The comparison of the efficacy of ultrasound-guided paravertebral block versus erector spinae plane block for postoperative analgesia in modified radical mastectomy: A randomized controlled trial

ABSTRACT

Introduction: The ultrasound (US)-guided erector spinae plane (ESP) block is a new regional anesthetic technique that offers significant advantages over paravertebral block as it is easy and safe to perform. We aim to compare the efficacy of US-guided paravertebral block with ESP block for postoperative analgesia in modified radical mastectomy (MRM).

Methods: Eighty female patients of age group 18–70 years, belonging to physical status American Society of Anesthesiologists (ASA) I and II, undergoing MRM were included in the study. In Group P, patients received paravertebral block and in Group E, patients received ESP block before induction of general anesthesia. Both the groups received 0.5% 20 mL ropivacaine. The time to first rescue analgesia and total doses of rescue analgesics were recorded in the postoperative period. Numeric Rating Scale (NRS) scores at 0 min, 30 min, 1 h, 2 h, 6 h, 12 h, and 24 h were noted, and patient satisfaction was evaluated at 24 h. Unpaired t-test or the Mann–Whitney U test was used to compare quantitative variables while Chi-square test or Fisher’s exact test was used to compare qualitative variables.

Results: The time for the first analgesic request was 232.5 min (140-1200) in ESP group as compared to paravertebral group in which the duration was 205 min (135-1190) (P value = 0.29). The total dose of rescue analgesics and NRS scores in postoperative period were comparable. However, the time to perform ESP block was significantly shorter than that of paravertebral block.

Conclusion: ESP block can be used as a safe and easy to perform alternative analgesic technique over paravertebral block in breast cancer surgeries.

Key words: Erector spinae plane block; modified radical mastectomy; paravertebral block

Introduction

As per the Global Cancer Observatory (GLOBOCON) 2018, the most reported malignancy worldwide in females is breast cancer. Surgery along with chemotherapy and radiotherapy is the curative form of treatment available.
Owing to the complex innervation of the breast, there is always a risk for the development of chronic pain if acute postoperative pain is not managed adequately. These conditions include paraesthesia, intercostobrachial neuralgia, and phantom breast pain. The overall incidence of these chronic clinical conditions ranges from 20% to 50% after breast surgery.\(^2\)

Although various regional analgesia techniques have been described for breast surgery, the understanding of the anatomy of the breast and the structures that are altered in various types of breast surgeries is incomplete and evidence in favor of these novel techniques is lacking.\(^3\)

The paravertebral block has been used for analgesia and primary anesthesia method for breast surgery for many years and is considered to be the gold standard.\(^4\) However, previous studies have reported complications such as epidural or intrathecal spread, pleural puncture, pneumothorax, vessel injury, and nerve damage.

The erector spinae plane (ESP) block is a new technique of regional anesthesia, which when performed at the transverse process of the T5 vertebra provides thoracic analgesia. ESP block acts probably by diffusion of local anesthetic into the paravertebral space. The advantages of ESP block are its ease of performance and safety. Owing to its superficial location, away from vessels and nerves, the complications associated with paravertebral block can be avoided.\(^5\)

There are very few randomized controlled trials in breast surgery, which compare paravertebral block with ESP block. The purpose of this randomized controlled trial was to compare the efficacy of ultrasound-guided paravertebral block with ESP block for postoperative analgesia in modified radical mastectomy (MRM).

**Methods**

This prospective, randomized, double-blinded, clinical trial was conducted after approval by the Institutional Ethics Committee and was registered in the Clinical Trial Registry, India (www.ctri.nic.in) prospectively with identification number CTRI/2018/04/012915. After obtaining written informed consent, 80 female patients in the age group ranging 18–70 years, belonging to physical status American Society of Anesthesiologists (ASA) I and II, who underwent modified radical mastectomy between April 2018 and May 2019 were included. Patients with body mass index (BMI) >35 kg/m\(^2\), infection at the site of injection, coagulopathy, spine deformity, history of opioid dependence, history of allergy to opioids, or local anesthetics were excluded.

