A Comparative Study between Erector Spinae Plane Block with General Anesthesia versus Conventional Intravenous Analgesics with General Anesthesia in Patients undergoing Conserving Surgery for Breast Cancer

Islam Abd Elfadel, Gamal Fouad, Ashraf Hazem, Ahmed Abd Elrahman and Mohamed Saleh

Anesthesia, Intensive Care and Pain Management, Faculty of Medicine, Ain Shams University, Cairo 11591, Egypt

ABSTRACT

Background: Acute pain is a common concern after breast surgery, and despite the conventional management of pain with different analgesics, many patients have poor responses. Paravertebral, epidural, pectoral and serratus plane blocks are the regional blocks, which are used commonly to control pain after breast surgeries. Each of these techniques has its advantages and disadvantages. Erector spinae plane block (ESPB) is a new regional approach which can provide analgesia to the chest wall, by which local anesthetic drugs can be deposited in the plane between erector spinae muscle and the transverse process producing hemithoracic analgesia. This study was intended to assess the efficacy of ESPB for postoperative analgesia after breast surgeries.

Results: Fifty-four patients were enrolled in this study and divided into two groups, 27 patients in each group. Group B patients received general anesthesia with ESPB and group C patients received general anesthesia with conventional intravenous analgesia. Group B showed statistically significant reduction in total opioid consumption at 24 hours postoperatively, lower VAS score and improved hemodynamic parameters in the first 8 hours postoperatively.

Conclusions: Ultrasound-guided ESPB performed at the level of T5 was found to be effective and safe in controlling postoperative pain after breast surgery.

1. Background

The demand for effective pain control is growing, as pain is considered a crucial vital sign and even can be considered as the fifth vital sign and has been linked to healthcare quality control [1].

Failure to control acute pain postoperatively following breast surgeries can lead to persistent chronic pain that can last for years [2].

It is estimated that females undergoing breast surgeries have an incidence of chronic postoperative pain ranging from 25% to 60% using pain scores as a main indicator [3].

The ideal nerve block technique to control pain postoperatively should be simple to perform, consistent and provide proper analgesia [4].

The availability of ultrasound leads to the widespread use of fascial or myofascial blocks. ESPB was first reported in 2016 and has been used for analgesia of the dorsal and ventral rami of thoracic and lumbosacral nerves [3].

Fero et al. described a simple and safe approach of ESPB with an effect equivalent to that of paravertebral and retrolaminar blocks [5].

To supply complete analgesia postoperatively for patients undergoing breast surgeries, it is essential to ideally block the dermatomes of the spinal nerves from C5 to T6. Many techniques have been used widely to control pain after breast surgeries as paravertebral block, epidural block, and intercostal block. Although no optimal method has been defined yet, each one of these techniques has some flaws. Epidural block can lead to unwanted block to the opposite side, epidural abscess, epidural haematoma and accidental dural puncture. Paravertebral block can result in an ideal analgesia, but it has drawback that it can be complicated by pneumothorax and it may be difficult to perform. The intercostal nerve block is simple to apply, but it requires to be performed in several segments [67].

ESPB is simple to perform and has an end-point which can be well defined using ultrasound by injecting local anesthetics in the plane between the transverse process and the erector spinae muscle. Thus, it can be done simply in awake patients or patient under general anesthesia, and due to the fact that it is a more superficial block, there is less risk of complications as
pneumothorax when compared to paravertebral block and less risk of neuraxial injury and hemodynamic instability when compared to neuraxial blocks [3].

The aim of this study was to evaluate the efficacy of ESPB for postoperative analgesia and opioid sparing in females undergoing conserving surgery for breast cancer under general anesthesia.

1.1. Patients and methods

This study was registered in Pan African Clinical Trials Registry (PACTR) with trial number: PACTR2020107535738159. After receiving approval (FMASU M D 237/2020) from the Research Ethical Committee of the Faculty of Medicine, Ain Shams University, this interventional randomized clinical trial was conducted at Ain Shams University Hospital. Informed written consent was taken from each participant in this study.

