



Efficacy and Safety of Erector Spinae plane Block versus Thoracic Epidural Analgesia for Pain Management for Conservative Breast Surgery: Randomized Comparative Double Blinded Study

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Abstract

Background: Breast cancer is among the most frequently diagnosed malignancies in women. A variety of surgical procedures are necessary to treat it, including lumpectomy and mastectomy.

Aim and objectives: To compare the efficiency of ESP block and thoracic epidural block in perioperative pain control for breast surgery regarding the period of effective analgesia from the block until the first analgesic dose is required.

Patients and Methods: This was a randomized, double-blinded comparative study performed on 80 female cases who were scheduled for conservative breast surgery in the operating room at Beni-Suef University Hospitals through the period from November 2020 to February 2023.

Results: The pain score at 1 hour, 8, 12, & 24 hours was statistically significantly greater in the thoracic epidural block group ($p < 0.001$), while there wasn't statistically significant variance among the two groups as regards VAS-4hr and the mean required dose of pethidine along the 24 hours ($p = 0.075$ & 0.376 , respectively), and the mean length of effective analgesia was statistically significantly longer in the ESP Block group ($p < 0.001$).

Conclusion: U/S-guided ESP block is a more beneficial choice with regard to outcome in cases being subjected to mastectomy than U/S-guided thoracic epidural analgesia in terms of less post-surgery opioid need, lower frequency of hypotension, and longer duration of effective analgesia.

Key words: Pain Management, Erector Spinae plane Block, Thoracic Epidural Analgesia, Breast Surgery

Introduction

Breast cancer is among the most frequently diagnosed malignancies in women. A variety of surgical procedures are necessary to treat this condition, including axillary lymph node

clearance and lumpectomy. Historically, general anesthesia (GA) has been the procedure most commonly employed; however, it is accompanied by inadequate pain management resulting from the absence of residual analgesics, as well as additional complications including nausea, vomiting [1], & immune system suppression [2].

For breast operations, numerous regional anesthesia procedures have been detailed. Wound infiltration, thoracic epidural anesthesia [3], thoracic paravertebral block [4], & ultrasound-guided interfascial plane blocks, including erector spinae plane block [5], are among these techniques.

Regional anesthesia has been associated with several positive outcomes, such as reduced perioperative anesthesia & analgesia requirements, fewer demands on opioids, alleviation of nausea & vomiting following surgery, absence of after-operation pulmonary complications, prolonged hospital stay, and inhibition of cancer progression.

[6,7].

Fascial plane blocks are pain management techniques that find application in both perioperative & chronic pain treatment conditions. Various fascial block types have been described recently, & their clinical applications have increased [8].

The objective of the investigation was to compare the period of effective analgesia from the time the ESP block is inserted until the first analgesic dose is needed in order to assess the comparative effectiveness of thoracic epidural block & ESP block in perioperative pain control for surgery on the breast.

Patients and methods

This was a randomized, double-blinded comparative study performed on 80 women who were scheduled for conservative breast surgery in the operating room at Beni-Suef University Hospitals through the period from November 2020 to February 2023.

Ethical approval

The study was conducted after being accepted by the department of anesthesiology, operating intensive care, & management of pain, after obtaining agreement from the local study and ethical committee of Beni-Suef University (the approval number is FMBSUREC/06122020), and following obtaining informed consent from the cases.

Inclusion criteria: women cases, from eighteen to sixty-five years of age & ASA physical status I–III, who were scheduled for a conservative breast operation.

Exclusion criteria: patients who refused to give consent; cases scheduled for bilateral surgery; patients for whom regional anesthesia is contraindicated; patients with infection at the site of block; patients with coagulopathy or allergies to local anesthetics; peripheral neuropathy or chronic neurological disease; and patients suffering from psychiatric disorders.

