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Bi-Level Ultrasound Guided Erector Spinae Block V/S Paravertebral Block in Post Operative Analgesia After Breast Cancer Surgeries

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ABSTRACT

Breast cancer is prevalent worldwide and the management of postoperative pain is crucial during the peri-operative period. The aim of present study was to compare the efficacy of bi-level ultrasound guided paravertebral block (PVB) with erector spinae block (ESP) for postoperative analgesia in breast cancer surgeries. A double blind, randomized controlled trial conducted on 60 patients (20-60 years, ASA grade I and II), randomly assigned into two groups of 30 each, Group E (ESP) and group P (PVB) undergoing breast cancer surgeries under general anaesthesia. 15ml of 0.25% of bupivacaine with 4 mg dexamethasone was given at T2 and T6 level each in both the groups. The mean block procedure time, duration of analgesia using VAS Score, total rescue analgesia, hemodynamic changes, sedation score, patient and surgeon satisfaction score and any complications was compared. The total procedure time of block was significantly shorter (14.75±3.89 minutes) in Group E as compared to Group P (22.65±4.68 minutes) (p=0.001). The duration of analgesia was longer in group E (12.40±5.60 hours) as compared to group P (10.60±5.40 hours) but it was statistically non-significant (p=0.09). The total rescue analgesia doses in group E was 1.60±0.99 and in group P was 1.80±1.06 (p>0.05). VAS score was >three in both the groups and was statistically non-significant (p>0.05) in first ten hours and it was <three in group P at 10 hours, in group E at 12 hours. Erector spinae block is a novel analgesic method and it provides effective pain management and duration of analgesia comparable to paravertebral block. Both the blocks are effective and safe techniques that give superior and comparable post-operative pain relief, provide prolonged duration of analgesia and limit the requirement of postoperative analgesic consumption.

INTRODUCTION

Breast cancer is one of the most common tumour in females and surgical management remains the main modality of treatment. According to reports, 40% of female patients experience moderate to severe pain in the post operative period subsequent to breast cancer surgery^[1]. Post operative analgesia after breast surgeries is challenging due to the extensive surgical procedure and the complex innervation of the breast^[2]. Poor post-operative analgesia management may lead to various acute as well as chronic complications. The poor management of acute post-operative pain may lead to chronic pain that affects the patient's postoperative quality of life and also increases the risk of postoperative complications thereby affecting the patient's postoperative recovery^[3]. Thus, effective post-operative pain control is pivotal for the enhanced recovery of the patient after breast cancer surgeries. Multi modal analgesia is used for the management of the post-operative pain including pharmacological methods (opioids and non-opioids), neuraxial techniques and regional anaesthesia. Regional anaesthesia forms an important part of multi modal anaesthesia by decreasing the stress response following surgery and minimizing the requirements for opioids and their undesirable side effects through better postoperative pain management^[4]. Regional anaesthesia techniques used for the management of postoperative pain following breast cancer surgeries include thoracic epidural, thoracic paravertebral block, serratus anterior plane block, pectoral nerve blocks (PECS-1, PECS-2) and erector spinae plane blocks. Hugo Selheim of Leipzig invented the concept of PVB in 1905^[5]. It has been used effectively for management of post-operative pain. But, due to the presence of pleura and the neuraxial system in the vicinity of paravertebral space it is a difficult technique. The potential complications of PVB include pneumothorax, vascular puncture, epidural or intrathecal spread and sympathetic spread leading to the haemodynamic instability^[6], but with the advancement in the ultrasound technology and its use in regional anaesthesia has enabled anaesthesiologist to carry out the block under direct visualization with successful results and minimal vascular and neurological complications. Forero *et al.* initially reported ESP block in 2016 for acute post surgical pain and neuropathic pain following thoracotomy. It involves the deposition of drug between transverse process and erector spinae muscle, which produces both anesthesia and analgesia to hemithorax^[7]. It is comparably safe due to absence of the vital structures in the vicinity^[8]. The local anaesthetic spreads cranio-caudally at multiple dermatomal levels blocking the dorsal rami and ventral rami of spinal cord^[9]. ESP block has been used in thoracic, spine, breast and abdominal surgeries as regional anaesthesia technique^[10]. Complications

