RESEARCH ARTICLE

COMPARISION OF THORACIC EPIDURAL BLOCK VS PARAVERTEBRAL BLOCK IN PATIENTS UNDER GOING BREAST SURGERY

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ABSTRACT

Objective: *Despite advances in medical treatment, surgical intervention is often associated with postoperative pain, nausea, and vomiting. While epidural analgesia is considered the gold standard for post-thoracic surgery pain relief even Paravertebral nerve block (PVB) has the potential to offer equal postoperative pain relief and fewer side effects when used for breast surgery.*
Method: *We compared thoracic PVB with epidural block in a double-blinded, prospective, randomized study of 60 women scheduled for unilateral breast surgery. Patients were divided into two groups of 30 each, Group E (Thoracic epidural group), Group P (Thoracic paravertebral group), each who received 15ml of 0.5% Ropivacaine either in the thoracic epidural region or thoracic paravertebral region.*
Results: *Patients receiving epidural showed a fall in mean arterial pressure leading to significant p-value at 10, 20, 30, 40, 50 min, 1hr, 1 hr PO. The fall was soon addressed with fluid bolus and if not responding vasopressors were given in form of 6 mg mephentermine. In Group E 33% (10/30) patients required vasopressors as compared to 0% (0/30) in Group P. The analgesic profile of the two regional technique were similar in both groups. In Group E (20%) patient experienced Nausea and Vomiting which was more than Group P (7%)*
Conclusion: *We conclude that Paravertebral nerve block has the potential to offer equivalent surgical condition and analgesia along with good patient satisfaction as compared to epidural anesthesia but better patient profile and tolerance and fewer postoperative side effects when used for breast surgery.*

Key Words: *Ropivacaine, Thoracic epidural, Thoracic paravertebral block, VAS (Visual Analogue Scale), Hemodyanamic complications*

INTRODUCTION

Breast surgery is usually performed under general anesthesia, and is associated with considerable post-operative pain, nausea and vomiting (PONV) [1] along with physical, psychological and immunological depression. So there is a search for optimal regional techniques for breast surgeries which would reduce PONV and also provide post-operative sensory block, minimizing narcotic requirements of the various local and regional anesthetic techniques evaluated in the past to reduce post-operative pain after breast surgery, [2,3, 4] thoracic paravertebral block (PVB) and thoracic epidural appears promising due to reduction in post-operative pain, decreased opioid consumption with reduction in PONV, drowsiness, risk of respiratory depression and cost saving. [5, 6] also decrease in the incidence of chronic post-surgical pain and improving wound healing. [7] Epidural analgesia [8] with local anesthetic, opioid, or both has become common place and has been regarded as the 'gold standard'.[9] Surveys of analgesic techniques in Australian and UK hospitals showed that majority of anesthetists considered epidural analgesia to be the best mode of pain relief[10,11]. Epidural blockade has been shown to reduce the intraoperative surgical stress response and has possible advantages for cardiovascular, respiratory, coagulation, gastrointestinal, metabolic and immune function [12,13]. However, thoracic epidurals can cause hypotension, neurological injury [14] and are contra-indicated in the presence of coagulopathy or local sepsis.

Thoracic paravertebral block (PVB) has enjoyed resurgence in recent years [15]. Placement of local anesthetic within the paravertebral space produces unilateral

somatic and sympathetic block, which is advantageous for unilateral surgical procedures of the chest and abdomen. [3]
Thoracic paravertebral block (TPVB) is the technique of injecting local anesthetic adjacent to the thoracic vertebra close to where the spinal nerves emerge from the intervertebral foramina. Clinical advantages [3] of this block is that single injection produces multidermatomal ipsilateral nerve block, It also maintains hemodynamic stability & reduces opioid requirements and there is low incidence of complications, preserves bladder sensation & lower limb motor power.