Sample size

The determination of the sample size was accomplished by comparing the time to the initial analgesic need between patients undergoing conservative breast surgery treated with ESP block & those treated with thoracic epidural. As stated in previous different publications, the mean $\pm$ standard deviation of time to the first analgesic requirement in the thoracic epidural group was approximately 253.3 ± 93.6 minutes in Group 1 (in which thoracic epidural block is used for analgesia in thoracic and abdominal surgeries), while in the ESP block group it was approximately 473.8 ± 99.6 minutes in Group 2. Accordingly, to achieve an eighty percent power level of significance at the $\alpha = 0.05$ level utilizing the student's t test for independent samples & detect a real distinction of sixty minutes, the minimum appropriate sample size for each group was determined to be 40 participants. The process of determining the sample size was carried out with the assistance of the PS Power & Sample Size Calculations software, version 3.0.11 for Microsoft Windows (William D. Dupont & Walton D., Vanderbilt University, Nashville, Tennessee, United States of America).

Methods

Preoperative preparation: Before the procedure, patients were given informed consent, and a peri-procedural "timeout" was performed to confirm the procedure's type, side, and location. Pre-operatively, patients underwent full history-taking, examinations, and routine investigations. Upon arrival, a 20G intravenous cannula was inserted, IV fluids started, and patients were premeditated with metoclopramide and midazolam.

Anesthetic technique

The study used a computer-generated randomization list to allocate patients to two study groups with a 1:1 ratio. Before inducing anesthesia, a team member performed blinding and chose and opened the block. Preoxygenation with 100% oxygen for 3 minutes, then anesthesia was induced with propofol 1-2 mg/kg IV, fentanyl 1µg/kg IV, & atracurium 0.5 mg/kg IV, and the lungs were mechanically ventilated through a face mask to maintain the ET CO₂ of 36–40 mmHg. Then intubation with a suitable-size endotracheal tube was done, and a balanced anesthesia technique using isoflurane was used in a 50 percent oxygen-air mixture & atracurium top-up doses of 0.1 mg/kg/30 min. **First group: (group T: Thoracic Epidural Group):** The study used a probe to locate the midline at the level of the T5 vertebrae, then a paramedian sagittal oblique scan (PMSOS) to see the laminae as flat hyperechoic structures. A Tuohy needle 18G was inserted via the paramedian axis and advanced until it contacted the lamina or entered the interlaminar space. Patients received a single shot of 0.375% bupivacaine at the T5 vertebrae level. **2nd group: (group E: the ESP block group):** ESP block procedures were conducted using a L12-3 linear array probe at T5 transverse process level. By positioning the instrument three centimeters laterally to the T1 spinous process, it was possible to observe the rhomboid major, trapezius, & erector spinae muscles located posterior to the transverse processes and superficial to them. Following negative aspiration, twenty milliliters of 0.375% bupivacaine were injected into T5 via spinal needle insertion. Hydroscis was utilized to validate the location. Following the conclusion of the surgical procedure, isoflurane was discontinued, Any residual neuromuscular blockade was antagonized with neostigmine 0.04 milligram per kilogram & atropine 0.02 milligram per kilogram, & the case was extubated in the operating room & transferred to the post-anesthesia care unit once adequate tidal volume and efforts were achieved for spontaneous breathing.

Statistical methods

The statistical package for the Social Sciences (SPSS) version 26 (IBM Corp., Armonk, NY, USA) was utilized to gather and analyze the data. For quantitative variables, the data were presented as mean and SD; for categorical variables, the information was presented as frequencies (number of cases) and relative frequencies (percentages). In order to compare groups, an unpaired student t-test was utilized. To compare categorical data, the chi-squared test (c2) was applied. P-values that were below 0.05 were deemed to indicate statistical significance.