associated with ESP block are minimal and may include infection, pneumothorax and block failure^[1]. The extent of the block depends on point of needle entry, volume and concentration of the local anaesthetic used. For providing complete post-operative analgesia after breast cancer surgery, it is important to block ten spinal nerve dermatomes from C5-T6. It has been reported that a single level injection of 15ml LA produces somatic block over a median of three dermatomes in PVB and about 2-3 levels in ESP. Also, multiple level blocks have shown to provide better pain scores with lesser opioid consumption, leading to shorter period of hospital stay. Therefore, the present study was carried out on patients undergoing MRM using bi-level technique. The analgesic efficacy of bi-level ESP block was compared with the already established thoracic PVB for providing post-operative analgesia in patients undergoing breast cancer surgeries under general anaesthesia.

MATERIALS AND METHODS

After obtaining the approval from Institutional Ethics and Thesis Committee, the study was registered with the CTRI database (registration number- CTRI/2023 /06/053769) and along with the written and informed consent, this prospective, randomized, double blind clinical study was conducted on 60 female patients belonging to ASA (American Society of Anaesthesiologists) Grade I and II, 18-60 years of age, admitted in tertiary care hospital in Punjab, scheduled to undergo breast cancer surgeries under general anaesthesia. 60 patients were randomly assigned using computer generated software in two groups of 30 each, Group E received ultrasound guided ESP block and group P received ultrasound guided thoracic PVB using 15ml of 0.25% of bupivacaine with 4 mg dexamethasone at T2 and T6 level each in both the groups. Patients who refused to take part in the procedure or to enlist in study, ASA Grade III and IV, clinically significant pulmonary pathology, coagulation disorders, anticoagulation therapy, having history of allergy to drug and known neuropathies involving forearm and hand, uncooperative patients, and pregnant patients were excluded. The primary outcomes included comparison of mean block procedure time, analgesia duration using VAS Score and total rescue analgesia. The secondary aims noted were sedation score, patient satisfaction score, surgeon satisfaction score, hemodynamic changes and any side effects and complications. All patients were examined one day before the surgery and a detailed pre-anaesthetic check up was done, written informed consent was taken from the patient after explaining the technique and its complications in patient's vernacular language, all routine investigations were reviewed. The patients were allocated into two groups based on computerized randomization table created by

a researcher not associated with the study. The researcher allotted a random ID number to each patient and a blinded anaesthesiologist used this number while collecting the data postoperatively in the ward. All patients were reassessed in the preoperative room and fasting of the patient was confirmed. Baseline vitals were recorded. An IV line secured and infusion with ringer lactate was started. Premeditation was given. Patients shifted to the operating room and monitoring was done using the multipara monitors (NIBP, ECG and SpO2) which were attached and baseline readings were recorded. General anaesthesia was given and surgery for breast cancer was allowed to proceed. After surgery, patient was turned laterally with surgical side up and block was given. The block was given by the expert anaesthesiologist, trained in regional anaesthesia using UGRA (Ultrasound Guided Regional Anesthesia) while patient was still under anaesthesia.