In Epidural blockade the drug is injected into spinal epidural space which extends from the foramen magnum to the sacral hiatus and surrounds the duramater anteriorly, laterally and posteriorly. The depth varies depending on the body habitus.[16,17]The primary site of action is the spinal nerve roots. Sensory blockade blocks painful stimuli, whereas motor blockade provides muscle relaxation with a varying degree of sympathetic blockade.[18]

Blockade of sympathetic fibers below T4 cause vasodilation, decrease in venous return and subsequently, cardiac output. [19] and the cardiovascular effects of a block above T4 causes profound hypotension and bradycardia [20,21] as a result of a high sympathetic block. Clinical advantages of this block is that it reduces the adverse physiologic responses to surgery and also decrease the incidence of postoperative myocardial infarction[22], pulmonary complications[23, 24] & the incidence of hypercoagulability.[25, 26] so it reduces overall mortality and morbidity. Authors like E. P. Lynch et al [27] (1995) studied the outcomes of patients undergoing breast surgery under general anesthesia and thoracic epidural anesthesia and found epidural technique to be associated with better patient profile. Sabyasachi Das et al [28] (2012) found that the anesthetic conditions provided by multiple-injection thoracic paravertebral block is better than general anesthesia in breast surgeries. T. Santhosh Kumar et al [29] (2003), Casati A et al [30] (2006) studied comparative hemodynamics and pain relief between continuous thoracic paravertebral and epidural after thoracotomy and concluded that paravertebral has lesser hemodynamic changes with similar analgesic conditions. But there is no study comparing the two regional techniques and their analgesic and hemodynamic effect in breast surgery.

AIMS AND OBJECTIVES

Out of the various studies on paravertebral and epidural block on different procedure in thoracic region, none of those compares the two techniques for surgical anesthesia in breast surgeries. So we conducted the present study to compare:

- The anesthetic and hemodynamic effects of paravertebral block & epidural block and
- The side effects and immediate postoperative analgesia in breast surgery patient using paravertebral block & epidural block

MATERIAL AND METHOD

After obtaining Institutional ethics committee approval, a total of 60 healthy ASA Grade I & II patients aged 18-65 years, scheduled for a unilateral breast surgery without axillary clearance were enrolled in this randomized observer blinded prospective clinical study and divided into two groups.

Group P: In this group, 30 randomly chosen patients were given single shot paravertebral block at T2 level using 0.3 ml/kg of 0.5% Ropivaciane.

Group E: In this group, 30 randomly chosen patients were given single shot epidural block at T4 level using 2ml/segment of 0.5% Ropivaciane.

All the patients associated with severe cardiovascular, respiratory, endocrine disease, bleeding disorders, allergy to any of the study drug, Kyphoscoliosis, presence of acute herpes zoster, chronic pain syndrome, chronic analgesic use, body mass index >35, known pregnancy, lactating mothers and psychiatric disease were excluded from the study.

During the pre-operative visit on the day before surgery, patients were thoroughly explained about the procedures to be undertaken and the risks and benefits associated. Written and informed consent was taken. They were made well conversant with the visual analogue scale (VAS) for post-operative pain. Patients were advised preoperative fasting for a period of 6 hrs and premedicated with Tab Diazepam (10 mg) the night before surgery.

On arrival to the operation theatre (OT) complex, patients were taken to a monitored block room where the PVBs & Epidurals were performed. IV infusion of lactated Ringer's solution as maintenance fluid was started. Prior to both the procedures, all necessary equipment for GA and resuscitation were kept ready in case of a block failure or any complication. Baseline vital parameters like pulse rate, non-invasive blood pressure (NIBP), respiratory rate, degree of sedation and peripheral arterial oxygen saturation (SpO_2) were noted. The patient was then shifted to the OT after surgical anesthesia was achieved. Monitoring was continued throughout the operative procedure, recorded at 10-min interval in the intraoperative and at 1-h interval in the post-operative period. Patients were given incremental doses of IV midazolam (up to a maximum dose of 0.06 mg/kg) in the block room before block placement to decrease anxiety and discomfort during the procedure while maintaining a meaningful patient contact. Fentanyl (2 μg/kg) was given as pre-emptive analgesic for block placement. Even-Odd number technique was used for randomization of patients into Group P or Group E.

