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Continuous thoracic paravertebral analgesia versus continuous thoracic epidural analgesia in a case of mastectomy under general anesthesia for perioperative pain management- A prospective observational study

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ABSTRACT

Background: Mastectomy is usually performed under general anesthesia (GA), but it is usually combined with different regional anesthesia techniques. Epidural and paravertebral blocks are both used for intraoperative and post-operative pain control. **Aims and Objectives:** The aim of this study was to compare the perioperative pain control, well-being of the patient, and recovery profile of patients who underwent mastectomy surgeries with two different modalities of anesthesia: Group A: GA with continuous thoracic paravertebral analgesia (TPVB), and Group B: GA with continuous thoracic epidural analgesia (TEA). **Materials and Methods:** In this prospective observational study, 64 consenting patients undergoing mastectomy requiring GA were selected who fulfilled the eligibility criteria and were assigned to either of the two groups alternatively: Group A – paravertebral block, or Group B – thoracic epidural block in a tertiary care hospital. Both the Group A and Group B patients were given 0.125% bupivacaine infusion at a rate of 5 mL/h for up to 48 h post-operative period by an infusion pump. Post-operative pain, the hemodynamic variables, and any adverse effects were assessed up to 48 h by a resident doctor. **Results:** Group A patients suffered minimal hemodynamic derangement intraoperatively. In the early post-operative period (early 24 h), Group A and Group B both had lower Visual Analog Scale scores and better pain control. Group A (9% pts) had required rescue analgesia in comparison to Group B, which did not require any rescue analgesia. Group A had a lower incidence of post-operative nausea and vomiting as compared to Group B. **Conclusion:** TPVB, though a difficult technique to learn, is a safe alternative to TEA in mastectomy surgery for its better hemodynamic control and longer post-operative analgesia, with minimal adverse events.

Key words: GA with continuous thoracic paravertebral analgesia; GA with continuous thoracic epidural analgesia; Post-operative pain control

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INTRODUCTION

Breast cancer, being the most common cancer among women with an estimated annual incidence of 2.3 million new cases, has now exceeded lung cancer as the leading cancer incidence globally in 2020.[1] Mastectomy is usually performed under general anesthesia (GA), but it is usually associated with different complications such as post-operative pain, nausea, vomiting, and increased analgesic requirements. Hence, GA combined with any regional

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anesthesia technique, such as thoracic paravertebral block, thoracic epidural block, pectoral nerve blocks (PECS I and PECS II), serratus anterior plane block, and transversus thoracic plane block, is preferred. Hence, there is a search for an optimal regional technique for breast surgeries that would reduce post-operative nausea and vomiting (PONV) and also provide post-operative sensory block, minimizing analgesic requirements to reduce post-operative pain after breast surgery.[2] Thoracic paravertebral analgesia (TPVB) and thoracic epidural analgesia (TEA) appear promising because of a reduction in post-operative pain, decreased opioid consumption with a reduction in PONV, drowsiness, risk of respiratory depression, and cost savings. There is a decrease in the incidence of chronic post-surgical pain, thereby improving the healing capacity of the wound.[3] When TEA was used, the incidence of pain, nausea, vomiting, and length of hospital stay was reduced. However, possible serious complications of continuous epidural analgesia, including hypotension, respiratory depression, infection, or even catheter migration to the subarachnoid space, may occur. TPVB has been used in thoracic and breast surgeries with minimal complications.[4] Our study aimed to compare TPVB and thoracic epidural block in patients undergoing mastectomy.

Aims and objectives

The aim of this study was to compare the perioperative pain control, well-being of the patient, and recovery profile of patients who underwent mastectomy surgeries with two different modalities of anesthesia.

- GA with continuous TPVB
- GA with continuous TEA.

Primary objective

- Post-operative pain control
- Intraoperative and post-operative hemodynamic stability
- Frequency of requirement of rescue analgesia.

Secondary objective

To compare adverse effects profiles between the two groups.