- ESP (Erector Spinae Block):** The spinous processes from C7 to T8 were marked. Using all aseptic precautions, ultrasound probe (linear probe with 5-12 MHz) with sterile cover was kept in the midline in craniocaudal direction at the T2 level, moved laterally about 2.5–3.0 cm to identify tip of the transverse process. The Quincke's needle (22G, 9cm) was inserted in caudo-cephalic direction till the tip of the needle lies between erector spinae muscle and the transverse process. The confirmation of erector spinae plane was done by injection of 3-5mL of normal saline and the elevation of erector spinae muscle from the transverse process can be seen. After confirmation, the drug (15ml of 0.25% of bupivacaine with 4mg dexamethasone) was given in the erector spinae plane. With the same technique transverse process tip at T6 level was identified and after confirmation of plane drug (15 ml of 0.25% of bupivacaine with 4mg dexamethasone) given in the erector spinae plane (Fig. 1).
- Paravertebral Block (PVB):** The spinous processes from C7 to T8 were marked. Under all aseptic conditions, ultrasound probe (linear probe with 5-12 MHz) was kept in the craniocaudal direction at T2 interspinous space, about 5 cm from the midline and transverse process and parietal pleura was identified by moving the probe medially. Ultrasound-guided paravertebral space identified, and a needle inserted through the superior costo transverse ligament. The correct placement of needle was confirmed by deflection of the pleura downwards on injecting 3mL of normal saline 0.9%. After the confirmation, drug (15 ml 0.25% of bupivacaine with 4mg dexamethasone) injected. With the same technique at T6 level, drug (15 ml of 0.25% of bupivacaine with 4mg

dexamethasone) injected in the paravertebral plane after confirmation of the plane(Fig. 2).

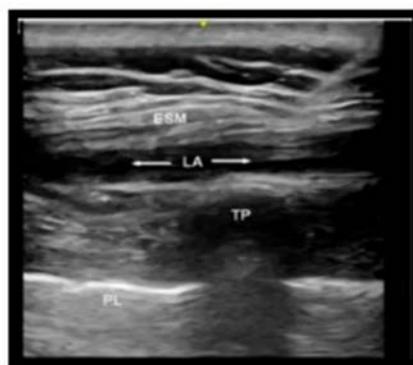
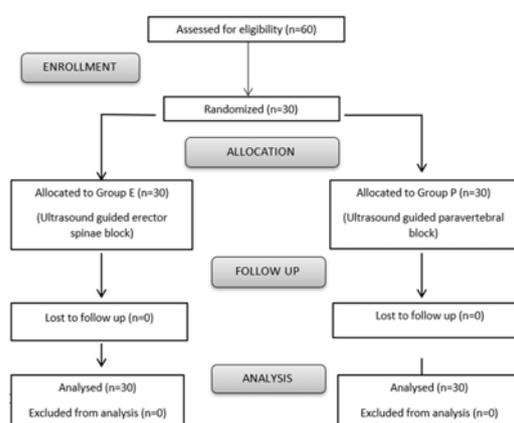


Fig. 1: ESP (Erector Spinae Block)



Fig. 2: Paravertebral Block (PVB)

After giving the block patient was shifted to supine position and patient was extubated. Patient was shifted and post-operative monitoring was done



Study Design

Following Parameters were Noted:

- Procedural time taken to complete the block in each technique was noted. It was defined as the time after placement of the ultrasound probe till the injection of local anaesthetic drug at both levels.

- Post operative analgesia was assessed by using VAS Score.
- VAS was assessed postoperatively at every 30 minutes interval for first 2 hours and 2 hourly afterwards till 12 hours and then 6 hourly upto 24 hours.
- When VAS was >3, then rescue analgesia was given.
- Rescue analgesia was given in the form of injection fentanyl (1mcg/kg) I/V. If pain was not relieved by fentanyl, Injection diclofenac (75mg) I/M was given.
- Time after which first rescue analgesia given and total dose of the rescue analgesia required by the patient in 24 hours was noted.
- hemodynamic changes, intraoperative and postoperative complications related to procedure and drug were noted and managed accordingly.
- Patient and Surgeon satisfaction score was noted after 24 hours.
- Sedation score was evaluated by using Ramsay sedation scale.