Procedure for thoracic paravertebral block: Point corresponding to 2.5 cm lateral to the upper border of spinous processes of the T_2 vertebra was marked as needle insertion sites, part was prepared painted and draped and space infiltrated with 2 mL of 1% lignocaine. A 20 G needle was introduced perpendicular to the skin in all planes to touch the transverse process of the lower vertebra. After identification of the transverse process, the needle was walked off the superior surface of the transverse process and slowly advanced 1-1.5 cm until a loss of resistance to air was obtained with a 5-mL glass syringe. Loss of resistance was said to occur while needle pierced superior costotransverse ligament to enter into the thoracic paravertebral space. [3] 0.3ml/kg of 0.5% Ropivaciane solution was then injected after repeated negative aspiration for blood or cerebrospinal fluid, irrespective of paraesthesia.

Procedure for Epidural: After identification of level, painting and draping, skin was infiltrated with local anesthetic using 25-gauge 1.5 inch needle. Epidural needle with stylet was inserted through same skin puncture using midline approach (approximately 3 cm depth) and the glass syringe attached to the hub of the needle. After confirming LOR to air 2ml/segment of 0.5% Ropivaciane was injected.

OBSERVATIONS

Performance time was the time required to serve the block after painting and draping that is from needle insertion to injection of the drug. The onset of unresponsiveness to unilateral pinprick at 5 min and every 5 min thereafter up to 30 min was assessed. A block was considered as 'unsuccessful' if onset of pinprick unresponsiveness was not evident within 15 min or failure to achieve adequate sensory block (T2-T6) within a maximum time of 30 min. If the block was considered as failed, the patient was administered GA and the case was excluded from the study. Intraoperatively, patients received an IV infusion of Propofol (30-70 mcg/kg/min) titrated to light sleep with easy arousability. Intermittent doses of Fentanyl 25 mcg and Propofol 10 mg were given for supplemental sedation if Ramsey sedation score of >2.Fluid was administered in the form of RL according to 4-2-1 rule. If blood pressure fell >20% below baseline fluid bolus of 100 ml was given. If blood pressure did not respond 100 ml bolus was repeated. Non responsive blood pressure was given vasopresser in form of mephentermine 6mg IV.

Induction time (time to surgical anesthesia) was defined as the time gap between the completions of local anesthetic injection to unresponsiveness to unilateral pinpricks at least three segments. Duration

of surgery was defined as the time between surgical incision and application of adhesive bandage after closure of the wound in both the groups. Post-operatively, all patients were monitored in the recovery room for the first hour. Patients were assessed for pain and nausea and vomiting just after shifting to recovery from OT by a resident not involved in the study. Post-operative pain was assessed with a VAS score of 0-10 (0=no pain and 10=worst imaginable pain). VAS scores ≥4 was treated with rescue analgesic Tramadol in boluses of 50 mg IV, repeated if necessary after 15 min. Time to the first analgesic requirement was noted. Duration of postoperative analgesia was defined as the time between the last suture application and the request for first rescue analgesic at VAS score ≥4. VAS of less than 4 cm was considered as effective analgesia, 4-7 will be considered ineffective analgesia and VAS of 7 or more was considered as failure of technique. Number of patients experiencing PONV were accounted for and treated accordingly. Apart from these, patients were monitored throughout the study period for any evidence of complications.

At the time of discharge, patients were asked to mention about their satisfaction of the respective anesthetic procedure (NRS 0-100).

DISCUSSION

Postoperative nausea and emesis are some of the most unpleasant side effects of anesthesia and under GA, 56% of patients suffer nausea and vomiting up to 24 h after breast cancer surgery [(27)] which is more debilitating. As result of IV narcotics for pain, recovery time is prolonged, hospital stay is lengthened, and hospital costs are increased [(27)].

In light of this situation, various regional anesthetic techniques for breast surgery have been suggested, including field block, local anesthetic infiltration, intercostal nerve block, epidural anesthesia, paravertebral block, and brachial plexus block. Out of which paravertebral block and epidural anesthesia both have been extensively used with consistent results.

