Original Article

Efficacy of single-shot ultrasound-guided erector spinae plane block for postoperative analgesia after mastectomy: A randomized controlled study

ABSTRACT

Background: The aim of this study is to understand the effect of ultrasound (US) guided erector spinae plane block (ESPB) in improving the intraoperative and postoperative analgesia in patients undergoing mastectomies, decreasing the use of opioids and in reducing postoperative nausea and vomiting.

Methods: After local ethics committee approval, 100 patients were divided randomly into two groups. Group A with 50 patients received US guided ESPB with 30 ml of 0.25% of bupivacaine under US guidance. Group B with 50 patients received no block. Visual analogue scale (VAS) was used to assess pain postoperatively. All patients received 1 g intravenous intravenous paracetamol 8th hourly and morphine was used as rescue analgesia if VAS score is more than 4. Patients were monitored for VAS scores, postoperative nausea/ vomiting and total morphine consumption for a 24-hour period in a high dependency unit.

Results: Postoperative morphine consumption was found to be significantly less in patients who received US-guided ESPB compared to control group (0.12 mg ± 0.59 mg in ESPB group compared to 1.70 ± 2.29 mg which was statistically significant, p=0.000). Only 3 patients in ESP group received rescue analgesia in the form of morphine whereas 22 patients in the control group received morphine. There was no difference in PONV score in either groups. There were no complications like vascular puncture, pneumothorax, or respiratory depression in both groups.

Conclusion: US guided ESPB is quite effective in reducing perioperative pain in patients undergoing mastectomy. The trial was registered prospectively with CTRI with registration number: CTRI/2018/09/015668.

Key words: Mastectomy; regional blocks; opioids; perioperative pain; postoperative nausea/vomiting; ultrasound

Introduction

The incidence of chronic pain after a mastectomy is as high as 25–60%.[1] Once it develops, it is not only difficult to treat but it has significant negative impact on the life of the patient. One important way of reducing this incidence is by providing multimodal analgesia after breast surgery.

The innervation of breast is very complex, and breast surgeries include extensive dissection of nerve fibers. Therefore, providing comprehensive perioperative analgesia is difficult after mastectomy, breast conservation surgery, and reconstructive surgeries.[2] Several new regional

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anesthesia techniques have been described recently like pectoralis blocks (PECS 1 and 2) and serratus anterior plane (SAP) block, which has been used with reasonable success.[3,4] Regional anesthesia techniques offer good pain relief, reduce perioperative opioid and anesthetic use, reduces postoperative nausea/vomiting (PONV), helps in reducing chronic pain, and facilitates early rehabilitation.

Erector spinae plane block (ESPB) is a recent addition to the ultrasound (US)-guided interfascial plane block described by Forero *et al*., which was used for treating thoracic neuropathic pain.[5] This paper led to a lot of interest in this interfascial plane block owing to the ease of performance and good analgesia provided by it. Erector spinae (ES) consists of three columns of muscles: iliocostalis, longissimus, and spinalis. The three muscles run parallel to each other along the vertebra and extend from the lower back of the skull down to the pelvis. Erector spine plan (ESP) is a potential space deep to erector spinae muscle (ESM), where the injected local anesthetic (LA) spreads cranio-caudally up to several levels from the point of injection. Chin *et al*. demonstrated that ES fascia extends from nuchal fascia cranially to the sacrum caudally (C7-T2 cranially and L2-L3 caudally) in cadavers.[6]

The LA injected traverses the costotransverse foramina and blocks ventral rami, dorsal rami of spinal nerves, and rami communicantes that gives the sympathetic fibers.[7] The dermatomes covered by ESPB depend on the point of entry, concentration, and the volume of LA used.

Hamilton *et al*. used ESPB at T5 level for a patient with rib fractures using 20 ml of 0.25% levobupivacaine, which provided extensive analgesia on the hemithorax.[8] Because of its initial description, ESPB has been used for providing perioperative analgesia for various thoracic, abdominal surgeries with reasonable success.[9]

The aim of this study was to evaluate the analgesic efficacy of preoperative US-guided ESPB for female patients undergoing a modified radical mastectomy. The primary aim was to compare 24 h morphine consumption in both groups. The secondary aims were to compare PONV and intraoperative fentanyl consumption in both groups.