Results

There wasn't significant variance among both groups as regards age and ASA I/II ($p = 0.434, 0.237$). (Table 1)

There wasn't significant variance among both groups regarding HR-0 minute, HR-30 minute, and HR-60 minute; MAP-0 minute and MAP-60-minute $p > 0.05$; but there was significant variance as regards MAP-30-minute $p = 0.005$. (Table 2)

The pain score at 1 hour, 8, 12, and 24 hours was statistically significantly greater in the thoracic epidural block group ($p < 0.001$). While there wasn't statistically significant variance among the both groups as regards VAS-4hr and the mean required dose of pethidine along the 24 hours ($p = 0.075$ & 0.376 , respectively), the mean period of effective analgesia was statistically significantly longer in the ESP Block group ($p < 0.001$). (Table 3)

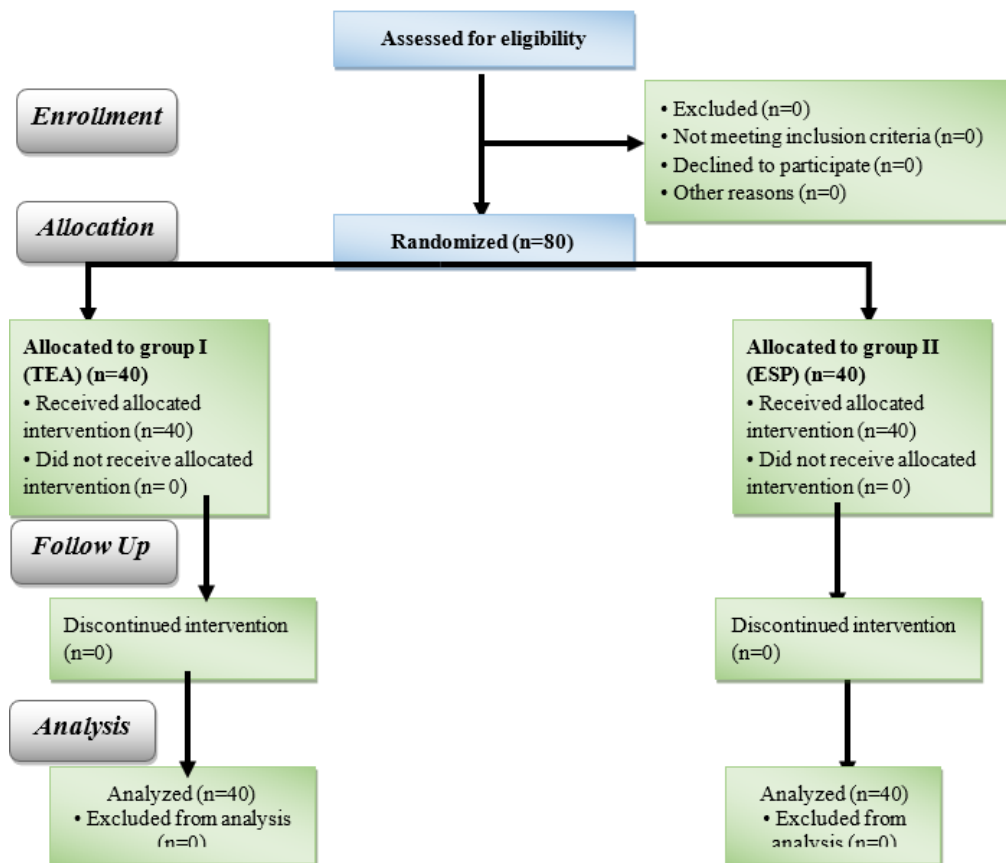


Figure 1 Flow diagram

Table 1 Demographic data,ASA classification

	Thoracic epidural Group (n = 40)	Erector spinae plane Block group (n = 40)	p-value
Age (years)*	34.5 ± 7.6	36.1 ± 10.1	0.434
ASA I/II**	29 (72.5%)/11(27.5%)	24 (60%)/16(40%)	0.237

* Data described in mean ± SD; **Data described in number and percentage; p-value <0.05 is statistically significant-value<0.01 statistically highly significant