Our rationale for the inclusion of thoracic epidural anesthesia (TEA) and paravertebral block (PVB) in this study was based on clinical evidence suggesting that extradural anesthesia has been associated with fewer post-surgical recovery complications, shorter hospital stays, and, consequently, decreased health care costs.

Extradural anesthesia selectively blocks cardiac sympathetic fibers, and this offers potential patient benefits: attenuation of the surgical stress response, improvement of myocardial oxygen balance, and stabilization of intraoperative hemodynamics [(13)].

Finally, although it is not yet scientifically proved, many clinical studies have embraced the concept that extradural anesthesia offers a preemptive analgesic effect. A limited number of studies have found that epidural or paravertebral block with local anesthetics co administered with opioids provide better outcomes after breast surgery than GA.

But there is a lack of studies comparing these two regional techniques. Anesthetic, analgesic and hemodynamic effects of epidural anesthesia have not been compared with the paravertebral block, despite their widespread clinical use. Therefore, we conducted the present study to demonstrate that Epidural anesthesia & Paravertebral Block in patients undergoing various breast surgeries are similar in terms of anesthetic requirements, analgesia, and patient satisfaction but there is a significant change in hemodynamics of patient receiving epidural anesthesia. Also the incidence of nausea & vomiting was more in Group E as compared to Group P. Our study results are in accordance with other studies in which the authors Sabyasachi Das et al (2012) [(28)], T. Santhosh Kumar et al (2003) [(29)], Casati A et al (2006) [(30)], Pusch F et al (1999) [(31)] R. G. Davies et al (2006) [(32)], Gultekin Gulbahar et al (2010) [(33)], Pintaric TS et al (2011) [(34)], did find significant changes in hemodynamics and side effects. Intraoperative and postoperative analgesia was similar.

CHARACTERISTICS OF BLOCK

Performance Time: Time to perform the Epidural Block & Paravertebral Block was similar. For Epidural block it was 7.07±1.78 min and for Paravertebral 6.8±1.74 min. p–value again was insignificant 0.288. The results are in accordance with Pusch F et al (1999) [31] who studied Single-injection paravertebral block compared to general anesthesia in breast surgery. Their time to perform the block also ranged from 4-9 min.

Induction Time: Time from injection of local anesthetic to unresponsiveness to unilateral pinpricks at least three segments in Epidural Block was 16.87±2.21 min and in Paravertebral Block was 17.57±1.98 min. p – value again was insignificant 0.101. The results are in accordance with the study done by Sabyasachi Das et al (2012) [28] who studied use of multiple-injection thoracic paravertebral block as an alternative to general anesthesia with induction time of 19.17±4.84 min.

Duration of Surgery: Time from skin incision to closure was 71.67±32.18 min in Epidural group and 69.33±31.90 min in Paravertebral group. p – Value again was insignificant 0.392.

Heart Rate: The heart rate of the two groups did not show any significant difference as the p-value was >0.05

Blood Pressure: Patients receiving epidural showed a fall in BP leading to significant p-value at 10 min, 20 min, 30 min, 40 min, 50 min, 1hr, 1 hr PO.

The cardiovascular effects of a block above T4 are the result of a high sympathetic block. The cardiac sympathetic fibers (T1 to T4) are blocked which may cause decrease in cardiac contractility, profound hypotension and bradycardia. In addition increased central venous pressure, splanchnic nerve blockade with blockade of medullary secretion of catecholamines, dilation of the capacitance vessels of the lower limbs may also occur.

When a sympathetic block occurs at such a high level, the cardiovascular reflexes for responding to low cardiac output states are abolished. This can be detrimental to a patient with limited cardiac reserve because profound hypotension and decreased contractility can result.