Methods and Materials

This prospective, randomized, single-blinded study was approved by local Institutional Ethics Committee. The study was prospectively registered with the Clinical Trials Registry of India (CTRI): CTRI/2018/09/015668. We enrolled 102 female patients aged 20–65 years with American Society of
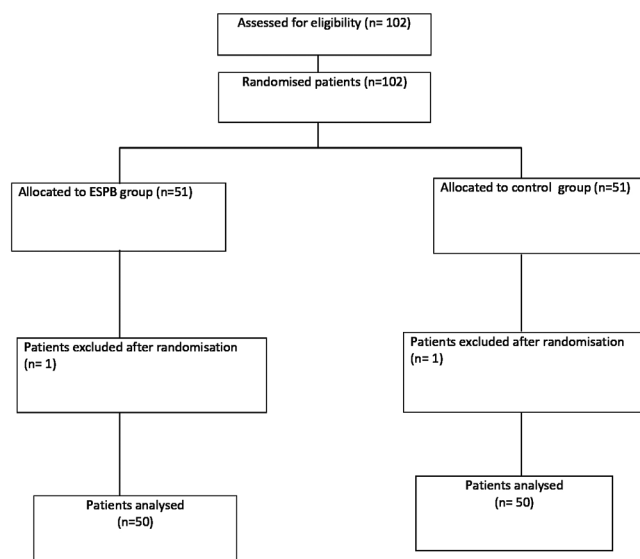

Figure 1: CONSORT diagram

Anesthesiologist's physical status (ASA-PS) I–II and scheduled for unilateral, elective modified radical mastectomy for breast cancer in the study. Exclusion criteria followed by us was patient not willing to participate, body mass index (BMI) more than 35 kg/m^2, known allergy to LA, ASA-PS 3 and beyond, underlying coagulopathies, renal, and hepatic dysfunction. The CONSORT flowchart is depicted in Figure 1.

Informed consent was signed by every patient after explaining the process involved in the language they understood. Computer generated randomization was performed for both groups (www.random.org). Patients were randomized to receive either a single-shot US-guided ESPB (ESP group) or no intervention (control group).

US-guided ESPB technique

With the patient in a sitting position, T3 spinous process was identified and marked after counting down from C7 spinous process. A linear array high-frequency US probe (Sonosite M-Turbo Inc., USA) was used for performing the block, which was placed in craniocaudal orientation in the midline. The probe was then moved laterally to identify T4 transverse process (TP), which is usually at 2.5–3 cm from spinous process laterally. ESM, rhomboidus major, and trapezius muscle were identified [Figure 2]. Under aseptic precautions and after skin infiltration with 2% lidocaine, 10 cm block needle (Stimuplex® Ultra 360® 22 G, B-Braun) was introduced in-plane craniocaudally under vision and navigated till the TP was encountered. Hydro dissection with 2 ml normal saline was done to confirm separation of ESM from TP. Under US guidance, 30 ml 0.25% bupivacaine was injected and drug spread was seen in the ESP plane craniocaudally in real time.

General Anesthesia details

All patients were evaluated for fitness at a pre-anesthesia check-up clinic by the Anesthesiologist. After confirming nil by mouth status, patients were premedicated with intravenous (IV) midazolam (0.03 mg/kg) followed by fentanyl (1.5 µg/kg, maximum 100 µg) after securing an appropriately sized IV line on the non-operating side. General anesthesia was induced with IV propofol 2–2.5 mg/kg and the airway secured with an appropriately sized supraglottic airway (SGA), AMBU^R Aura40™. Patients in ESP group received the block prior to induction. Neuromuscular block was achieved with 0.5 mg/kg atracurium. General anesthesia was maintained with oxygen–medical air and isoflurane using volume-controlled ventilation, and dial concentration was adjusted to target a minimum alveolar concentration of 1.0.