Table 2 Hemodynamic parameters

	Thoracic epidural Group (n = 40)	Erector spinae plane Block group (n = 40)	p-value
HR-0 min	71.3 ± 6.7	71.1 ± 6.4	0.905
HR-30 min	70.1 ± 4.2	71.3 ± 3.9	0.167
HR-60 min	67.4 ± 3.9	68.7 ± 3.7	0.155
MAP-0 min	71.6 ± 5.3	71.3 ± 6	0.813
MAP-30 min	66.4 ± 4.2	69.1 ± 4.2	0.005
MAP-60 min	65.6 ± 4.1	67.5 ± 4.4	0.058

HR: Heart rate; MAP: Mean arterial blood pressure (mmHg); Data described in mean ± SD

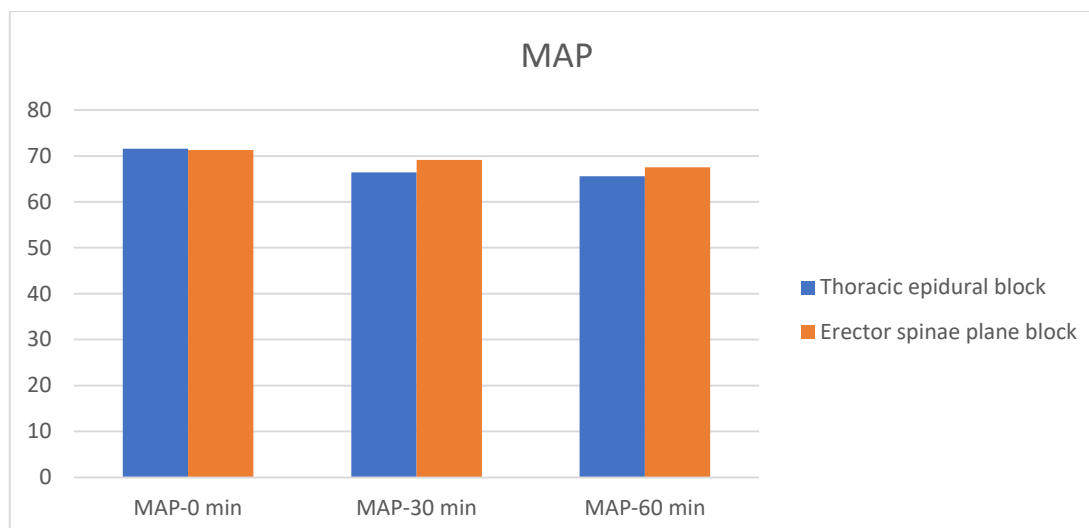


Figure 2 Comparison between Thoracic epidural block & ESP block regarding MAP intraoperative

Table 3 Duration of effective analgesia, VAS score, pethidine consumption -24 hour

	Thoracic epidural Block Group (n = 40)	Erector spinae plane Block group (n = 40)	p-value
Duration of EA (h)*	12.7 ± 6.4	22 ± 4.6	< 0.001
VAS-1hr**	1 (1 - 2)	1 (0 - 1)	< 0.001
VAS-4hr**	2 (1 - 2)	1 (1 - 2)	0.075
VAS-8hr**	2 (1 - 3)	1 (1 - 2)	< 0.001
VAS-12hr**	3 (2 - 4)	2 (1 - 3)	< 0.001
VAS-24hr**	3 (2 - 4)	2 (1 - 3)	< 0.001
Pethidin-24h*	60.2 ± 20.9	67.9 ± 18.9	0.376

EA: effective analgesia; VAS: Visual Analog Pain Scale; *Data described in mean ± SD;