MATERIALS AND METHODS

This was a prospective, observational comparative study on patients scheduled for unilateral mastectomy surgery conducted in the operation theater followed by surgical H.D.U., Ward of General Surgery Department in DHB OT of Medical College, Kolkata, West Bengal, which was approved by the institutional ethics board (MC/KOL/IEC/NONSPON/927/01/2021). The selected study population was the patients between the ages of 18 and 60 years, of either sex, scheduled for elective surgery requiring GA with American Society of Anesthesiologists Physical Status I and II (ASA-PS I-II) category.

Inclusion criteria

1. Patients between the ages of 18 and 60 years of either sex
2. Scheduled for elective surgery requiring GA
3. ASA-PS I-II category
4. Patients are willing to participate in the study.

Exclusion criteria

All the patients associated with:

1. Bleeding disorders
2. Allergy to any of the study drugs
3. Refusal to give informed consent
4. Sepsis
5. Thrombocytopenia
6. Raised intracranial pressure
7. Anticoagulants therapy
8. Those with severe spine or chest wall deformity.

Eligible patients (n=64) were offered the study-related information verbally and in writing. Sixty-four patients were prospectively enrolled in the study after obtaining their written informed consent. The group distribution was performed by the principal investigator by consigning consecutive study participants alternatively to each group (Figure 1). A total of 64 patients were divided into:

- Group A: 32 patients were given continuous TPVB along with GA
- Group B: 32 patients were given continuous TEA along with GA.

Standard fasting protocols were ensured, and patients were pre-medicated with tablet ranitidine 150 mg on the night before surgery. Patients of both groups were cannulated in the procedure room with a wide-bore intravenous (IV) cannula and infused with lactated Ringer's solution at 3–4 mL/kg. Supplemental O_2 through a nasal cannula was given. A multichannel monitor was attached for monitoring the peripheral arterial oxygen saturation (SpO_2), electrocardiogram (ECG), and non-invasive blood pressure (NIBP) at baseline as per ASA basic monitoring standards. A baseline hemodynamic parameter was monitored and recorded by a resident doctor.

Patients in Group A (paravertebral) were given a single-needle paravertebral block with aseptic precautions at the level of T4 on the side to be operated. An epidural catheter was inserted 2–3 cm into the paravertebral space. In Group B (epidural) patients, an epidural block was performed using an 18-G Touhy epidural needle at the level of T4-T5 interspinous space. After appreciation