The results obtained are in accordance with study done by Casati A et al [30] (2006), who did comparison between continuous thoracic paravertebral and epidural infusion of 0.2% Ropivaciane after lung resection surgery. They found that median (range) percentage reduction of systolic arterial pressure from baseline was -9 (0 to -9) % in group PVB and -17 (0 to -38) % in group EPI (P = 0.02); while clinically relevant hypotension (systolic arterial pressure decrease >30% of baseline) was observed in four patients of group EPI only (19%) (P = 0.04)

The results match with R. G. Davies et al (2006) [32] who found that hypotension was less common with PVB, Odds Ratio 0.23 (0.11, 0.48), The results also run parallel to the study done by T. Santhosh Kumar et al (2003) [34]. 50% of patients showed hypotension in group Epidural and 8% group Paravertebral. The mean arterial pressure differences at 10, 20, 30, 40, 50, 60 minutes between 2 groups were statistically significant at the above mentioned intervals. Respiratory rate, SPO_2, Ramsey sedation score were observed intra operatively and the p-value was insignificant throughout the study duration. The study results match with other studies done by Gultekin Gulbahar et al (2010) [33]. They also found no significant difference in terms of Respiratory Rate and SPO_2.

Total Fentanyl Required: The requirement of Fentanyl in Group E was 120.83±18.35 µg and that in Group P was 122.5±19.74 µg. The p-value was 0.365.

The results are in accordance with study done by Sabyasachi Das et al (2012) [28] who studied paravertebral block as an alternative to general anesthesia for elective breast surgeries. In their study the requirement of Fentanyl for Paravertebral group of patient was 107.76±11.77 mcg.

Total Propofol Required: The requirement of Propofol in Group E was

125.67±49.37 mg and that in Group P was 142.33±60.14 mg. The p-value was 0.132.The results are in accordance with study done by Sabyasachi Das et al (2012) [28]. In their study the requirement of Propofol for Paravertebral group of patient was 219.82±74.48 mg.

Total Fluid Required: The requirement of IV Fluids in form of RL in Group E was 1986.67±210.92 ml and that in Group P was 1480±164.11 ml. The p-value was <<0.001 showing significant difference in requirement of IV Fluids among two groups. The results match with Pintaric TS et al (2011) [33] who compared continuous thoracic epidural with paravertebral block on perioperative analgesia and hemodynamic stability in patients having open lung surgery.

Requirement of Vasopressors: The requirement of vasopressors in Group E was 33% (10/30) and that in Group P was 0% (0/30). The results obtained are in accordance with study done by Casati A et al [30] (2006), clinically relevant hypotension (systolic arterial pressure decrease >30% of baseline) requiring vasopressors was observed in four patients of group EPI only (19%) (P = 0.04)

Vas Score: The quality of analgesia was observed in terms of VAS score PO and 1 h PO. For Group E it was 0.47±0.49 and 1.2±1.24 respectively. In Group P the values were 0.53±0.56 and 1.03±1.17 respectively. The p-values were 0.323 and 0.304 respectively.

Time to First Dose of Rescue Analgesic: For Group E it was 307.5±37.29 min and in Group P the value was 304±42.94 min respectively. The p-values was 0.376. This shows similar analgesic profile of both the regional techniques. The results match with Pintaric TS et al (2011) [34]. In their study also pain intensity before and after respiratory physiotherapy as well as 24 hr rescue piritramide consumption was similar in the epidural (4.1 ± 3.1 mg) and the paravertebral (2.5 ± 1.5 mg) groups (P = 0.14).

Patient Satisfaction Score: In Group E it was 87.5±14.93 and in Group P the values were 85.83±12.72 respectively. The p-value was 0.320. The results are in accordance with study done by Casati A et al (2006) [30]. In their study Patient satisfaction with the technique was 8.5 (8-9.8) cm in group EPI and 9 (7.5-10) cm in group PVB (P = 0.65).

SIDE EFFECTS:

In Group E 20% (6/30) patients experienced Nausea and Vomiting where as in Group P the figure was 7% (2/30) showing that patients in paravertebral group suffered from less nausea and vomiting. The results match with R. G. Davies et al (2006) [32] who found that Nausea and vomiting occurred less often with PVB, Odds Ratio 0.47 (0.24, 0.53)

In this study, no patient in both group had any other side effect like pneumothorax, epidural abscess or hematoma, skin site infection, spinal or nerve root injury and urinary retention.