Intraoperatively, we monitored electrocardiogram (lead II, V5), non-invasive blood pressure, oxygen saturation (SpO$_2$), end-tidal isoflurane, and end-tidal carbon dioxide. The end-tidal carbon dioxide was monitored using a capnograph targeted to 35–40 mm Hg. Fentanyl 0.5 µg/kg (maximum 50 µg) was administered to all the patients who had a sympathetic response to pain on incision i.e. if the heart rate and blood pressure raised by at least 20% of baseline. During skin closure, 1 g IV paracetamol was administered over 15 min. At the end of the surgery, SGA was removed after reversing neuromuscular blockade with 0.05 mg/kg neostigmine and 0.01 mg/kg glycopyrrolate. Patients were then transferred to a high-dependency unit. The visual analogue scale (VAS) was used to assess pain postoperatively. Intravenous paracetamol 1 g every 8 h was continued in the postoperative period. Intravenous morphine was used as rescue analgesic in both groups, if the VAS score was more than 4, as follows: 2 mg IV for patients 50 kg or less and 3 mg IV for the patient over 50 kg. PONV and total morphine consumption for the 24-h period was recorded.

The primary outcome of this study was to compare total morphine consumption between both groups at the end of 24 h, with the secondary outcome being a comparison of PONV in both groups.

In a previous study, a sample size of 25 in each group was required to achieve 80% power and an error of 0.05 to detect a 30% difference in postoperative morphine requirements at 24 h.[10] This study was conducted in a high-volume center performing various breast surgeries daily. To avoid possible drop-outs, to have reliable and valid results, we enrolled 50 patients in each group. This sample size and study was approved by the Hospital Ethics committee. As we used a sample size of 50, which is more than that used in previous studies, we performed power analysis using OpenEpi software (https://www.openepi.com/Menu/OE_Menu.htm). The power of our study is 83%.

Statistical Package for the Social Sciences (SPSS) version 21 was used for statistical analysis. Continuous variables were expressed as mean ± standard deviation. Comparisons of normally distributed continuous variables between the groups were performed using unpaired t test. The *P* value less than 0.05 was considered as statistically significant.

Results

In total, 102 patients were enrolled in this study with 51 patients in each group. Two patients were excluded as they underwent re-exploration for surgical site bleeding. Finally, 100 patients (50 in each group) were analyzed. Demographic data (age, weight) and ASA-PS were comparable in both groups. There was no statistical significance in baseline parameters and immediate postoperative parameters (heart rate, systolic, diastolic, and mean arterial pressure), PONV score in both groups [Table 1].

Total morphine consumption in 24 h in ESP group was statistically significant ($P = 0.000$, degree of freedom-98, mean difference-1.58, and standard error difference-0.336:
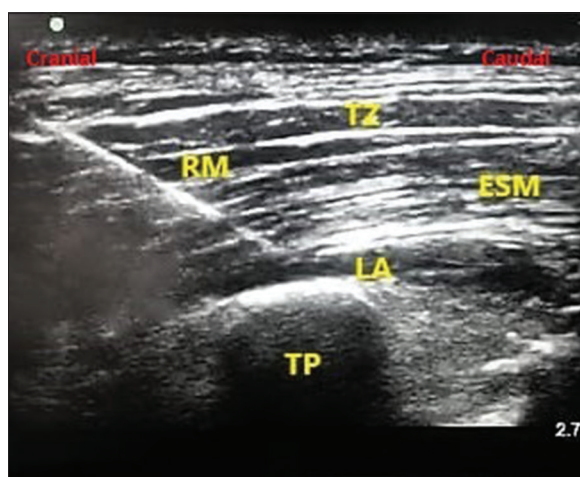

Figure 2: Figure shows sonoanatomy relevant to US-guided ESPB. (TZ- trapezius muscle, RM- Rhomboidus major muscle, ESP- Erector spinae muscle, TP- Transverse process of T3 vertebra)

Table 1: Comparison of demographic profile in both groups (age, weight, ASA-PS, and PONV)

	ESP group	Control group	*P*
Age (years)	50.56±11.61	52.68±8.14	0.293
Weight (kg)	57.46±11.16	60.66±11. 41	0.160
ASA-PS (I/II)	24/26	20/30	0.425
PONV	0.26±0.565	0.3±0.678	0.749

Table 2: Comparison of hemodynamics in both groups

	ESP group	Control group	P
Heart rate (per min)			
Baseline	86.54±13.86	82.58±14.19	0.161
Immediate postoperative	82.94±14.59	77.80±12.40	0.061
Systolic BP (mm Hg)			
Baseline	136.46±13.82	136.72±15.32	0.929
Immediate postoperative	140.60±16.74	143.10±16.71	0.457
Diastolic BP (mm Hg)			
Baseline	81.66±8.53	79.46±8.65	0.204
Immediate postoperative	83.40±10.04	82.96±9.35	0.821
Mean arterial pressure (mm Hg)			
Baseline	99.96±8.71	98.54±9.65	0.442
Immediate postoperative	102.56±10.71	12.78±10.13	0.916