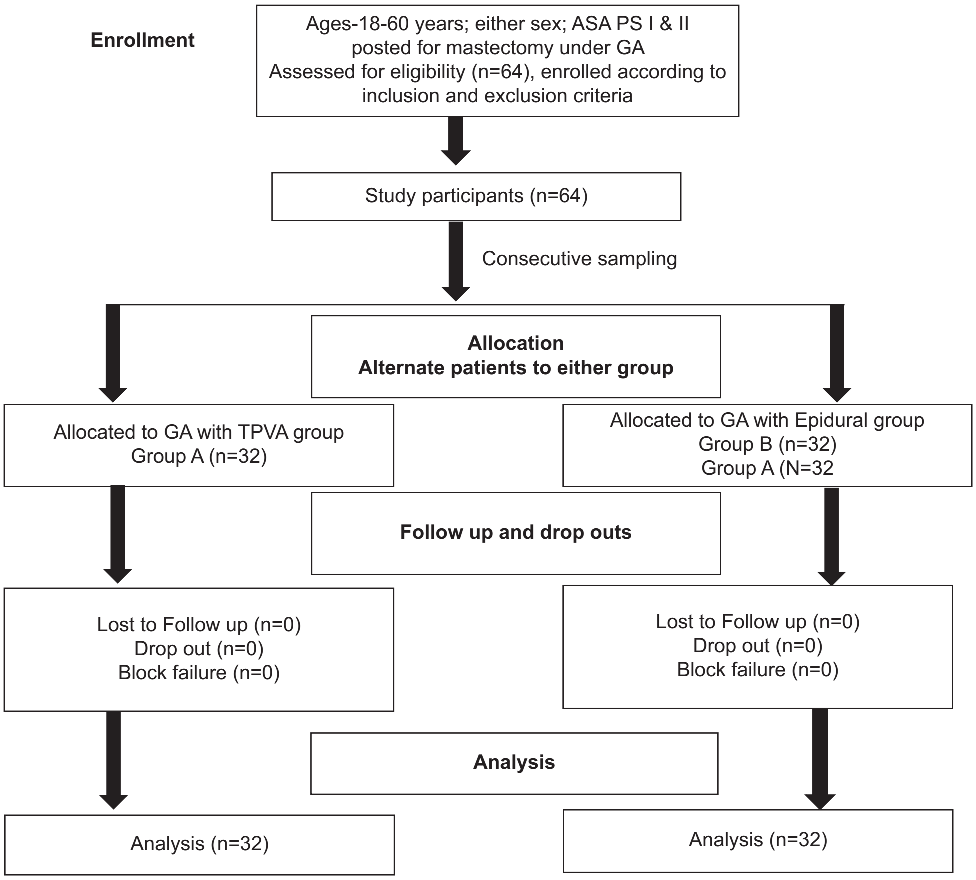

Figure 1: Study design

of loss of resistance, the syringe was removed, and the epidural catheter was threaded into the epidural space. The catheter was fixed to the back of the patient in both groups, and the patient was made supine. A test dose of 3 mL of 2% lignocaine with adrenaline was administered through the catheter in both groups after negative aspiration for blood and cerebrospinal fluid (CSF). The test dose was considered negative if the heart rate (HR) did not increase by >20% within 1 min or if a significant motor block did not develop within 5 min. Then a bolus dose of 10 mL of 0.125% bupivacaine was given to both groups after negative aspiration of blood or CSF. Unilateral loss of sensation to a pin prick and an ice bag was used to determine the upper limit of analgesia.

Anesthesia and surgical teams were the same for all patients. All patients received GA as per institutional protocol. The pre-medication was injection of glycopyrrolate (0.005–0.01 mg/kg body weight [BW] IV), injection of ondansetron (0.06–0.1 mg/kg BW IV), injection of midazolam (0.1–0.3 mg/kg BW IV), and injection of fentanyl (1–2 mcg/kg BW IV). After adequate pre-oxygenation, injection of propofol (1–2.5 mg/kg BW IV) was used for induction. Succinylcholine (1–1.5 mg/kg BW IV) was used for intubation, and injection of atracurium was used for maintenance (0.08–0.1 mg/kg BW IV) along with inhalational agent sevoflurane 1 MAC to maintain the deep plane of anesthesia.

Infusion of paracetamol 1 g was given with proper IV fluid maintenance therapy as per the Holliday-Segar formula. Intra-operative hemodynamic parameters were monitored and recorded at 0 min, 5 min, 15 min, 30 min, 1 h, 2 h, 3 h, and 4 h, respectively, by a resident doctor. Injection of neostigmine (0.05 mg/kg BW IV) and injection of glycopyrrolate (0.01 mg/kg BW IV) were given after ensuring adequate recovery of muscle power for reversal. Post-extubation hemodynamic parameters were monitored and recorded by a resident doctor.

Both the Group A and Group B patients were shifted to the surgical high-dependency unit ward for post-operative hemodynamic monitoring and pain assessment. A multichannel monitor was attached for monitoring the peripheral arterial oxygen saturation (SpO_2), ECG, and NIBP as per ASA basic monitoring standards. Both the Group A and Group B patients were given 0.125% bupivacaine infusion at a rate of 5 mL/h for up to 48 h post-operative period by an infusion pump with a 50 mL syringe filled with 50 mL volume of 0.125% bupivacaine.

