomes when comparing general anesthesia and segmental thoracic spinal anesthesia.<sup>[11]</sup> Furthermore, the available literature on hemodynamic stability, postoperative pain score, opioid use, postoperative nausea and vomiting (PONV), and satisfaction of patients is still inconsistent between the different regional anesthesia techniques.<sup>[12]</sup> There is also no uniform opinion on the most appropriate anaesthetic approach for a modified radical mastectomy (MRM) as there is some variation in effectiveness between the rhomboid intercostal block, erector spinae block and serratus plane block (SPB).<sup>[13]</sup> Thus, practical and comparative assessment of TEA and GA still has its relevance in clinical practice, especially in health care resource-impooverished environments. With patients undergoing modified radical mastectomy, thoracic epidural anesthesia may have several benefits over general anesthesia. TEA has been linked to better postoperative pain, lower perioperative opioid consumption and better post-operative recovery after breast cancer surgery.<sup>[14]</sup> Improved pain control can help to promote early mobility, improved respiratory function, decreased stress response, and increased patient comfort. Comparative studies, comparing thoracic spinal

anesthesia and general anesthesia techniques have also shown reduced postoperative analgesics and opioid use with regional anesthesia.<sup>[15]</sup> Newer methods like segmental thoracic spinal anesthesia are becoming more popular but, due to the expertise needed and risks of hypotension, these methods may not be broadly applicable in developing countries.<sup>[16]</sup> Thoracic epidural anesthesia, on the other hand, is a well-known, inexpensive and readily available method of localized anesthetic that can be applied to prolonged postoperative analgesia as well as for better perioperative outcomes. The effectiveness of TEA for postoperative pain reduction after modified radical mastectomy (MRM) is further backed by recent randomized controlled evidence, which compared TEA with general anesthesia (GA).<sup>[17]</sup> So, the goal of the current investigation was to examine intraoperative hemodynamic parameters, postoperative pain levels, and postoperative adverse outcomes for patients undergoing MRM surgery between thoracic epidural anesthesia and GA. The present study was conducted to compare thoracic epidural anesthesia (TEA) and general anesthesia (GA) in patients undergoing modified radical mastectomy (MRM), with emphasis on intraoperative hemodynamic stability, postoperative pain, analgesic requirement, and recovery outcomes. The study also evaluated postoperative adverse effects, including postoperative nausea and vomiting (PONV), along with overall patient satisfaction between the two anesthetic techniques.

## MATERIALS AND METHODS

This prospective randomized comparative study was conducted in the Department of Anaesthesiology at the J.K. Cancer Institute to compare the perioperative outcomes of thoracic epidural anesthesia (TEA) and general anesthesia (GA) in patients undergoing modified radical mastectomy (MRM). A total of 40 patients with carcinoma breast scheduled for unilateral MRM were enrolled and randomly allocated into two equal groups: Group A (TEA) and Group B (GA), with 20 patients in each group. Patients aged 20–60 years belonging to American Society of Anesthesiologists (ASA) physical status I–III and willing to provide informed consent were included in the study. Patients with coagulation abnormalities, local or systemic infection, spinal deformity, body mass index >35 kg/m<sup>2</sup>, uncontrolled hypertension or diabetes mellitus, significant cardiac, renal, or respiratory disease, allergy to anesthetic agents, or psychiatric illness affecting cooperation were excluded. All participants underwent detailed preoperative evaluation including clinical history, physical examination, baseline hemodynamic assessment, complete blood count, coagulation profile, renal function tests, viral markers, chest radiography, electrocardiography, and two-dimensional echocardiography whenever indicated.