All patients visited one day before the surgery and routine preoperative assessment was performed. They were explained about the study protocol and the potential benefits and side effects of both paravertebral and ESP block techniques. All patients were explained about the Numeric Rating Scale (NRS) ranging from 0 that corresponds to no pain to 10 that corresponds to worst pain. The patients were kept fasting 8 hours before the surgery, and tablet ranitidine in a dose of 150 mg was given in the night before surgery and in the morning of surgery as per the hospital protocol.

The allocation of the patients into two groups was done randomly using computer-generated random numbers. A sealed opaque envelope concealing the group allocation number was opened after enrollment of the patients. In Group P, patients received paravertebral block with general anesthesia and in Group E, patients received ESP block along with general anesthesia. Twenty mL of 0.5% ropivacaine was used in both the groups. The blocks were performed in the preoperative room 30 min before surgery with a 22-G 10 cm (100) mm stimuplex needle using an ultrasound machine (Sonosite Edge II) and a linear array probe (7–12 MHz frequency) by an anesthesiologist experienced in performing at least 20 successful blocks, who did not assess the patient in the preoperative and postoperative period, and who had no role in intraoperative management and data collection. The time to perform the blocks and the number of attempts were noted.

Paravertebral block was given in sitting position with the arms of the patient extended. Local infiltration with 2.0 mL of 2% lignocaine using a 24-G hypodermic needle at the site of puncture was done. The ultrasound probe was placed in the craniocaudal direction at the level of T4 interspinous space, about 5 cm from the midline, and the transverse process and parietal pleura were identified by moving the probe medially. The superior costotransverse ligament was identified as echogenic homogeneous bands extending between the transverse processes. US-guided paravertebral space was identified, and a needle was passed through the superior costotransverse ligament, and the confirmation of the correct placement of needle was done by deflection of the pleura downwards on injecting 3 mL of saline [Figure 1].

ESP block was given in sitting position with the arms of the patient extended. Local infiltration with 2.0 mL of 2% lignocaine using a 24 G-hypodermic needle at the site of puncture was done. The ultrasound probe was placed 3-cm...
lateral to the midline at the level of T5 interspinous space and transverse process and three muscles were identified: trapezius, rhomboid major, and erector spinae. A 10-cm needle was inserted craniocaudally in-plane, to reach the transverse process. After hydrodissecting the plane with 3 mL of normal saline, 20 mL of 0.5% ropivacaine was deposited, and thus erector spinae muscle was lifted off the transverse process [Figure 2].

The patients were kept in observation for 30 min after giving the block. A blinded observer assessed the sensory level of the block every 5 min with pin-prick sensation from T1 to T9 dermatomes. If up to 30 min, there was no decrease in pinprick sensation in any segment, then it was considered as a block failure (at least two segments should have decreased sensation to be considered as block success). The patient’s heart rate (HR), noninvasive blood pressure (NIBP), and oxygen saturation (SpO₂) were monitored continuously and recorded at baseline and every 5 min after giving the block till the patient was in the preoperative area. Any complications due to block such as hypotension, bradycardia, vessel injury, pneumothorax, and Horner’s syndrome were noted.

All patients received general anesthesia in a standardized manner by the anesthesiologist who was blinded to the group allotment. IV dexamethasone 8 mg was given before induction of anesthesia. General anesthesia was induced with 2 µg/kg fentanyl, 1–2 mg/kg propofol, and 0.6 mg/kg rocuronium. Three minutes later, supraglottic device (I-gel) was placed. Anesthesia was maintained with 50% air and oxygen and desflurane (0.8–1 MAC). The heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), oxygen saturation (SpO₂), and end-tidal carbon dioxide (ETCO₂) were recorded every 5 min till 30 min after induction and then every 10 min till the completion of surgery. If systolic BP or HR exceeded 20% of baseline values, fentanyl 0.5 µg/kg bolus was given. Total intraoperative fentanyl consumption was recorded. Hypotension (SBP <20% of baseline) was treated with boluses of fluid, and if required mephentermine in dose of 3–6 mg was given. Bradycardia (HR <40 beats min or <20% of baseline) was managed with 0.6 mg atropine. Antiemetic prophylaxis with 0.1 mg/kg ondansetron was given to all patients towards the end of surgery. Paracetamol 1 gm was given 30 min before the end of surgery. Neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg were given for reversal of the neuromuscular block, supraglottic device was removed once the patient gained full consciousness and was spontaneously breathing.