The post-operative pain assessment was done at 0 min, 5 min, 15 min, 30 min, 1 h, 2 h, 3 h, 4 h, and then every 5 h up to 24 h, and then every 6 h up to 48 h by a resident doctor, till the patient was receiving continuous infusion of bupivacaine. Pain was assessed using the Visual Analog Scale (VAS) score from 0 to 10. The patient was considered pain-free if VAS <3. Injection of diclofenac 75 mg IM was given as rescue analgesia to patients with VAS >3 or on demand.

Patients were also monitored at the same interval for any adverse effects such as difficulty in breathing or allergic reactions, itching, drowsiness, nausea or vomiting, hypotension (mean arterial pressure [MAP] <65 mmHg). The epidural catheters were removed after 48 h of bupivacaine infusion, and the analgesic treatment was switched to parental or oral analgesics. Any hypotension was treated by discontinuation of bupivacaine infusion, elevation of lower limbs, and a 500 mL bolus of 0.9 %NaCl. If no response was obtained to the initial resuscitation, phenylephrine 100 mcg boluses were given and titrated according to effect.

Statistical analysis

All statistical analyses were performed using Statistical Package for the Social Sciences (SPSS), version 26.0 for Windows (IBM Corp, Armonk, NY). All statistical analyses and charts, tables were prepared using different software such as MS Excel, SPSS (version 26.0), Windows (IBM Corp, Armonk, NY). Continuous variables were tested for normality using the Shapiro–Wilk test and presented as mean ± SD or median (IQR), whereas categorical variables were described as frequencies and percentages. Normally distributed continuous variables were compared using the Student t-test. Categorical variables were analyzed using Pearson's Chi-square test. For comparison of percentages between the two groups, a t-test was performed. P<0.05 was considered to be statistically significant.

Sample size calculation

A total sample size of 50 with 25 in each group is required to get a power of 80% and an alpha error of 5%. We included 64 patients (32 in each group), considering a dropout of 10%. Calculation was done based on a pilot study, considering both alpha and beta error with a significance level of 5% and a confidence level of 95%.

$$\text{Sample size} = (Z_{alpha} + Z_{beta})^2 (S_1^2 + S_2^2)/d^2$$

Where S_1=Standard deviation of VAS score of "Epidural block" group

S_2=Standard deviation of VAS score of "TPVB block" group

$$d = (x_1 - x_2)$$

x_1=Mean of VAS Scores of "Epidural block" group

x_2=Mean of VAS Scores of "TPVB block" group

By using the data, it was estimated that 32 patients would be required per group.

RESULTS

The collected data from each group were analyzed and interpreted statistically. The demographic baseline data, such as mean values of age, height, weight, or ASA-PS class, between the groups were comparable (Table 1).

During the intraoperative period, the hemodynamic parameters such as mean HR (Table 2), systolic blood pressure (SBP), and diastolic blood pressure (DBP) were higher in Group A (paravertebral) than in Group B (epidural group), which were statistically significant (P<0.05). MAP was also higher in Group A (98.31±3.34) (paravertebral) than in Group B (89.47±6.65) (epidural group), which was statistically significant (P<0.05) during the initial part of surgery (Figure 2).

There were no statistically significant differences in mean values of RR, $etCO_2$, and SpO_2 between the groups intraoperatively. Postoperatively, there were no statistically significant differences between mean values of VAS Score (Figure 3), RR, or SpO_2 but there were statistically significant differences in HR, SBP, and DBP between the groups. In Group A 9% (3/32) required rescue analgesia as an injection of IM diclofenac 75 mg, in comparison to Group B, which did not require any rescue analgesia. In Group B 15% (5/32) of patients experienced nausea and vomiting, whereas in Group A, the figure was 6% (2/32), showing that patients in the paravertebral group suffered from less nausea and vomiting in the post-operative period.