Statistical Analysis: Sample size of 27 was required per group for the comparison keeping in view at most 5% risk, with minimum 80% power and significance level of 5% (significant at 95% confidence interval). To account for expected dropouts, 30 patients were taken in every group. The above mentioned parameters and characteristics of the patients were compared using appropriate statistical tests. The results were analyzed and compared with the previous studies. Data was recorded in a Microsoft excel spread sheet and analyzed using Statistical Package for the IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp., Chicago. Continuous data was presented as mean with standard deviation. Categorical data was expressed as numbers and percentages. Power analysis was done to calculate the power of study which was 95% by taking a error 0.05. The p-value was then determined to evaluate level of significance.

RESULTS AND DISCUSSIONS

In the present study, two groups were found to be comparable with respect to patient demographic characteristics i.e. age, ASA (American Society of Anaesthesiologists) grade, body mass index and duration of surgery as shown in (Table 1).

Table 1: Demographic Characteristics of Patients in Group E and Group P

S. No.	Demographics	Group E	Group P	p-value
1.	Mean Age	49.83±12.67	50.33±12.01	0.410
2.	BMI	25.30±5.38	24.83±5.52	0.240
3.	ASA grade			
	I	17	15	0.605
	II	13	15	
4.	Duration of surgery	90.50±16.40	89.87±16.33	0.15

NS: Non-Significant(p>0.05)., Significant (p<0.05)., HS: Highly Significant (p<0.001).

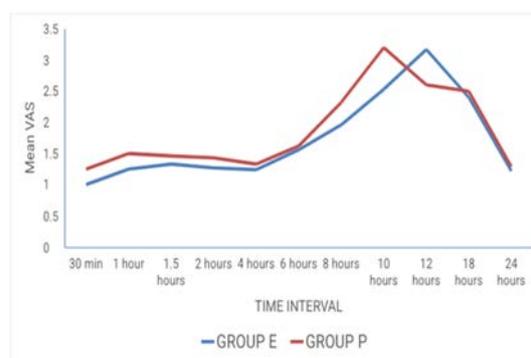
The total block procedure time was noted as 14.75±3.89 minutes in Group E and 22.65±4.68 minutes in Group P and difference between the two groups was noted to be highly significant with p value =0.001 as depicted in (Table 2). Duration of analgesia was longer in group E (12.40±5.60 hours) as compared to group P (10.60±5.40 hours). The difference between both the groups was statistically not significant with p-value of 0.09. (Table 2). Number of doses of rescue analgesia in group E was 1.60±0.99 and in group P was 1.80±1.06. The difference was found to be statistically non-significant (p>0.05). Total fentanyl consumption in 24 hours postoperatively was found to be 86.33±52.36 mcg in Group E and 95.67±48.69 mcg in Group P. The difference was found to be statistically non-significant with p-value=0.24. (Table 2).

Table 2: Procedure Time, Duration of Analgesia, Number of Rescue Analgesia Doses and Total Dose of Rescue Analgesia in Goup E and Group P

Sr. .No.	Parameters	Group E	Group P	p-value
1.	Procedure time	14.75±3.89	22.65±4.68	0.001 (HS)
2.	Mean duration of analgesia	12.40±5.60	10.60±5.40	0.090
3.	Total number of doses of rescue analgesia	1.60±0.99	1.8±1.06	0.18
4.	Total rescue analgesia -fentanyl (mcg)	86.33±52.36	95.67±48.69	0.240

NS: Non-Significant(p>0.05)., Significant (p<0.05)., HS: Highly Significant (p<0.001).

(Graph 1) shows the VAS which was evaluated post operatively at every half an hour interval for 1st 2 hours and then 2 hourly till 12 hours then 6 hourly till 24 hours. In group E, VAS score started increasing at 10th hour and at 12th hour patient demanded first dose of rescue analgesia (3.17+1.51). In group P, VAS score started increasing at 8th hour and patient demanded first dose of the rescue analgesia at 10th hour where VAS was (3.20+1.27). So at 10th hour, VAS score was significantly higher in group P as compared to group E and at 12th hour VAS was significantly higher in group E as compared to group P. Later on, VAS remained comparable in both groups.