Inclusion Criteria: Female patients scheduled for breast conserving surgery aged ≤65 years and with ASA physical status II to III were recruited in the study.

Exclusion Criteria: Patients with major spine deformities, patients with bleeding disorders or coagulopathy, patients who had infection at the injection site, patients who had allergy to local anesthetics, patients with pre-existing myopathy or neuropathy and patients with significant cognitive dysfunction were excluded from the study.

1.2. Sample size calculation

Assuming an effect size for visual analogue scale (VAS) of 1.0, a sample of 27 patients in each group would be enough to detect such effect at 0.05 alpha error and 0.95 power of the study [6].

Patients were randomized into two equal groups using computer generated random numbers:

Group B: Patients received ultrasound-guided ESPB with 0.25% bupivacaine with general anesthesia.

Group C: Patients received conventional multimodal intravenous analgesia with general anesthesia.

All patients underwent preoperative assessment including history taking, examination and preoperative investigations. Patients followed routine preoperative fasting guidelines. After admission to the operating room, IV cannula was inserted in the arm opposite to the surgical site and monitors were attached, including pulse oximetry, 5-lead electrocardiogram and non-invasive arterial blood pressure. Side stream capnography was attached after induction of general anesthesia.

In Group B: ESPB was done in the operating room before general anesthesia using complete aseptic technique under conscious sedation with titration of midazolam and supplemental oxygen was given through nasal prongs.

SonoSite M-Turbo C® Ultrasound device with Linear probe was used in imaging of the patients. The ultrasound probe was placed on the paravertebral region in a Sagittal plane about 3 cm lateral to the T5 spinous process on the operating side to locate erector spine muscle, rhomboid major and trapezius from inward (To reach T5, we used C7 as an anatomical landmark, which is the most prominent vertebrae in the back and count downwards to reach T5. To locate C7, we used palpation or ultrasound guidance if there was difficulty in palpation). Following visualization of these muscles and the transverse process of T5, the skin was infiltrated with 5 ml of 2% lidocaine, and then bupivacaine 0.25% in a dose of 1 mg/kg was injected in the plane between the erector spinae muscle and transverse process using a 22-G 10-cm nerve block needle (Figure 1).

After confirmed negative intravascular aspiration, the drug was injected and spread of the drug solution was seen in tissue planes using ultrasound imaging.

![Figure 1. Ultrasound image showing anatomy and point of injection of ESPB.](image-url)
After injection, ESPB was assessed by perception of cold sensation and after the establishment of sensory block, general anesthesia (GA) was induced using propofol 1.5–2 mg/kg, atracurium 0.5 mg/kg, and fentanyl 1 μg/kg. Anesthesia was maintained using isoflurane with a target end tidal concentration of 0.8–1.2%.

In Group C: Patients in this group received GA and conventional multimodal intravenous analgesia using morphine 5 mg, paracetamol 1 gm, and diclofenac 75 mg given after induction of anesthesia.

Induction of anesthesia was done using propofol 1.5–2 mg/kg, atracurium 0.5 mg/kg, and fentanyl 1 μg/kg. Anesthesia was maintained using isoflurane with target end tidal concentration 0.8–1.2%.

Postoperative pain in both groups was assessed by using VAS score, and a score of more than 3 was managed by injection of 3 mg of morphine intravenously as a rescue analgesic.

Patients in both groups received preoperative training on how to use VAS score for postoperative pain assessment.

Patients were followed up for any complications either related to the procedure or related to the drugs injected. Data were recorded every 8 hours for the first 24 hours postoperatively.

1.3. Measured outcomes

Primary outcome was postoperative pain assessment using VAS score.

Secondary outcomes was the total amount of opioid consumption in the first 24 hours postoperatively. Time to ask for the first dose of rescue analgesia, hemodynamic parameters (MAP, HR) and complications.

The end point of the study was 24 hours postoperatively.