The primary objective of the study was to measure the duration of postoperative analgesia (that is, time to first analgesic request from the time of giving block). The secondary objectives were to measure the total rescue analgesic requirement in the postoperative period and to evaluate patient satisfaction in the postoperative period.

All patients were monitored in the postoperative period for pain by the NRS score at rest and ipsilateral arm abduction at 90 degrees at immediate postoperative (0 min), 30 min, 1, 2, 6,12, and 24 hours. The assessment was done by an independent anesthesiologist who had no role in giving the block or intraoperative management of the patient. All patients received paracetamol 20 mg/kg (rounding off to 500 mg or 1 gm) 6 hourly in the postoperative period. However, if the patient had pain in between, he/she was asked to inform the nursing staff around who further informed the attending anesthesiologist. If NRS >4 at any time, then rescue analgesic diclofenac (1.5 mg/kg) rounded off to the nearest 50 mg or 75 mg was given. The time to first rescue analgesia
(from the time of giving the block) was noted. The pain was reassessed after 30 minutes of giving the first rescue if still NRS > 4 then tramadol (1 mg/kg) was given as the second rescue. After half an hour of the second rescue analgesia, if the patient still had NRS > 4, additional tramadol was given to a maximum of 100 mg in 6 hours or a total of 400 mg in 24 hours. The total dose of rescue analgesics required in 24 hours was recorded.

Side effects of opioids such as nausea, vomiting, respiratory depression, and itching were noted. Postoperative nausea and vomiting (PONV) were assessed using a 4-point numerical scale (0 = no PONV, 1 = mild nausea, 2 = severe nausea or vomiting once, and 3 = vomiting more than once). If the score was 2 or more, then ondansetron 0.1 mg/kg was given as rescue antiemetic. Patient satisfaction was evaluated and recorded at 24 hours after surgery on a 7-point Likert scale. (1- Extremely dissatisfied, 2- Very dissatisfied, 3- Dissatisfied, 4- Neither satisfied nor dissatisfied, 5- Satisfied, 6- Very satisfied, 7- Extremely satisfied).

The sample size was calculated based on a study by Kapil Gupta et al[6] in which they have reported the meantime for the first rescue analgesic 346 +/- 54 min approximately for the paravertebral block in MRM. We considered 30 min as the equivalence margin for our clinical trial with a 5% level of significance and 80% power, the required sample size for each group was 40, so the total sample size for our study was 80.

The statistical analysis was performed using STATA 14 (Statoscope, Lakeway Drive, College Station, Texas, USA) software. Shapiro–Wilk test was used for determining the normality of distribution. Quantitative data were expressed as mean ± standard deviation and median (minimum-maximum) and qualitative data as counts (percentages). Mann–Whitney U-test was used for non-normally distributed variables such as duration of block and NRS scores, while demographics, duration of surgery, time to perform blocks, the total dose of rescue analgesics, patient satisfaction score, and hemodynamics (normally distributed variables) were compared using two-tailed Student’s t-test. Fisher’s exact test or the Chi-square test was used for the analysis of categorical data. A P value of <0.05 was considered statistically significant for all comparison between the groups.

Results

Ninety patients were analyzed initially for eligibility but ten patients were excluded as six of them did not fulfill the inclusion criteria, and four patients were not willing to participate. Thus, eighty patients were randomized into two groups and analyzed. No patient was excluded from the final analysis. The consolidated standards of reporting trials (CONSORT) flow diagram for this study is shown in [Figure 3]. The groups were comparable in terms of demographic characteristics and duration of surgery [Table 1]. The time required to perform ESP block (8.92 ± 3.40) was significantly shorter as compared to paravertebral block (10.92 ± 3.61) (P < 0.05). In ESP group, the block was performed successfully in the first attempt in 28 (70%) cases as compared to 19 (47.5%) cases in the paravertebral group.