Table No. 1: Baseline Parameters

	Group E	Group P	p VALUE
Age (in years)	39.33±14.93	38.53±11.76	0.4102
BMI (in kg/m2)	23.69±2.47	23.05±1.98	0.135
Pulse (per min)	86.53±10.93	86.93±16.01	0.449
Mean Blood Pressure (mmHg)	89.16±9.78	89.97±9.29	0.385
Respiratory Rate (per min)	20.33±3.67	19.9±3.36	0.315
SPO_2 (in %)	99.14±0.97	99.13±1.04	0.5
Ramsey Sedation Score	1.67±0.47	1.8±0.40	0.105

(n=30 in each group), all the baseline characteristics and vital parameters of the patients in two groups were comparable.

Table No. 2: **Mean Blood Pressure (MMHG)**

Time	**Group G**		**Group P**		p-Value
	Range	Mean±SD	Range	Mean±SD	
0 min	89.17±9.62	73-101	89.97±9.13	75-101	0.3850
10 min	74.93±11.40	56-95	85.27±9.19	71-98	0.0008*
20 min	75±11.07	55-92	84.67±9.33	71-98	0.0014*
30 min	75.43±11.13	56-92	84.97±9.09	70-98	0.0012*
40 min	75.93±10.58	58-92	84.93±9.51	69-97	0.0020*
50 min	76.73±11.71	57-93	85.33±8.85	71-97	0.0035*
1 hr	77.5±11.32	59-95	85.17±9.52	69-98	0.0073*
1 hr PO	80.27±10.74	62-97	86.13±8.95	71-97	0.0245*

(n=30 in each group), Blood Pressure measured in mm of Hg showed significant fall in epidural group and statistically significant difference was found between Group E and Group P at 10 min, 20 min, 30 min, 40 min, 50 min, 1 hr and 1 hr PO (post operative).

Table No. 3: Observations

Observation	**Group G**		**Group P**		p-Value
	Mean±SD	Range	Mean±SD	Range	
Performance Time (in min)	7.07±1.78	4-10	6.8±1.74	4-10	0.288
Induction Time (in min)	16.87±2.21	13-22	17.57±1.98	14-21	0.101
Duration of Surgery(in min)	71.67±32.18	35-125	69.33±31.90	25-120	0.392
Total Propofol Required (in mg)	125.67±49.37	60-220	142.33±60.14	60-270	0.132
Total Fentanyl Required(in µg)	120.83±18.35	100-175	122.5±19.74	100-175	0.365
Total Fluid (RL) Required (in ml)	1986.67±210.92	1600-2300	1480±164.11	1300-1900	<0.0001*
VAS score PO	0.47±0.49	0-1	0.53±0.56	0-2	0.323
VAS score 1 hr PO	1.2±1.24	0-4	1.03±1.17	0-4	0.304
Time to Rescue Analgesic (in min)	307.5±37.29	210-375	304±42.94	210-360	0.376
Patient Satisfaction Score (0- 100)	87.5±14.93	50-100	85.83±12.72	50-100	0.320

(n=30 in each group), all the intra and post operative characteristics of the two regional techniques were similar with exception of fluid requirement.
(PO- post-operative, RL –Ringer's Lactate, VAS- Visual Analogue Score)

Table No. 4: Observations for Side Effects

Observation	**Group E**		**Group P**	
	Number	%	Number	%
Hypotension requiring Vasopressors	10	33	0	0
Nausea & Vomitting	6	20	2	7
Other Delayed complication	0	0	0	0

(n=30 in each group), side effects like nausea, vomiting, puncture site infection, urinary retention etc. were observed.

CONCLUSION

Hence, this study concluded that both Epidural and Paravertebral provide optimal surgical condition and analgesia along with good patient satisfaction. But the hemodynamic perturbations are more in Epidural group of patients, so it is associated with more fluid & vasopressor requirement and side effects like nausea and vomiting. Eventually, Paravertebral block is a more promising regional technique with better patient profile and tolerance.

STATISTICAL ANALYSIS

Statistical analysis was done by computer statistical software system instat and results were presented in tabulated manner. Comparison between groups were performed by using unpaired't' test or Chi-square test, as appropriate. The results were expressed in mean±SD and number (%).

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