Patients in the TEA group received thoracic epidural anesthesia at the T6–T7 intervertebral level using epidural bupivacaine and fentanyl, along with intravenous midazolam sedation, whereas patients in the GA group received standard general anesthesia according to institutional protocol. The primary outcome measures included intraoperative hemodynamic parameters such as heart rate, systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean blood pressure (MBP). Secondary outcomes included postoperative pain assessment using the Numerical Rating Scale (NRS), postoperative analgesic requirement, postoperative nausea and vomiting (PONV), other postoperative adverse effects, and patient satisfaction. Continuous variables were expressed as mean  $\pm$  standard deviation, while categorical variables were presented as frequency and percentage. Data

normality was assessed using the Shapiro–Wilk test. Independent Student’s t-test was used for comparison of continuous variables, and Chi-square test was applied for categorical variables. A p-value  $<0.05$  was considered statistically significant.

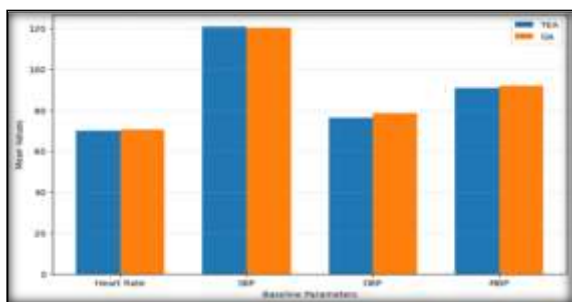
## RESULTS

**Baseline Demographic and Hemodynamic Characteristics:** 40 patients who were undergoing MRM were designated for the study and split into two groups: TEA and GA groups, with 20 patients in group A and B. There was no substantial variance among the two groups in the baseline hemodynamic parameters, and they were considered to have adequate homogeneity before anesthetic intervention [Table 1].

**Table 1: Baseline Hemodynamic Parameters in TEA and GA Groups**

Parameter	TEA (Mean $\pm$ SD)	GA (Mean $\pm$ SD)	p-value
Heart Rate (beats/min)	70.10 $\pm$ 3.31	70.60 $\pm$ 3.44	0.642
SBP (mmHg)	120.90 $\pm$ 6.88	120.20 $\pm$ 7.07	0.753
DBP (mmHg)	76.40 $\pm$ 3.47	78.40 $\pm$ 4.48	0.123
MBP (mmHg)	90.90 $\pm$ 3.39	91.95 $\pm$ 4.84	0.432

Comparable hemodynamic parameters at baseline is graphically presented in Figure 1 for the TEA and GA groups.



**Figure 1. Baseline Hemodynamic Parameters in TEA and GA Groups**

[Figure 1] shows a comparison of the baseline HR, SBP, DBP and MBP in TEA and GA patients. There

was no statistically substantial variance between the two groups, and comparable baseline values were found.

**Comparison of Intraoperative Hemodynamic Parameters:** Intraoperative hemodynamics parameters were different for GA and TEA groups. Intraoperatively, the TEA group had lower HR, SBP, DBP, and MBP than the GA group at 15 min ( $p < 0.001$ ), demonstrating the better attenuation of the sympathetic response with thoracic epidural anesthesia. Comparatively lower blood pressure values were recorded at 60 minutes in the GA group and it was found that the postoperative hemodynamic parameters were still significantly higher in the GA group. Generally, TEA was more effective in maintaining the perioperative hemodynamic stability in the patients undergoing modified radical mastectomy surgery [Table 2].