**Data described in median (range)

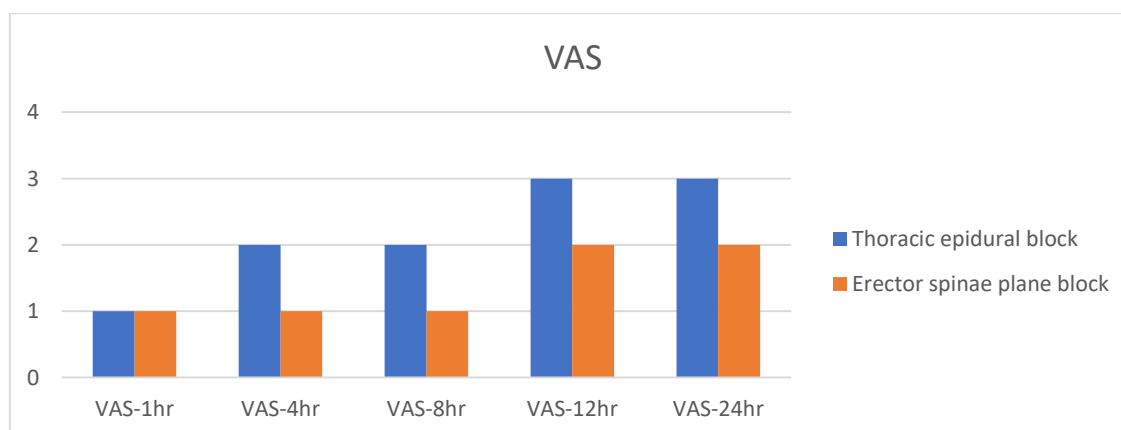


Figure 3 Comparison among Thoracic epidural block & ESP block regarding VAS score after-operative

Discussion

Approximately sixty percent of cases who undergo mastectomy operation suffer severe acute discomfort after the procedure. The primary source of this discomfort can be related to the axillary component of the operation. The inadequate management of pain following surgery results in adverse physiological & psychological effects. Effective management of acute pain

inhibits the surgical stress response & reduces the necessity for general anesthetics and analgesics; this results in immune response preservation. Furthermore, regional anesthesia has the potential to lessen the stress response induced by surgical trauma.[8].

The main results of our study were the following:

Regarding the hemodynamic changes among the studied groups, the present study revealed a statistically significant decrease in MAP-30 min among the thoracic epidural group in comparison with the ESP block group (P value = 0.005). However, no statistically significant distinction was observed with regard to heart rate (beats per minute), MAP-0 minutes, or MAP-60 minutes among the groups in investigation (P value > 0.05).

Elsabeeny et al. [9] conducted a comparative analysis of perioperative pain management using serratus anterior plane block, ESP block, & thoracic epidural analgesia in sixty-eight cases of cancer undergoing lung surgeries. The authors found that intraoperative MAP values were significantly reduce in the thoracic epidural analgesia group than in the other both groups.

A randomized prospective single-blind pilot research by **Karoo et al. [10]** discovered that the thoracic epidural group and the spinae plane block group had similar blood flow.

however, the thoracic epidural group reported five cases of intra-operative hypotension, whereas the ESP block group only had one case of hypotension needing mephentermine & fluid boluses.

Previous research by **Ahmed et al. [11]** that compared the incidence of hypotension among sixty mastectomy patients in thoracic epidural analgesia and ESP block groups revealed that hypotension was further documented in the thoracic epidural group cases, with statistical significance at 0-minute. Following surgery, readings of MAP tended to be less in the thoracic epidural group patients at one hour to 24 hours, but without statistically significant variance.

Regarding the period of effective analgesia among studied groups, the current research indicated a statistically significant rise in the period of effective analgesia (hr) among the ESP block group in comparison with the thoracic epidural group (22 ± 4.6 vs. 12.7 ± 6.4 hr, respectively) (P value<0.001).

An extended period of analgesia was documented by **Malawat et al. [12]**, who discovered that after a modified radical mastectomy, an ultrasound-guided single-shot ESP block administered long-lasting following-surgery analgesia for an average of 41.73 hours & completed surgical anesthesia in all thirty cases involved in the research within an average of 31.50 minutes.

