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Ultrasound-guided erector spinae plane block

for postoperative analgesia in modified radical

mastectomy: A randomised control study

#### ABSTRACT

Background and Aims: Several locoregional techniques have been described for providing postoperative analgesia after breast surgery. The optimal technique should be easy to perform, reproducible and provide good analgesia. This randomised control study was designed to evaluate the postoperative analgesic effect of ultrasound-guided erector spinae plane (US-guided ESP) block for modified radical mastectomy (MRM) surgery. Methods: A total of 40 females belonging to American Society of Anesthesiologists 1 or 2 posted for MRM were randomly allocated into Group 1 (control group) and group 2 (ESP group). Patients in Group 1 received only general anaesthesia (GA) and were managed for pain postoperatively according to routine protocol, while group 2 (ESP group) patients received unilateral US-guided ESP block preoperatively (20 mL 0.5% bupivacaine to the operating side) followed by GA. The primary objective of study was to record postoperative 24 h cumulative morphine requirement. Differences between the two groups were analyzed using the Mann–Whitney U-test or a two-tailed Student's t-test. Results: Postoperative morphine consumption was found to be significantly less in patients receiving US-guided ESP block compared to control group  $(1.95 \pm 2.01 \text{ mg required in ESP group vs } 9.3 \pm 2.36 \text{ mg})$ required in control group, P value = 0.01)). All the patients in control group required supplemental morphine postoperatively compared to only two patients requiring that in US-guided ESP block group (P < 0.01). Conclusion: US-guided ESP block when given prior to MRM surgery provided effective postoperative analgesia. CTRI registration no. - CTRI/2018/03/012712 registered in the clinical trial registry, India.

Key words: Analgesia, modified radical mastectomy, nerve block

## **INTRODUCTION**

Modified radical mastectomy (MRM) is one of the commonly performed breast surgery.<sup>[1]</sup> Postoperative pain following mastectomy should be minimised, as in a number of women it may chronically persist for months in the form of postmastectomy pain syndrome (PMPS).<sup>[2]</sup> Regional anaesthesia has a promising role in pain management after breast surgeries. Thoracic epidural,<sup>[3]</sup> interscalene brachial plexus block,<sup>[4]</sup> paravertebral block,<sup>[5,6]</sup> pectoral nerve I and pectoral nerve II blocks<sup>[7]</sup> have been used in different studies with good results. A newly described technically simple regional block, ultrasound-guided erector spinae plane (US-guided ESP) block can also be used effectively for this purpose.<sup>[8-10]</sup> In this block, local anaesthetic is deposited deep to the erector spinae muscle which results in blocking of the ventral and dorsal rami of multiple spinal nerves. This block can be given unilaterally for MRM surgery with anaesthesia similar to that of thoracic epidural block which is considered gold standard for postoperative pain management, but without its haemodynamic side effects.

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The purpose of the present randomised, double-blind study was to examine the effectiveness of US-guided ESP block in enhancing postoperative analgesia after breast cancer surgery. The primary outcome of this study was to measure cumulative morphine consumption for 24 h after surgery.

## **METHODS**

The protocol of this study was approved by Institutional Research Committee and prospectively registered in the Clinical Trial Registry, India (www.ctri.nic.in) with identification number CTRI/2018/03/012712. We conducted this study on 40 female patients between age group 20–55 years with American Society of Anesthesiologists' physical status I–II scheduled to undergo MRM. The study was conducted between April 2018 and September 2018 in our tertiary care center.

All patients underwent a preoperative assessment on the day before surgery and written informed consent was obtained for the participation in the study. They were premedicated with oral diazepam 0.1 mg kg<sup>-1</sup> at the night and 2 h before surgery. Patients were randomly allocated into groups by using computer generated random table. Randomisation was done by statistician and group of the patient was revealed only when the included patient was shifted to preanaesthetic room. Group 1 (control group) patients only received general anaesthesia. Group 2 patient received US-guided ESP block before general anaesthesia.