Table 3: Comparison of intraoperative fentanyl, 24 h morphine consumption, and patients in both groups requiring morphine

	ESP group	Control group	P
Intraoperative fentanyl used (mg)	118.70±28.88	142.20±28.66	0.000
24 h morphine consumption (mg)	0.12±0.59	1.10±2.29	0.000
Patients requiring morphine	3/50	22/50	

unpaired t test) [Tables 2 and 3]. Only 3 patients (6%) in the ESP group received rescue analgesia in the form of morphine, whereas 22 patients (44%) in the control group received morphine. Two patients, one from each group were excluded from the study as they were re-explored for bleeding from the surgical site in the first 24 h. The mean intraoperative fentanyl used in ESP was 118.70 ± 28.88 μg and in the control group was 145.20 ± 28.66 ug, which was statistically significant ($P = 0.000$-unpaired t test) [Table 3]. There were no complications noted in both groups such as vascular puncture, pneumothorax, LA systemic toxicity, or respiratory depression.

Discussion

In our study, 24 h morphine consumption was significantly less in patients with carcinoma breast who received US-guided ESPB than patients who did not receive the block. The incidence of PONV was comparable in both groups, and intraoperative fentanyl used was significantly less in patients who received a preoperative ESPB. On the basis of results of this prospective study, it is evident that US-guided ESPB leads to less postoperative morphine consumption at least in the first 24 h thus providing good postoperative analgesia.

Thoracic paravertebral blocks (TPVB) have been used for decades for managing perioperative pain after mastectomy. TPVB not only provided comprehensive opioid-sparing analgesia it also had a role in reducing the incidence of chronic post-mastectomy pain syndrome.[11,12]

Although very effective, there is a possibility of pneumothorax with TPVB, which can have significant morbidity in the postoperative period. With single point TPVB, there are chances of spread of LA to central neuraxial space. Use of US have made the block safe as vital structures such as lung and pleura can be identified and inadvertent punctures avoided.[13] In spite of this, US-guided TPVB is a technically challenging block.

US-guided ESPB is a relatively easy block to learn and master. As the end-point of injection is away from pleura, there is less risk of pneumothorax after an US guided ESPB. Owing to this reason, ESPB might soon replace TPVB as the regional anesthesia technique for breast surgery. Supraclavicular nerve does not get anesthetized with this block; postoperative analgesia is adequate requiring less rescue analgesia for managing breakthrough pain. Supraclavicular nerve arises from the superficial cervical plexus and innervates a part of anterior chest wall below the clavicle along with intercostal nerves.[14] Because of the incomplete dermatomal block, it is difficult to use ESPB as the sole anesthetic for breast surgeries and may be combined with supraclavicular nerve block for comprehensive analgesia, which requires further studies. If ESPB is performed prior to general anesthesia, intraoperative anesthetic and perioperative opioid consumption are definitely reduced.[15-17]

Role of US-guided ESPB for analgesia after breast surgeries has been explored by several researchers in recent years. Finneran *et al*. had used ESPB for providing pain relief after mastectomy in 3 cases out of which one injection was performed at T3 level with 20 ml ropivacaine, and in other 2 patients, it was made at T4 level using 15 ml ropivacaine.[18] Altıparmak *et al*. conducted a randomized controlled trial in 42 patients (21 in each group) using different concentrations of bupivacaine. Authors concluded that although both concentrations provided effective analgesia, the higher concentration injections provided better pain relief with lesser tramadol consumption.[15] They used 20 ml of 0.375% bupivacaine in one group and 20 ml of 0.25% bupivacaine in another group. In their study, the mean weight was 72.33 ± 8.64 and 75.00 ± 8.81. In our study, the mean weight was 57.46 ± 11.16 in ESPB group and 60.66 ± 11. 41 in the control group, which is less compared to that in Altıparmak *et al*.'s study. It is obvious that with a higher concentration of bupivacaine we would reach close to the toxic dose of bupivacaine (up to 3 mg/kg) as our mean age was less. Moreover, we used 30 ml LA for the block. Gürkan *et al*. conducted a randomized, single-blind study involving 42 patients divided into ESPB group and control group.[16] They found that 24 h morphine consumption was significantly less in ESPB group (5.76 ± 3.8 mg vs. 16.6 ± 6.92 mg). They performed a preoperative ESPB at T4 vertebral level