The difference in the duration of analgesia was nonsignificant among the groups. The duration of analgesia (time to first analgesic request) was 232.5 min (140-1200) in ESP group as compared with paravertebral group in which the duration was 205 min (135-1190) P value = 0.29. [Figure 4]

Intraoperative fentanyl consumption and the dose of rescue analgesics required in the 24-hour postoperative period were comparable [Table 2]. Twenty-four patients in ESP group required the first rescue analgesia (diclofenac) while 20 patients required it in paravertebral group (P = 0.5), whereas the second rescue analgesia (tramadol) was given in 4 patients, and the mean dose of tramadol required was 50 mg in both the groups.

The difference was insignificant in NRS at rest and NRS at movement at 0, 30 min, 1, 2, 6, 12, and 24 hours between both the groups [Figure 5].

Table 1: Demographic profile of patients and duration of surgery

| Parameters                  | Group E (n=40) | Group P (n=40) | P   |
|-----------------------------|----------------|----------------|-----|
| Age (years)                 | 48±11.89       | 51.32±10.12    | 0.18|
| Height (cm)                 | 151.0±7.72     | 152.8±4.18     | 0.21|
| Weight (kg)                 | 61.3±10.92     | 62.0±7.77      | 0.72|
| BMI                         | 27.41±4.25     | 26.93±3.23     | 0.57|
| ASA (1-2)                   | 25/15          | 24/16          | 1.00|
| Duration of Surgery (min)   | 120.87±27.50   | 113±24.30      | 0.17|
| *BMI (Body Mass Index), ASA (American Society of Anesthesiology) Data is expressed as Mean±SD |

Table 2: Duration of analgesia, intraoperative fentanyl consumption, and a dose of rescue analgesics

| Parameters                  | Group E (n=40) | Group P (n=40) | P   |
|-----------------------------|----------------|----------------|-----|
| Duration of analgesia (min) | 323.5 (140-1200) | 205 (135-1190) | 0.29|
| Intraoperative Fentanyl (µg)| 35±16.83       | 36.6±12.58     | 0.89|
| Total dose of Diclofenac (mg)| 87.5±28.5     | 91.66±32.08    | 0.65|

Duration of analgesia is expressed as median (minimum-maximum). Intraoperative Fentanyl consumption and total dose of diclofenac is expressed as mean±SD.
There was no difference in patient satisfaction between ESP group (5.5 ± 0.90) and paravertebral group (5.7 ± 0.99) $P = 0.4$.

The hemodynamics were comparable in both the groups. However, three patients developed hypotension in paravertebral group as compared with ESP group where one patient developed hypotension requiring fluid boluses and mephenteramine. None of the patients in any group had technique-related complications such as pneumothorax, vascular puncture, Horner’s syndrome, and local anesthetic toxicity. Two patients in ESP group had nausea and vomiting requiring ondansetron while three patients in paravertebral group had nausea and vomiting. None of the patients had side effects such as pruritus and respiratory depression.

**Discussion**

This randomized controlled trial compared the efficacy of US-guided paravertebral block with ESP block in MRM and showed that both the blocks were equally effective with respect to duration of analgesia. The dose of rescue analgesics required in the postoperative period, postoperative pain scores, and patient satisfaction scores were comparable in both the groups. However, ESP block was technically easy to perform and it took a shorter time to perform the block. No block related complications were reported in any of the groups.
Thoracic PVB is a well-established technique for postmastectomy pain.[7,9] Because of the risks associated with performing this block, anesthesiologists sometimes feel uncomfortable using this block. Besides, it needs more technical skills and has a longer learning curve.[10] Lonnqvist et al. reported the frequency of complications in paravertebral block: hypotension in 4.6% cases, 3.8% had a vascular puncture, 1.1% had a pleural puncture, and pneumothorax was reported in 0.5%. [11] Clinicians found many interfascial blocks such as serratus anterior plane block (SAP), pectoralis nerve block (PECS), and ESP block while they were searching for a safer technique to paravertebral block.

ESP block is a recently found new regional block, which offers an advantage as it is simple and safe to perform.