All the patients belonging to group 1 were straightaway shifted to operating room. Patients assigned to group 2 were shifted to the procedure room for the block. After securing intravenous cannula and routine monitors {electrocardiogram (ECG), oxygen saturation ((SpO<sub>a</sub>), noninvasive blood pressure (NIBP)}, an anaesthesiologist with an experience of more than 50 successful blocks performed the procedure. The patient was placed in sitting position. The spine was palpated from C7 downward to T5 and point was marked to identify the spinous process. After ensuring skin asepsis, we placed the high frequency (5-13 MHz) linear probe of ultrasound machine (Sonosite, Bothwell, USA) in a sterile sheath 3 cm lateral to the T5 spinous process. The three muscles from outward were recognised trapezius, rhomboidus major, and erector spinae muscle [Figure 1]. A 18-gauge Tuohy needle was inserted using an in-plane superior to inferior approach to place the tip into fascial plane

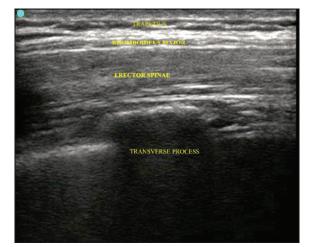


Figure 1: Ultrasound view of erector spinae plane

on the deep (anterior) aspect of erector spinae muscle. The location of the needle tip was confirmed by visible fluid spread below erector spinae muscle off the bony shadow of the transverse process [Figure 2]. A total 20 ml of 0.5% bupivacaine was injected through the needle. The patients were observed for 30 min after performing the block. The sensory level of block was assessed by a blinded observer with pin-prick sensation every 5 min in each dermatomal distribution from T1 to T8. The total number of dermatomes that had less pain to pin prick compared with opposite side was noted. If the pin-prick sensation did not decrease in any segment up to 30 min, it was considered as a block failure. The patient's ECG and SpO, were monitored continuously, and heart rate (HR) and NIBP were recorded at baseline, after performing the block, and every 5 min for 30 min. Any block-related complications, such as hypotension or vascular puncture, were recorded. Then, they were shifted to operating room.

Anaesthesia was induced with propofol 2–3 mg kg<sup>-1</sup> and morphine 0.1 mg kg<sup>-1</sup> in both the groups. Tracheal intubation was facilitated by vecuronium 0.1 mg kg<sup>-1</sup>. Anaesthesia was maintained by isoflurane (1-2%) and 66% nitrous oxide in oxygen. Patients were monitored using Datex-Ohmeda S5 Avance work station. Intraoperative monitoring included electrocardiogram (lead II and V5), noninvasive arterial pressure (at 5 min intervals), oxygen saturation, end-tidal carbon dioxide, and nasopharyngeal temperature.

The primary outcome of this study was defined as cumulative morphine consumption for 24 h after surgery. The secondary outcomes included to evaluate pain at rest, severity of postoperative nausea and vomiting, and patient satisfaction score. The patients were observed for 24 h after surgery in the postanaesthesia care unit (PACU) by an anaesthesiologist who was not aware of the patients' group assignment and was not present in operating room complex. Postoperative analgesia was provided with intravenous diclofenac 1.5 mg kg<sup>-1</sup> every 8 h. The pain score was evaluated by means of a numerical rating scale (NRS; 0, no pain; 10, the worst pain imaginable) at the time of arrival in PACU and then after 2, 4, 6, 12, and 24 h after operation. Rescue analgesia was given with intravenous morphine 3 mg boluses on demand or whenever NRS pain score was  $\geq 4$  in both the group. The number of patients requiring rescue analgesia and total morphine consumption during the first 24 h after operation was recorded. The incidence and severity of nausea was assessed by four-point categorical scale (0 = none, 1 = mild, 2 = moderate, 1 = moderate,and 3 = severe) at three points of time 30 min, 1 h and 24 h postoperatively. Intravenous metoclopramide 10 mg was given for severe nausea or vomiting. Any other adverse events like hypotension, bradycardia, dry mouth, dizziness, and diplopia were also recorded. Patients' satisfaction with the technique was assessed at 24 h after operation on an 11-point satisfaction score (0 = unsatisfied, 10 = most satisfied).<sup>[11]</sup>