**Table 2: Assessment of Hemodynamic Parameters Between TEA and GA Groups**

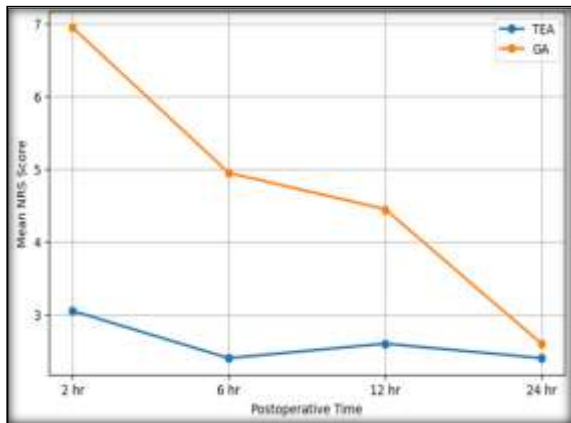
Parameter	Time Interval	TEA (Mean $\pm$ SD)	GA (Mean $\pm$ SD)	p-value
Heart Rate (beats/min)	Baseline	70.10 $\pm$ 3.31	70.60 $\pm$ 3.44	0.642
	15 min	65.35 $\pm$ 3.91	76.55 $\pm$ 3.39	$<0.001$
	60 min	69.95 $\pm$ 2.84	66.60 $\pm$ 3.60	0.002
	Postoperative	69.95 $\pm$ 3.71	76.20 $\pm$ 4.03	$<0.001$
Systolic Blood Pressure (SBP)	Baseline	120.90 $\pm$ 6.88	120.20 $\pm$ 7.07	0.753
	15 min	112.95 $\pm$ 6.81	127.35 $\pm$ 7.60	$<0.001$
	60 min	120.20 $\pm$ 7.19	112.25 $\pm$ 7.41	0.001
	Postoperative	120.70 $\pm$ 7.20	128.05 $\pm$ 7.47	0.003
Diastolic Blood Pressure (DBP)	Baseline	76.40 $\pm$ 3.47	78.40 $\pm$ 4.48	0.123
	15 min	69.00 $\pm$ 4.18	86.15 $\pm$ 4.86	$<0.001$
	60 min	76.00 $\pm$ 4.21	70.85 $\pm$ 3.96	$<0.001$
	Postoperative	76.55 $\pm$ 4.49	85.35 $\pm$ 4.31	$<0.001$
Mean Blood Pressure (MBP)	Baseline	90.90 $\pm$ 3.39	91.95 $\pm$ 4.84	0.432
	15 min	83.40 $\pm$ 3.89	99.70 $\pm$ 5.12	$<0.001$
	60 min	90.50 $\pm$ 3.87	84.40 $\pm$ 4.57	$<0.001$
	Postoperative	91.00 $\pm$ 3.68	99.25 $\pm$ 4.51	$<0.001$

**Comparison of Postoperative Pain Scores:** Using the NRS for postoperative pain assessment, pain scores were meaningfully lower in the TEA group throughout the initial postoperative phase. There was a substantial variance between pain scores in both GA and TEA group at 2, 6 and 12 hours after

surgery. But this was not found to be statistically substantial at 24 hours following surgery. The results show that thoracic epidural anesthesia was more operative for the early postoperative pain after MRM surgery (Table 3).

**Table 3: Comparison of TEA and GA Groups' Postoperative NRS Pain Scores**

Time Interval	TEA (Mean ± SD)	GA (Mean ± SD)	p-value
2 hours	3.05 ± 0.69	6.95 ± 0.94	<0.001
6 hours	2.40 ± 0.50	4.95 ± 0.89	<0.001
12 hours	2.60 ± 0.50	4.45 ± 0.60	<0.001
24 hours	2.40 ± 0.50	2.60 ± 0.82	0.360



**Figure 2: Comparison of Pain Scores Following Surgery**

The trends in postoperative pain scores over various postoperative time intervals among TEA and GA are shown graphically in [Figure 2].

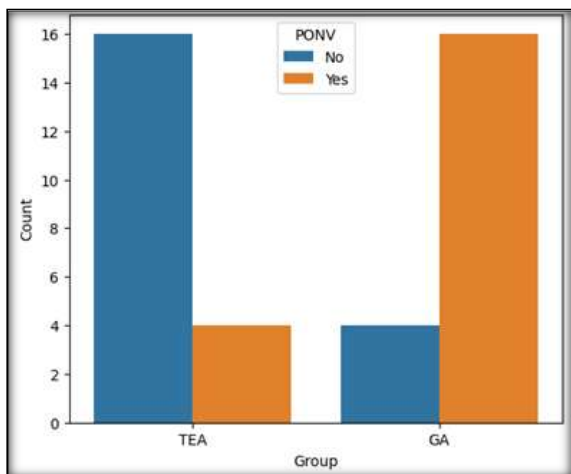
[Figure 2] illustrates that, in comparison to the GA group, the TEA group had reduced pain scores following surgery at all time points during the early postoperative period.