In our study, the time to first rescue analgesia was found to be 232.5 (140–1200) min in ESP group as compared with paravertebral group where it was found to be 205 (135–1190) min (P = 0.29). Similar results showing the comparable duration of analgesia in both the groups were found in other studies. Ghamry M R E et al. also found that time to first rescue analgesia was comparable in paravertebral group (6.35 ± 0.42 hour) and ESP group (6.5 ± 0.60 hour), P = 0.075.[12] Moustafa et al. also reported that the difference was statistically insignificant for the duration of analgesia in ESP and paravertebral groups when compared in breast surgeries. The time to first rescue analgesia was 11.04 ± 1.09 hours in ESP group and 11.22 ± 1.95 hours in paravertebral group. (P = 0.66).[13] This wide variation in the duration of the blocks may be explained by the use of varying concentration, volume, and type of local anesthetic used. The comparable duration of analgesia may be due to the mechanism of action by which ESP block acts. The ESP block is considered to be periparavertebral regional anesthesia technique. The local anesthetic is given within the erector sheath; the local anesthetic then moves craniocaudally along the sheath and through gaps in the sheath gains access to the paravertebral space.[14]

We found that the total dose of rescue analgesics required in postoperative period was comparable in both the groups. In previous studies also, the postoperative opioid consumption showed no significant difference between the two groups. Ghamry M R E et al. found that the total postoperative morphine consumption was 27.3 ± 2.9 mg in paravertebral group while 26.7 ± 2.1 mg in ESP group (P = 0.32).[12] Gurkan et al. found in their study comparing ESP block and paravertebral block to IV morphine in breast surgeries that the morphine requirement at 24 hours postoperatively was 5.6 ± 3.43 mg in the ESP group and 5.64 ± 4.15 mg in the paravertebral group (P > 0.05).[15]

The difference in postoperative NRS scores at rest and movement was nonsignificant in both the groups at 0, 0.5, 1, 2, 6, 12, and 24 hours in our study. Similar findings were seen in previous studies where NRS scores were found to be comparable in both the groups.[12,13,15-17]

In our study, the time to perform ESP block (8.92 ± 3.40 min.) was significantly shorter than in paravertebral group (10.92 ± 3.61 min.) (P < 0.05). Wittayapairoj A et al. also found similar results to our study. The scanning time (38 vs 200 sec, P = 0.005) and block performing time (220 vs. 457 s, P = 0.003) were significantly shorter in ESP block as compared to paravertebral block in breast surgery.[16] Moustafa et al. also found that the time to perform the ESP block was less (4.39 ± 1.2 min) as compared to the paravertebral group (8.18 ± 2.42 min) (P < 0.0001). Success rate among residents was 100% in ESP group versus 77.8% in paravertebral group (P = 0.002).[13] US-guided paravertebral block is a regional anesthetic technique where special skills need to be developed for manipulation of the needle towards the paravertebral space. El-Boghdally stated that a good amount of training is required for thoracic paravertebral block as it is a very challenging technique.[18]

There was no significant difference in patient satisfaction scores in both these groups. Singh S et al. showed that patient satisfaction was better in ESP group as compared to control group.[19] The groups were comparable with regards to hemodynamics, and the incidence of hypotension was low in both the groups. These findings were similar to previous studies.[20,21] No technique-related complications were noted in any of the groups. Various studies done previously also showed no block-related complications in both these groups.[22,23] This can be attributed to an US-guided technique, which is associated with very few complications.

The incidence of nausea and vomiting was less in both the groups. It can be due to the less use of opioids in the postoperative period and prophylactic administration of dexamethasone in both the groups.

One of the strengths of our study is the use of a fixed volume and concentration of the drug in both the blocks. Hence, our study has done a fair comparison between the groups. We performed both the blocks before induction of anesthesia.
so we had assessed the dermatomal level and could identify any block failure.

The limitations of the study were that we did not follow the patients for long-term to observe the effect of these blocks on the reduction of chronic postmastectomy pain. Secondly, we did not insert a catheter to avoid complications such as epidural migration or pleural puncture in paravertebral group and avoid discomfort for the patient. Lastly, we did not use patient controlled analgesia (PCA) pump, which could help standardize the administration of analgesics in the postoperative period.

Conclusion

ESP block and paravertebral block are comparable for postoperative analgesia in MRM, but ESP block can be used as a safe and easy to perform alternative analgesic technique over paravertebral block in breast cancer surgeries.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patients have given their consent for their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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