Sample size was calculated based on a pilot study, which indicated that the mean  $\pm$  SD 24 h consumption of morphine following mastectomy under general anaesthesia was 12  $\pm$  8 mg. We considered that achieving a 50% reduction in morphine consumption 24 h in postoperative period in erector spinae group with a statistical power of 0.8 and a type 1 error rate of 0.05, a sample size calculation determined that

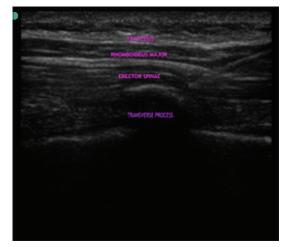


Figure 2: Needle localisation between erector spinae and transverse process

20 patients per group was required to demonstrate this difference using a two-tailed Student's *t*-test.<sup>[12]</sup> Sample sizes were calculated using StatMate 2 for Macintosh (GraphPad Software, San Diego, CA, USA). Differences between the two groups were analysed using the Mann–Whitney U-test (non-normally distributed continuous data and noncontinuous data) or a two-tailed Student's *t*-test (normally distributed continuous data). Normality of distribution was determined using the Shapiro–Wilk test. Categorical data were analysed using Fisher's exact test or the Chi-square test. A *P* value of <0.05 was considered statistically significant for all comparison between the groups.

## RESULTS

A total of 40 consecutive patients were randomised, and all patients placed in group 2 received their allocated intervention. No patients were excluded during the follow-up period; hence, 20 patients per group were included in the final analysis as seen in consort diagram [Figure 3]. The groups were comparable with respect to age, height, weight, ASA physical status, and the duration of surgery [Table 1].

The 24 h morphine consumption was less in Group 2 who received US-guided ESP block when compared with the control group and it was statistically significant (1.95  $\pm$  2.01 mg vs 9.3  $\pm$  2.36 mg, P = 0.01) [Table 2]. All the patients in group 1 (control group) required supplemental morphine, while only three patients in US-guided ESP block group required morphine [Table 2]. The difference in pain score was significantly high in group 1 [Table 3].

There was no significant difference between the groups with respect to HR,  $\text{SpO}_2$ , and mean arterial pressure during the perioperative period. In group 2 no block failure was observed. There were no complications related to the block, such as vascular puncture or local anaesthetic toxicity. In control group (group 1), five patients developed severe nausea and vomiting

Table 1: Patients characteristics and duration of surgery in   both the groups					
	Group 1 (GA group) <i>n</i> =20	Group 2 (ESP-block group) <i>n</i> =20	Ρ		
Age (yrs)	46 (29-63)	45 (25-65)	0.84		
Weight (kg)	56.6 (18-84)	55.4 (19-88)	0.87		
ASA class (I, II, III)	7/6/7	9/8/3			
Duration of surgery (min)	80 (35)	89 (56)	0.89		

Data are mean (range) (age and weight), mean (SD) (duration of surgery) or number of patients. ESP – Erector spinae plane

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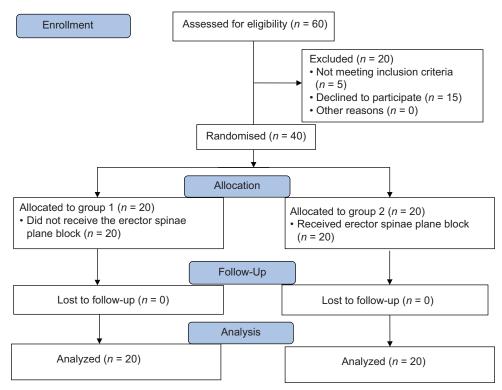


Figure 3: Consort Diagram

Table 2: Postoperative morphine requirement				
Group 1 (GA group) <i>n</i> =20	Group 2 (ESP-block group) n=20	Р		
9.3 (2.36)*	1.95 (2.01)	0.001		
20 (100)	2 (20)	<0.001		
	Group 1 (GA group) <i>n</i> =20 9.3 (2.36)*	Group 1 (GA group) n=20 Group 2 (ESP-block group) n=20   9.3 (2.36)* 1.95 (2.01)		