**Comparison of PONV:** The TEA group's PONV incidence was statistically considerably lower than that of the GA group. PONV was there in TEA and GA groups of patients, 20% and 80% respectively. This decreased incidence of PONV in the TEA group may be due to decreased peri-operative opioid consumption and better postoperative pain control seen with thoracic epidural anesthesia [Table 4].

**Table 4: Comparison of PONV Between TEA and GA Groups**

Group	PONV Present	PONV Absent	p-value
TEA	4 (20%)	16 (80%)	0.0005
GA	16 (80%)	4 (20%)	0.0005

[Figure 3] illustrates the distribution of PONV for both groups.



**Figure 3: Comparison of PONV Between TEA and GA**

As seen in [Figure 3], the prevalence of PONV is significantly reduced in the thoracic epidural anesthesia group as associated to the general anesthesia group.

Thoracic epidural anesthesia showed to be beneficial in terms of perioperative outcomes in

patients undergoing MRM. TEA was found to be associated with improved perioperative sympathetic response, decreased early postoperative pain scores and decreased PONV, thus supporting the effectiveness of TEAs as anesthetic technique for modified radical mastectomy surgery.

## DISCUSSION

This study showed that TEA offers beneficial perioperative outcomes in patients undergoing MRM surgery when associated with GA. The TEA group's patients had better intraoperative BP and heart rate readings throughout the early intraoperative period, which indicated a better attenuation of the sympathetic response during peri-operation. Thoracic epidural anesthesia may have been responsible for the sympathetic blockade resulting in better modulation of hemodynamics and less stress responses perioperatively. Moreover, the postoperative pain scores were also meaningfully reduced in early postoperative period in TEA group in contrast to the other group that highlights the better analgesic effect of the epidural blockade. The reduced postoperative pain may also have accounted for the lower post-operative use of opioids and, hence, the incidence of PONV seen in the TEA

group. Improved pain control and decreased discomfort may also help to improve postoperative mobility, patient comfort and the overall postoperative recovery profile after breast cancer surgery.

The outcomes of the current research are similar to the previous researchs which presented the advantages of thoracic epidural anesthesia and regional anesthesia techniques in breast surgery. Thoracic epidural techniques for analgesic control were shown to be effective in providing postoperative analgesia and better pain control post mastectomy by Raheem et al. (2022).<sup>[18]</sup> In a similar vein, Ravi and Jaiswal, (2017) found that thoracic epidural anaesthesia could be a better choice than general anaesthesia in oncological surgery of the breast due to better analgesia and better perioperative outcomes.<sup>[19]</sup> In comparison to newer techniques like erector spinae plane block and thoracic paravertebral block, comparative studies have also shown good postoperative analgesic effects and better recovery characteristics in postoperative modified radical mastectomy patients.<sup>[20]</sup> Sayed et al. (2024) also found better perioperative respiratory outcomes in patients undergoing breast surgery with regional techniques.<sup>[21]</sup> A comparison of erector spinae plane block and thoracic epidural techniques has also shown the efficacy of TEA in perioperative pain management and opioid reduction.<sup>[22]</sup> The use of thoracic paravertebral and erector spinae blocks for breast surgery is increasing, and Sharma et al. (2023) found them to provide good postoperative pain management.<sup>[23]</sup> Singh and Kumar (2019) reported patients who underwent modified radical mastectomy under ultrasound-guided erector spinae plane block had reduced postoperative pain and improved analgesic outcomes similar to our findings.<sup>[24]</sup> Additionally, thoracic epidural anesthesia is thought to be especially advantageous in patients of high-risk breast surgery due to its hemodynamic and analgesic characteristics.<sup>[25]</sup> The outcomes of the current study thus generally corroborate the literature in favor of using methods of regional anesthesia during breast cancer surgery. TSSA is a new provincial anesthesia technique, which has recently become popular for breast surgery due to its quick onset and high density of surgical anesthesia. Nevertheless, TSSA has also several important drawbacks which might limit its application in the everyday clinical practice. This technique is very difficult and requires precise technique due to the spinal cord being very close at thoracic levels. Also, there is an increased risk of severe hypotension and neurological complications with TSSA. Poor availability of trained personnel and infrastructure in many developing healthcare centers may further hinder the use of TSSA in daily breast surgical practice. As a result, thoracic epidural anesthesia remains in many institutions a safer, more convenient and technique familiar regional anesthetic technique.