Graph 1: VAS Score

All the hemodynamic parameters (heart rate, respiratory rate, SpO2, systolic blood pressure,

diastolic blood pressure) in intraoperative and postoperative period were comparable in both the groups and difference was statistically non-significant ($p>0.05$). Sedation score, surgeon satisfaction score and patient satisfaction score were comparable and difference was statistically non-significant in both the groups.

The breast cancer surgeries are associated with varying degrees of postoperative pain^[2]. Acute pain following surgery also raise the risk of thromboembolism, myocardial infarction, paralytic ileus and immune system dysfunction. It also leads to the delayed discharge from the post-operative recovery area and lengthens the hospital stay^[12-15]. It has been established that stress and post operative pain are the factors responsible for increased risk of metastasis^[11]. Therefore, it is crucial to provide patients undergoing breast surgery with an efficient perioperative pain management. The pain management is done using multi modal analgesia which includes opioids, non-opioids analgesics, as well as regional anaesthesia techniques. In addition to contributing to respiratory depression, opioids cause side effects such as ileus, post operative headache, nausea, pruritus and urine retention. They also cause opioid tolerance and dependence^[9]. As a part of multi modal analgesia techniques, regional anaesthesia effectively provide post-operative pain relief by preventing the neuroendocrine response to the surgery and decrease the requirement of post-operative analgesics. By reducing the stress response to surgery, improving analgesia, reducing the requirement of opioids, and direct protective action of local anaesthesia on migration of cancer cells, regional anaesthesia may slow the progression of cancer^[16,17]. In present study the efficacy of PVB was compared with ESP for postoperative analgesia in breast cancer surgeries at two levels. The study done by Adhikary SD *et al.* revealed that with the use of 20 ml LA at single level in thoracic ESP block, the neuronal foramina and epidural extent was restricted to two to three levels, whereas spread to five levels was seen in the intercostal plane^[12]. Tulgar *et al.* compared the effect of bi-level ESP block with single-level ESP in thoracotomy surgeries and found better pain scores and less opioid consumption with bi-level technique^[14]. SQM T *et al.* reported that for PVB if distribution of four or more dermatomes are required then multiple injections are more reliable^[18]. Walid Youseef *et al* concluded that multiple level PVB is better than single level block in view of reducing the severity of pain in early postoperative period and was also associated with a lower need for opioid analgesics^[19]. Hence, we opted for bi-level block technique due to the extensive innervation of breast and requirement of multiple

levels of dermatomal coverage. The results revealed that ultrasound guided ESP block procedure is technically easier and safer to perform as compared to ultrasound guided PVB with significantly shorter procedure time. A trial conducted by Çiftçi B *et al.* to assess the efficacy of ESP and PVB for management of post-operative pain in Video-assisted thoracic (VATS) patients found that the procedure time for block was significantly shorter in the ESPB group (7.13±1.59 minutes) compared to the TPVB group (13±2.49 minutes) ($p<0.001$)^[20]. Similarly, in our study observations we found that the procedure time was significantly (p -value=0.001) shorter in the erector spinae block (14.75±3.89 minutes) compared to paravertebral block (22.65±4.68 minutes). However, as compared to their study the total time was more in our observations as in our technique bi-level block was given. Similarly Fang B *et al* conducted a trial to compare analgesic effectiveness of erector spinae block to thoracic paravertebral block following thoracotomy noted that procedure time was 6.82±1.47 minutes in erector spinae block and 10.67±1.94 minutes in thoracic paravertebral block. The difference between both the groups was highly significant (p -value=0.001)^[21]. Likewise, in our observations the difference was statistically highly significant ($p=0.001$) between both the groups with shorter block procedure time in erector spinae block compared to paravertebral block. However, the total block procedure time was more in our study group (Group E=22.65±4.68 minutes, Group P=14.75±3.89 minutes) owing to the use of bi-level block in our study technique. We also noted the block procedure time at individual levels (T2 level Group E=7.53±1.97 minutes, Group P=11.56±5.39 minutes and at T6 level Group E=7.22±1.97 minutes, Group P=11.16±2.31 minutes) which was comparable with their study results. A study conducted by Swisher MW *et al* to compare single-injection ESPB (erector spinae plane block) and PVB (paravertebral block) for unilateral or bilateral breast surgery in a subject-blinded manner. Compared with PVB, the median time to perform the ESPB block procedure was shorter to a statistically significant degree (1.9minute/side for ESPBs versus 4.1 minute/side for PVBs with p -value <0.001)^[22]. In our study observations the procedure block time was significant between both the groups similar to their study results but it was longer in both the groups as compared to their study observations. However, they recorded the procedure time from the time of block needle insertion to removal of block needle and the time of ultrasound scanning and localization was not included. Our results revealed that duration of analgesia was longer in group erector spinae as compared to group paravertebral with p -value of 0.09. In a study done by El Mourad MB *et al*