Mean (SD) and number (%); ESP - Erector spinae plane

Table 3: Postoperative pain scores (Numerical rating scale score)					
Time periods (h)	Numerical rating scale score	Score	Р		
	Group 1 (GA group) <i>n</i> =20	Group 2 (ESP-block group) <i>n</i> =20			
0	6 (5-7)	2 (1-3)	0.001		
2	4 (3-5)	2 (1-3)	0.00		
4	5 (4-6)	3 (2-4)	0.042		
6	4 (35)	3 (2-4)	0.08		
8	4 (3-5)	5 (3-7)	0.09		
10	6 (4-8)	2 (1-3)	0.14		
12	3 (2-4)	3 (2-4)	0.78		
24	2 (1-3)	2 (1-3)	0.87		

Data are expressed as the median (interquartile range).  $\ensuremath{\mathsf{ESP}}\xspace - \ensuremath{\mathsf{Erector}}\xspace$  plane.

and required parenteral metoclopramide at 24 h time period. None of the patient in ESP group developed nausea and vomiting requiring medication.

Patients in group 2 who received US-guided ESP block were more satisfied than control group (satisfaction score, median (interquartile range IQR), 8.00 (0), 6.00 (1) for Groups 1 and 2, P < 0.001).

## DISCUSSION

In this prospective, randomised study US-guided ESP block was given preoperatively to female patients for MRM surgery. The result was a significant decrease in requirement of postoperative morphine in patients who received erector spinae plane block. Patient satisfaction score was better in ESP group without complication of postoperative nausea and vomiting requiring medications.

We have used a relatively new block in our study US-guided ESP block,<sup>[8-10]</sup> which can be given unilaterally to the concerned side, is less invasive, and is having all the benefits of thoracic epidural anaesthesia. A recent randomised control trial done by Gürkan *et al.* on analgesic effect of single shot US-guided ESP for breast surgery showed a similar effect like our study.<sup>[12]</sup> They observed a decrease in postoperative morphine consumption by 65% which was statistically significant, thus establishing its role for analgesia and postoperative opioid sparing effect. Nair *et al.* published efficacy of this block in a similar surgery on a case series of five

patients.<sup>[13]</sup> They also had a very encouraging result of no requirement of opioid in any of their patient for rescue postoperative analgesia. Most of case reports/ series has used this block for perioperative analgesia but Kimachi et al. used US-guided ESP for complete surgical anaesthesia for a right-sided mastectomy and axillary dissection in a patients with high cardiovascular risk.<sup>[14]</sup> They not only accomplished complete surgical anaesthesia but also requirement of postoperative analgesia was minimal. Compared with the epidural zone, the erector spinae plane is not a limited area surrounded by the spinal column. Local anaesthetic instilled in the myofascial plane deep to the erector spinae muscle and superficial to the tip of the transverse process is likely to provide sensory block at multidermatomal levels across the posterior, lateral, and anterior thoracic wall. The analgesic effect seems to be due to the diffusion of LA into the paravertebral space, acting at both the dorsal and ventral rami of the thoracic spinal nerves, in addition to its effect at the rami communicans that supply the sympathetic chain. The ESP plane is larger than the epidural space as the erector spinae muscle runs along the length of the thoracolumbar spine, thus providing extensive craniocaudal spread.<sup>[15]</sup> The ESP-block has a clear and simple sonoanatomy, it is easy to perform, not time-consuming, and generally well tolerated by the patients. The major limitation of our study was that patients knew they were receiving some intervention to decrease their pain, thus increasing the chance of bias.

## CONCLUSION

In conclusion, the ultrasound-guided ESP block appears to be an effective block for postoperative analgesia in breast cancer surgery. It decreases postoperative morphine requirement.

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## **Conflicts of interest**

There are no conflicts of interest.

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