2. Results

Sixty five patients were enrolled in the study. Four patients fulfilled the inclusion criteria but refused to participate, three patients were excluded, one patient had a history of allergy to local anesthetic drugs, two patients had spine abnormalities and another four patients were excluded due to block failure (Figure 2).

2.1. Demographics

Fifty-four patients were finally enrolled in the study, 27 patients in each group. Groups were comparable in demographic data as demonstrated (Table 1).

![Figure 2. CONSORT diagram.](image-url)
Table 1. Comparison between groups as regards demographic data and duration of surgery.

| Demographic data                  | Group B (n = 27) | Group C (n = 27) | p-Value |
|-----------------------------------|------------------|------------------|---------|
| Age (years)                       | 49.8 ± 11.3      | 51.6 ± 11.3      | 0.55    |
| Weight (Kg)                       | 80.1 ± 7.6       | 76.6 ± 6.5       | 0.07    |
| ASA                               | II 19 (70.4%)    | 16 (59.3%)       | 0.4     |
|                                  | III 8 (29.6%)    | 11 (40.7%)       |         |
| Duration of surgery (minutes)     | 56.3 ± 15.2      | 57.6 ± 11.5      | 0.7     |

2.2. Hemodynamics

Both groups were compared as regards mean arterial blood pressure (MAP) at regular intervals preoperative base line, at 8 hours, 16 hours and 24 hours postoperatively.

At 8 hours, MAP showed a statistically significant decrease in group B.

At baseline, 16 and 24 hours, MAP showed no statistically significant difference between both groups (Table 2) (Figure 3).

Both groups were compared as regards heart rate (HR).

At 8 hours, HR showed statistically significant decrease in group B.

At baseline, 16 and 24 hours, HR showed no statistically significant difference between both groups (Table 3) (Figure 4).

Table 2. Comparison between groups as regards MAP.

| MAP (mmHg) | Group B | Group C | p-Value |
|------------|---------|---------|---------|
| Baseline   | 79.6 ± 5.2 | 81.9 ± 6.7 | 0.15 |
| 8 hours    | 76.9 ± 5.7 | 86.1 ± 5.9 | <0.001* |
| 16 hours   | 84.7 ± 5.7 | 86.5 ± 3.9 | 0.17 |
| 24 hours   | 85.1 ± 4  | 87.7 ± 5.6 | 0.06 |

*p-Value <0.001

Table 3. Difference in HR between both groups.

| HR (beat/min) | Group B (n = 27) | Group C (n = 27) | p-Value |
|---------------|------------------|------------------|---------|
| Baseline      | 81.3 ± 9.9       | 79.3 ± 8.4       | 0.4     |
| 8 hours       | 76 ± 9.9         | 83.7 ± 6.98      | 0.002*  |
| 16 hours      | 84.7 ± 5.7       | 86.5 ± 3.9       | 0.17    |
| 24 hours      | 87.3 ± 4.7       | 89.4 ± 5.3       | 0.14    |

*p-Value 0.002

Figure 3. Bar graph demonstrating changes in MAP in both groups.

Figure 4. Bar graph demonstrating changes in HR in both groups.

2.3. Pain control

Both groups were compared as regards postoperative pain control using VAS score and total opioid consumption at regular intervals preoperative base line, at 8 hours, 16 hours and 24 hours post-operative.

At 8 hours group B showed statistically significant decrease in VAS score <0.001. At baseline, 16 and 24 hours both groups showed no statistically significant difference in VAS score (Table 4) (Figure 5).

As regards 24 hours total opioid consumption, group B showed a statistically significant decrease in total morphine intake as compared to group C at the end of the first 24 hours postoperatively <0.001 (Figure 6) (Table 5). Also, there was a statistically significant difference between both groups in time to ask for the first dose of rescue analgesia post-operatively being more prolonged in group B <0.001 (Table 5) (Figure 7).

2.4. Postoperative nausea and vomiting (PONV)

Although more cases in group C complained of PONV, there was no statistically significant difference between both groups (Table 6).