in 2018, adding dexamethasone to bupivacaine for ultrasound-guided thoracic paravertebral block in patients undergoing breast cancer surgeries prolonged the time to first rescue analgesia requirement was, that is, 10.3 ± 4.5 hours^[23]. Similarly, we also found that the time to first rescue analgesia in paravertebral group was 10.60 ± 5.40 hours which was comparable to this study group. Mohammed Ali DS *et al.* conducted a study in 2022 using dexamethasone as an adjuvant in ultrasound-guided erector spinae block for analgesia and the median time to first rescue analgesia was found to be 720 minutes (12 hours) in the dexamethasone group^[24]. Likewise, in our study the time to first rescue analgesia after erector spinae plane block was noted as 12.40 ± 5.60 hours which was comparable to the above mentioned study. A randomized control trial conducted by Elewa AM *et al* to compare the erector spinae plane block and paravertebral block regarding postoperative analgesic consumption following breast surgery found that the ESPB groups ($4.9 \text{mg} \pm 1.2 \text{mg}$) had insignificantly lower total morphine consumption than the PVB group ($5.8 \text{mg} \pm 1.3 \text{mg}$) with p-value of 0.001^[25]. Similarly, we also found in our study results that total dose of fentanyl consumption was less in erector spinae group (86.33 ± 52.35 mcg) as compared to paravertebral group (95.67 ± 48.69 mcg) but it was statistically non-significant ($p=0.24$). The mean sedation score remained ≤ 2 in both groups at all the time intervals and the difference was statistically non-significant ($p>0.05$). Surgeons and patients were satisfied with both group E and group P for postoperative analgesia.

Limitations:

- Single shot analgesia was given and catheter was not inserted to prolong the analgesic effect of local anaesthetic to avoid patient discomfort.
- In the postoperative period, pain referring to dermatome levels could not be evaluated immediately after block as it was given after surgery when patient was still under general anaesthesia.
- Postoperative monitoring was done for only 24 hours and the duration of analgesia exceeding 24 hours was not noted. There were patients in both the groups who did not complain of pain in 24 hours postoperatively, so we cannot comment on the duration of analgesia.
- We used VAS score as a pain measurement method which is not an objective method and could have some variability in patient's ability to use that scale.
- To perform the ultrasound guided block techniques, trained and registered anaesthesiologist are needed which may not be

available in all the other centres. So, this study cannot be used as a reference for future in the institutions where ultrasound or trained anaesthesiologist in UGRA is not available.

CONCLUSION

We concluded that erector spinae block being a recent analgesic technique is effective in providing postoperative pain control and duration of analgesia comparable to paravertebral block. Our study revealed that ESP is technically simple and has significantly shorter procedure time as compared to paravertebral block. Both the blocks are effective and safe techniques that give superior and comparable post-operative pain relief, provide prolonged analgesia and limit the requirement for postoperative analgesic consumption.

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