Thoracic epidural anesthesia provides many perioperative benefits in patients undergoing a modified radical mastectomy. One of the major advantages is improved and prolonged postoperative analgesia, thereby minimizing systemic opioid use and enhancing postoperative comfort. Improved pain control can help promote early mobility, decreased post-operative pain and improved functional recovery. TEA can also help to reduce the surgical stress response by lowering sympathetic activation and stress hormone levels. The maintenance of perioperative immune function might also have clinical implications for oncological surgery. Practically, thoracic epidural anesthesia is still useful in developing countries due to its relative cheapness, availability, and familiarity to anesthesiologists. Even with the development of the new regional anaesthetic techniques, TEA still offers reliable postoperative pain management and is still a practical alternative for many healthcare facilities that do not have the resources.

Based on the outcomes of the present study, thoracic epidural anesthesia may be considered an substitute to general anesthesia in selected patients undergoing MRM. Better perioperative analgesia, improved modulation of the hemodynamical parameters and decreased incidence of PONV may lead to better recovery and patient satisfaction. Thus, TEA might be useful in the context With improved recovery procedures in breast surgery.

The current study has many drawbacks. Forty patients was a rather small number. The results may not be broadly relevant since the research was carried out at a specific location. Furthermore, follow up only focused on the early postoperative phase and long term oncological or chronic pain analysis was not performed.

The findings of the current study need to be replicated in future studies using larger multicentric randomized controlled trials. Comparative studies with newer regional anesthesia techniques like thoracic segmental spinal anaesthesia and paravertebral block may give some other clinical clues. Also long-term immune, oncological and cost-effectiveness results in low-resource settings would be useful.

## CONCLUSION

The present Research revealed that TEA is a useful and beneficial anesthetic approach for patients undergoing modified radical mastectomy surgery. TEA resulted in better attenuation of perioperative sympathetic response as evidenced by improved intraoperative hemodynamic stability in early intraoperative period when compared with GA. Additionally, there was a considerable decrease in the postoperative pain levels for patients receiving TEA during the first 12 postoperative hours, reflecting the postoperative analgesia and lower need for systemic analgesics. The study's other key

finding was a suggestively reduced PONV incidence in the TEA group as opposed to the GA group. A decrease in opioid use, using epidural analgesia may have positively affected postoperative comfort and recovery. Additionally, improved pain control and less pain after surgery can help to maintain mobility and overall recovery after breast cancer surgery. While newer regional anaesthetic techniques like thoracic segmental spinal anaesthesia and interfascial plane blocks are being investigated, thoracic epidural anaesthesia remains a practical, cost-effective and technically familiar anaesthetic approach, especially in developing healthcare systems. The outcomes of the present investigation suggest that TEA is a secure and operative substitute for GA when performing MRM surgery and showed beneficial effects on perioperative haemodynamics, postoperative analgesia and postoperative recovery.

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