2.5. Statistical analysis

The Statistical Package for Social Science (SPSS) version

Table 4. Comparison between groups as regards VAS score.

| VAS (0–10 CM) | Group B (n = 27) | Group C (n = 27) | p-Value |
|---------------|------------------|------------------|---------|
| Baseline      | 0–2              | 0–2              | 1       |
| After 8 hrs   | 0–5              | 0–7              | 1       |
| After 16 hrs  | 3–5              | 4–5              | 0.11    |
| After 24 hrs  | 1–5              | 4–6              | 0.25    |

*p-Value <0.001
22.0 was used to analyse the data. Quantitative data were expressed as mean standard deviation (SD) or median (IQR) when indicated. The frequency and percentage of qualitative data were used.

**Table 5.** Comparison between groups as regards opioid consumption.

|                          | Group B (n = 27) | Group C (n = 27) | p-Value          |
|--------------------------|------------------|------------------|-----------------|
| Total Morphine consumption (mg) 24 hrs | 6.1 ± 1.8        | 12.7 ± 2.3       | <0.001*         |
| Time for request of first dose rescue analgesia (minutes) | 468.2 ± 80       | 34.8 ± 44.1      | <0.001*         |

*p-Value <0.001

**Table 6.** Difference in PONV between both groups.

|                   | Group B (n = 27) | Group C (n = 27) | p-Value |
|-------------------|------------------|------------------|---------|
| PONV              | 4 (14.8%)        | 1 (3.7%)         | 0.16    |

2.6. The following tests were used

When comparing two means, independent-samples t-test of significance was used.

To compare proportions between two qualitative parameters, the Chi-square (X2) test of significance was used.

Mann–Whitney U test was used in non-parametric data for two-group comparisons.

The confidence interval was set at 95%, and the acceptable margin of error was set at 5%. As a result, the p-Value was deemed significant as follows:

- Probability (p-Value)
  - p-Value <0.05 was considered significant.
  - p-Value <0.001 was considered as highly significant.
  - p-Value >0.05 was considered non-significant.

3. Discussion

In this randomized controlled clinical trial, US-guided ESPB was performed preoperatively on females scheduled for conserving surgery for breast cancer in order to assess efficacy of ESPB in producing adequate pain control and opioid sparing effect. The results showed that ESPB provided optimum analgesia with reduced total amount of morphine consumption and improved hemodynamic parameters and VAS score.

Favoring these results, Singh et al., in a study, performed on 40 female patients to assess the analgesic effect of ESPB in the first 24 hours postoperatively after modified radical mastectomy (MRM). Their results showed that 17 of 20 patients who received ESPB did not ask for morphine compared to the control group where all 20 patients asked for additional analgesic doses [4].

Similarly, Gurkan et al. mentioned a statistically significant decrease by 65% in total opioid consumption in the first 24 hours postoperatively in patients who received ultrasound-guided ESPB with GA when compared with patients who received conventional...
analgesia only with GA for breast surgery. They concluded that ESPB is an effective technique for supplying pain relief postoperatively after breast surgery [8].

Seelam et al. showed similar results. Their study showed that opioid intake was significantly decreased in patients who received ESPB for breast surgeries when compared to the control group who did not receive ESPB (p-Value = 0.000). They stated that only three patients in ESPB group received rescue doses of morphine, while 22 patients in the control group asked for analgesics. They also reported no complications from the block, such as pneumothorax, vascular puncture or respiratory depression [9].

Zhang et al. conducted a meta-analysis where they searched Cochrane Library, Web of Science, EMBASE, ClinicalTrials.gov and PubMed, aiming at collecting randomized controlled trials comparing postoperative analgesia in patients who received ESPB with GA and patients who received GA with conventional intravenous analgesia in surgeries for breast cancer. Their primary outcome was total opioid consumption in the first 24 hours after surgery, while their secondary outcomes included pain scores and incidence of PONV. Zhang et al. reported a statistically significant decrease in pain scores (VAS/NRS) at all time-points in the first 24 hours postoperatively in the group of patients who received ESPB with GA compared to that in the GA group. They also mentioned that there was a significant reduction in opioid consumption in the first 24 hours postoperatively. They noted that there was no statistically significant difference regarding complications after ESPB. This was probably due to the fact that the site of injection was away from the pleura and major vessels. In addition, their meta-analysis showed that the incidence of PONV was significantly decreased in the group of patients who received ESPB with GA compared to GA alone with multimodal analgesia and this has contributed to the decreased opioid requirements which was recorded with ESPB [10].