DISCUSSION

Our rationale for the inclusion of TEA and TPVB in this study was based on clinical evidence suggesting

Table 1: Demographic data comparison

Parameters	Group	Mean	Standard Deviation	P-value
Age (Years)	Group A	45.19	7.311	0.056
	Group B	48.69	4.631	
Weight (kg)	Group A	59.72	5.101	0.099
	Group B	61.66	4.093	
Height (cm)	Group A	154.47	2.328	0.109
	Group B	153.69	1.401	
ASA		Grade I	Grade II	P-value (Chi-square)
	Group A	18	15	0.576
	Group B	14	17	

Table 2: Intraoperative HR comparison

Group statistics				
Group	**n**	**Mean**	**Standard Deviation**	**P-value**
HR baseline				
Group A	32	101.78	4.210	0.530
Group B	32	102.41	3.697	
HR 0 min				
Group A	32	102.91	4.223	<0.001
Group B	32	92.31	2.571	
HR 5 min				
Group A	32	98.13	4.094	<0.001
Group B	32	84.69	2.833	
HR 15 min				
Group A	32	99.34	4.367	<0.001
Group B	32	75.66	4.433	
HR 30 min				
Group A	32	90.25	4.819	<0.001
Group B	32	76.38	4.584	
HR 1 h				
Group A	32	88.06	4.970	<0.001
Group B	32	76.00	4.235	
HR 2 h				
Group A	32	86.81	5.503	<0.001
Group B	32	76.66	4.209	
HR 3 h				
Group A	32	85.94	5.908	<0.001
Group B	32	76.41	3.800	
HR post-extubation				
Group A	32	102.09	5.114	0.178
Group B	32	100.66	3.075	

HR: Heart rate

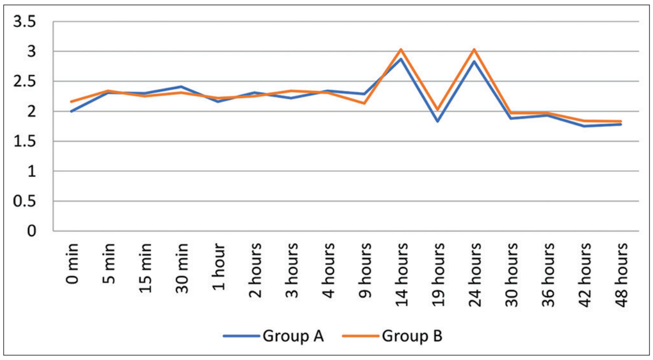

Figure 2: Post-operative Visual Analog Scale score comparison

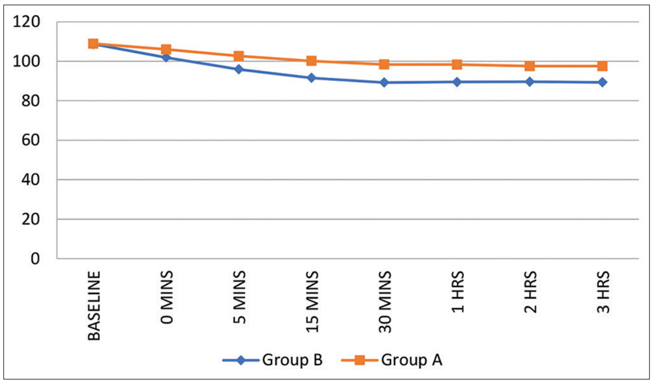

Figure 3: Comparison of intraoperative mean arterial pressure

that epidural anesthesia is associated with fewer post-surgical recovery complications, shorter hospital stays, and, consequently, decreased health care costs.[5] Regarding demographic variables (age, height, weight, ASA), and there was no significant statistical difference among the groups. In the epidural Group B, there was a significant fall in HR within the first 30 minutes of the bolus dose. In the TPVB Group A, there was no significant fall in the HR, indicating more hemodynamic stability than in Group B. Hence, there was a significant statistical difference in HR among the studied groups intraoperatively. Giri et al. compared combined GA with TPVB versus GA alone in modified radical mastectomy (MRM) and found that intraoperative and post-operative tachycardia and hypertension were more common to a statistically significant extent in the GA group.[6] There was a study that compared TEA and TPVB for post-thoracotomy pain relief, found that the HR decreased after activation of the epidural when compared with the baseline. Then, it remained stable after the initial fall (in the first 20 min). In the paravertebral group, no such decrease in HR was observed after giving the bolus dose. In both groups, the HR remained stable in the post-operative period.[7]