and used 20 ml of 0.25% bupivacaine. Our study might appear similar to that of Gürkan *et al.*, but there are certain important differences. We used 30 ml of 0.25% bupivacaine compared to 20 ml LA. We used T3 vertebral level instead of T4. The purpose of selecting T3 level was depending on clinico-radiological report presented by Forero *et al.* and our own experience of opioid-free mastectomy in 5 cases in which we performed ESPB at T3 level.[19,20] Forero *et al.* performed US-guided ESPB in patients with chronic shoulder pain using 20 ml of 0.5% bupivacaine at T2-T3 vertebral level. On examination, they found diminished pinprick sensation over neck and cape of the shoulder, which is supplied by the superficial cervical plexus, posterior and anterolateral thorax (T1-T5 dermatomes), and axilla. Nair *et al.* published a series of 5 cases in which mastectomy was performed using opioid-free anesthesia along with a preoperative ESPB at T3 vertebral level. Postoperatively, all our patients had unilateral T1-T6 dermatomal sensory block. In an attempt to cover maximum dermatomes and also nerves of superficial cervical plexus (supraclavicular nerve) and remain within toxic dose of bupivacaine, we selected T3 vertebral level as the point of injection and 30 ml LA. Finally, Gürkan *et al.*, used morphine patient-controlled analgesia and our patients received IV morphine directly.

Talawar *et al.* reported their experience with 10 patients who underwent different types of breast surgery and received a preoperative US-guided ESPB at T5 vertebral level using 20 ml of 0.375% ropivacaine. They found the block to be very effective except for sparing at infraclavicular area.[21] In our study, we did not check sensory or motor block after ESPB. Recently, Singh *et al.* randomized 40 patients into 2 groups: ESPB and control. Authors performed US-guided ESPB at T5 vertebral level using 20 ml of 0.5% bupivacaine in one group and no intervention in the control group.[17]Authors concluded that postoperative morphine consumption was significantly less in patients receiving US-guided ESPB compared to the control group and all the patients in the control group required morphine postoperatively compared to only two patients requiring that in US-guided ESP block.

Compared to previous studies, morphine consumption in patients enrolled in our study who received ESPB was less or negligible. We feel the reason for this could be injection point at T3 level and a volume of 30 ml. In previous studies, 20 ml of LA was used or injections were performed at T4/T5 levels. ESPB with 30 ml LA appears to block T1-T6 dermatomes along with supraclavicular nerve, which is a branch of superficial cervical plexus and axilla. This provides comprehensive analgesia after a mastectomy at rest and at movement thereby reducing postoperative opioid consumption.

There are several regional anesthesia techniques described to provide postoperative analgesia after mastectomy. TPVB has been described earlier in the discussion as it is the most extensively studied block with breast surgeries. Blanco *et al.* described PECS I and II blocks that are quite easy to perform and provide reasonable analgesia after breast surgery.[22,23] However, there are issues with this block like problems with using electrocautery intraoperatively and obliteration of surgical planes.[24] Moreover, pleura and pectoral vessels need to be identified carefully while performing the block. SAP covers only the axilla and pectoro-intercostal fascial block covers medial part of the breast only.[25,26] None of the above mentioned recently described blocks appear to provide comprehensive analgesia after mastectomy like ESPB.

There are certain limitations to our study. Being a single-blind study, there was no sham block performed in the control group. We agree with Sites *et al.* who considers interventional placebo injections in regional anesthesia as potential risk and no benefit to patients involved in a study.[27] Immediately, after the block was performed in ESPB group, general anesthesia was administered. Thus, we did not check the dermatomal block area in any patient.

Conclusion

US-guided ESPB is a safe and effective regional anesthesia technique for providing analgesia after breast surgeries. Further study needs to be performed to know the correct vertebral level of injection, optimal volume, and concentration of LA used for performing ESPB.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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