Conversely, **Karoo et al. [10]** demonstrated non-statistically significant variance among the ESP block group & the thoracic epidural group regarding the mean duration of analgesia (20.60 ± 5.77 vs 21.72 ± 4.73 , respectively).

The results of this study showed that the ESP block group had statistically lower VAS-1hr, VAS-4hr, VAS-8hr, VAS-12hr, and VAS-24hr scores than the thoracic epidural group (P value<0.001). The analgesic effect of the ESP block appears to be mediated by the diffusion of local anesthesia into the paravertebral space. It is able to produce its effects not only at the rami communicans that supply the sympathetic chain but also at the dorsal & ventral rami of the thoracic spinal nerves.

Such findings are in agreement with **Ahmed et al. [11]**, who compared after-mastectomy pain control in thoracic epidural analgesia & the ESP block groups and reported that the ESP block patients have significantly lesser pain scores according to the visual analog scale.

Similarly, **He et al. [13]** reported that satisfactory pain relief (mean visual analog scale score less than three) was noticed in the erector spinae plane block group throughout 48 hours post-surgery in 40 females, ASA I or II, undergoing mastectomy. At 1, 6, 12, 24, and 48 hours

following operations, the rest & motion visual analog scales of the ESP block group were significantly lesser than those of the control group.

At rest and during motion, the greatest VAS score within forty-eight hours following operation was significantly decreased in the ESP block group compared to the control group.

In contrast, **Karoo et al. [10]** provided evidence that the postoperative visual analog scale score at rest at each of the following time points (zero, one, two, four, eight, twelve, & twenty-four hours) was similar in both the ESP block group and the thoracic epidural group. Furthermore, the mean VAS score in both groups was lower than four at each of these time points (zero, one, two, four, eight, twelve, & twenty-four hours).

The results of the current investigation demonstrated a notably higher requirement for opioids in the group that received thoracic epidurals compared to the group that received erector spinae plane blocks (P value < 0.001).

The obtained results agree with the findings stated in **Ahmed et al. [11]**, who compared the post-mastectomy morphine requirements in two groups: thoracic epidural analgesia & ESP block. Their comparison showed that the ESP block group had a significantly reduced following surgery morphine requirement, with only 3.3 percent of cases requiring three boluses, compared to twenty-seven percent in the thoracic epidural group.

In their study, **Yao et al. [14]** examined the impact of ESP block on quality of recovery (QoR) in eighty-two cases who underwent modified radical mastectomy. The researchers found that the Global QoR-15 scores of the ESP block group were significantly higher (which indicates better quality) at twenty-four hours following surgery than those of the control group. ESP block with ropivacaine decreased pain scores up to eight hours following operations, as well as cumulative opioid consumption & post-anesthesia care unit discharge time, in comparison to the control group.

Additionally, that which followed total mastectomy was the subject of retrospective observational research by **Hong et al. [15]**, which examined the analgesic effects of ESP block in forty-eight cases. In comparison to the control group, the ESP block group had a substantially lesser median cumulative fentanyl consumption throughout the first twenty-four hours, according to the findings of this research. In the ESP block group, pain levels in the initial following surgery duration (less than three hours) & the frequency of nausea & vomiting following surgery were substantially reduced compared to the control group.

Conclusion

In women who are having a mastectomy, S-guided ESP block is better than U/S-guided thoracic epidural analgesia because it reduces the need for opioids after surgery, lowers the risk of hypotension, and provides longer-lasting pain relief.

Limitations

There were a limited number of cases in the single research center, & all the cases in the present study were ASA I or II. How effective the block is in patients with multiple comorbidities needs to be evaluated.

Recommendations

A larger-scale study is recommended, with a longer time for follow-up of the patients, to observe the effects of the ESP block & the thoracic epidural analgesia on persistent post-mastectomy pain. This is a multi-center study. Use of ESP block in other surgeries other than mastectomy.

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