In our study, there was a significant statistical difference among the studied groups regarding MAP, as patients receiving a thoracic epidural (Group B) showed a significant fall in MAP within 20–30 min of bolus dose. In Group B, 18% patients had shown a fall of MAP >30% of baseline value after bolus and were treated with IV fluids. In patients receiving TPVB (group A), there was no significant fall in BP; therefore, they were hemodynamically more stable than Group B. The cardiovascular effects, such as cardiac contractility, profound hypotension, and bradycardia, are due to high cardiac sympathetic fibres (T1–T4) block, which can be detrimental to a patient with limited cardiac reserve.[8] Kumar compared the thoracic epidural and paravertebral analgesia (PVB) group for post-thoracotomy pain relief using 0.25% bupivacaine and found that 50% of patients showed hypotension in the epidural group.[9] Mukherjee et al. found that there were statistically significant MAP differences between thoracic TPVA and TEA, which were lower in the epidural group.[10] There was another study that found no significant differences with respect to HR and MAP.[11] In the intraoperative period, there was no significant statistical difference in RR, $etCO_2$, and SpO_2 among our studied group. In our study, the quality of analgesia in the post-operative period till 48 h was assessed using VAS. There was no significant statistical difference among the studied groups about VAS, as both groups showed better pain control.

Debreceni et al.[12] found that thoracotomy pain management with continuous epidural analgesia was superior to that with continuous TPVB in the early post-operative period. In a study conducted by Kairaluoma et al.,[13] PVB with bupivacaine (1.5 mg/kg), performed before GA in patients scheduled for MRM, resulted in less need for post-operative opioid analgesics during the initial hours after surgery and less overall intensity of pain on the 1st post-operative day.

In our study, HR was better controlled in Group A as compared to Group B in the early post-operative period (first 24 h), but was almost similar in the next 24 h. In Group A, there was a requirement for rescue analgesia as 75 mg diclofenac IM in 9% (3/32) patients in the early post-operative period (first 24 h). In Group B 15% (5/32) of patients experienced nausea and vomiting, whereas in Group A, the figure was 6% (2/32), showing that patients in the paravertebral group suffered from less nausea and vomiting in the post-operative period. The results are similar to Davies et al.[14] found that the incidence of nausea and vomiting was less often with TPVA. In the post-operative period, there was no significant statistical difference in RR among the studied group. In our study, no patient in either group had any complications due to technique, such as pneumothorax, epidural abscess or hematoma, skin site infection, spinal or nerve root injury, or urinary retention.

Limitations of the study

a. Intraoperative pain monitoring could not be done as the patient was under GA
b. Due to a shortage of time, further study with a larger number of patients with the use of a nerve stimulator or USG guidance, which is known to improve the efficacy of the block, could not be done.

CONCLUSION

To the best of our knowledge and keeping the previous study trials in mind, we draw the impression that TPVB, though a difficult technique to learn, is a safe alternative to TEA in mastectomy surgery for its better hemodynamic control and longer post-operative analgesia, with minimal adverse events.

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Authors' Contributions:
PB- Definition of intellectual content, literature survey, prepared first draft of manuscript, implementation of study protocol, manuscript preparation, and submission of article; **AP-** Concept, design, clinical protocol, data collection, manuscript preparation, editing, and manuscript revision; **SC-** Design of study, statistical analysis, and interpretation**; RB-** Review manuscript and analysis.

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