A meta-analysis by Weng et al. analyzed 495 cases in 8 randomized controlled trials comparing ESPB to systemic analgesics and paravertebral block in breast surgery concluded that ESPB is superior to systemic analgesics within 24 hours after breast surgery and can provide a similar analgesic effect as paravertebral block [11].

In this study, the local anesthetic was injected at the level of fifth thoracic vertebrae (T5). In contrast, Malawat et al. recommended that it is better to inject the drug above the level of T5. They suggested that the lateral and median pectoral nerves, which are claimed to be the cause for post-mastectomy pain, are not anesthetized if ESPB was performed at a lower thoracic level. If ESPB was performed at thoracic levels T2 or T3, C5 and C6 nerve roots will be blocked and thus will block the suprascapular, the axillary and the lateral pectoral nerves [12].

Their study differs from our study in that they used ESPB as a sole surgical anesthesia as well as for postoperative pain control. Also, all the patients included in their study were scheduled for MRM.

Ueshima and Otake, De Cassai et al., Singh et al., Talawar et al., Altiparmak et al., Bonvicini et al., Kumar et al., Veiga et al., Bonvicini et al., Kimachi et al., Kwon et al., Jain et al., Ohgoshi et al., Tanaka et al. all are studies where ESPB is done at T5 in breast surgeries and reported effective postoperative analgesia [13].

Altiparmak et al. published a double-blind prospective and randomized study where they compared the use of ESPB with two different local anesthetic concentrations 0.25% and 0.375% bupivacaine in female patients undergoing unilateral MRM before general anesthesia. They concluded that although ESPB performed with the two different local anesthetic concentrations managed to control postoperative pain effectively, the block with the higher concentration of bupivacaine significantly decreased postoperative opioid consumption [14].

Altiparmak et al. compared injecting 20 ml of either 0.25% or 0.375% bupivacaine. Our study used 0.25% bupivacaine in a volume equivalent to 1 mg/kg bupivacaine, which was a relatively larger volume compared to that used by Altiparmak et al.

3.1. This larger volume may have contributed to the effective postoperative analgesia recorded

The reason for this effective block with extended regional anesthesia and sustained analgesia is possibly a result of the spread of the local anesthetic cranio-caudally to the intercostal spaces, epidural spaces and neural foramina, as well as achievement of paravertebral spread of three or four vertebral levels, both cranially and caudally, leading to block of both ventral and dorsal branches of the spinal nerves and the communicating branches supplying the sympathetic chain, which is responsible for the sympathetic block and the somatic and visceral analgesia [15].

3.2. Conclusion

Ultrasound-guided ESPB performed at the level of T5, using 0.25% bupivacaine, was found to be effective and safe in controlling post-operative pain after breast surgery.

3.3. Limitations

Chronic pain follow-up would have given us more informations about whether ESPB managed to avoid the development of chronic pain or not.

Also, follow-up of the spread of local anesthetics was radiologically one of the study limitations.
Ethics approval and consent to participate
This study was approved by the Research Ethics Committee at the Faculty of Medicine, Ain Shams University (FMASU M D 237/2020) and registered with Pan African Clinical Trial Registry, identifier: PACTR20210753738159. Written informed consent was obtained from each patient.

Availability of data and material
The datasets used and/or analyzed during the current study are available from the corresponding authors on reasonable requests.

Disclosure statement
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ORCID
Islam Abd Elfadel http://orcid.org/0000-0002-1576-6506

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