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Original Article

MODIFIED RADICAL MASTECTOMY: DEEP VERSUS SUPERFICIAL ERECTOR SPINAE BLOCK - A RANDOMIZED TRIAL.

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Abstract

Background
The quality of life, recovery, and functionality of patients are adversely affected by the intense pain that often follows breast cancer surgery, such as a modified radical mastectomy.

Objectives
This study was conducted to assess the effectiveness and safety of superficial and deep erector spinae plane (ESP) blocks in individuals undergoing modified radical mastectomy.

Materials and Methods
It was a randomized-controlled pilot study that was conducted at Sri Krishna Medical College and Hospital, Muzaffarpur, Bihar, India. The study was conducted for one year, i.e., from September 2023 to August 2024. The study comprised 50 female patients.

Results
The average age of the fifty female participants in the study was 52 years. A consistent distribution of baseline clinical features and socioeconomic data was seen among the study groups. With a p-value < 0.05, the superficial ESP block group only lasted 04 hours before the first request for rescue analgesia; in contrast, the median length of 10 hours was significantly longer for the deep ESP block group.

Conclusion
This research shows that deep ESP blocks are more successful than superficial ESP blocks at lowering postoperative pain in patients having a modified radical mastectomy.

Recommendations
Deep ESP block is recommended for postoperative analgesia in mastectomy patients due to superior pain relief and reduced opioid use.

Keywords: *Opioid Consumption, Postoperative Pain, Erector Spinae Plane Block, Mastectomy.*
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Introduction
One type of breast cancer surgery that commonly results in excruciating pain after the procedure is a modified radical mastectomy, which negatively affects the quality of life, recovery, and usefulness of patients [1]. Numerous analgesic techniques have been studied as a result of the requirement for effective pain management. The block of erector spinae plane (ESP) has gained popularity as a method for thoracic analgesia due to its efficiency and simplicity of usage [2, 3].

An easy and secure myofascial plane block is the ESP block [1]. It has been demonstrated that ultrasound-guided ESP block has a role in breast surgeries [4, 5]. In patients undergoing modified radical mastectomy (MRM), it has been observed that preoperative block delivery tends to decrease the consumption of opioids and thus lessens opioid-related side effects. An example of opioid-free anesthesia in patients slated for MRM was presented in a case series [6].

During stomach, thoracic, and some orthopedic procedures, this technique has been shown to effectively reduce pain by

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blocking the ventral and dorsal rami of the spinal neurons. Improvements to the ESP block are constantly being researched, especially concerning the optimal depth of anesthetic injection to reduce problems and maximize pain management [7, 8].

This study was conducted to assess the effectiveness and safety of superficial and deep ESP blocks in individuals undergoing modified radical mastectomy. The study intends to improve postoperative pain management and overall patient satisfaction by concentrating on these methods and providing more thorough recommendations on the best use of ESP blocks after breast surgery. This study will also look into the connection between postoperative complications, analgesic use, the depth of the block, and the duration of pain relief.

Materials and Methods

Study Design

It was a randomized-controlled pilot study that was conducted at Sri Krishna Medical College and Hospital, Muzaffarpur, Bihar, India. The study was conducted for one year, i.e., from September 2023 to August 2024.

Study Setting

The study was conducted in the Department of Anesthesia at Sri Krishna Medical College and Hospital, a tertiary care teaching hospital specializing in surgical interventions, including oncology procedures. It is located in Muzaffarpur, Bihar, and caters to a diverse population with varying socioeconomic backgrounds.

Sample Size Estimation

The sample size was calculated based on an expected difference in opioid consumption between the two groups. Using a power of 80% and a significance level of 0.05, a sample size of 50 participants (25 in each group) was deemed sufficient to detect statistically significant differences.

Study Population

Between the ages of 18 and 65, 50 female patients with ASA physical status I–III undergoing elective modified radical mastectomy were included in the study. Block site infection, coagulopathy, local anesthetic allergy, chronic opioid use, and unwillingness to cooperate were among the exclusion criteria. For the deep or superficial ESP block, a third-party administrator blinded patients and outcome assessors and split participants into two groups of 25 using a computer-generated sequence.

Eligibility Criteria

- Inclusion: Female patients, aged 18-65, ASA physical status I-III, undergoing elective modified radical mastectomy.
- Exclusion: Patients with block site infection, coagulopathy, local anesthetic allergy, chronic opioid use, and those unwilling to cooperate.

Data Collection

Primary outcomes were measured by VAS at 1, 6, 12, and 24 hours after surgery. Complications, analgesic duration, patient satisfaction, and opioid use were considered outcomes secondarily.

Ethical Consideration

The study was approved by the Institutional Ethics Committee of Sri Krishna Medical College and Hospital (Approval No). All participants provided written informed consent before inclusion in the study.

Informed Consent

All participants provided written informed consent before enrollment, acknowledging their voluntary participation in the study and understanding the purpose, procedures, potential risks, and benefits.

Randomization Sequence Generation

A computer-generated random allocation sequence was used to assign participants into two groups. This method ensured an unbiased allocation to either the deep or superficial ESP block groups.

Allocation Concealment Mechanism

The random allocation sequence was concealed using sequentially numbered, sealed opaque envelopes. These envelopes were opened only after the participant's eligibility was confirmed to prevent any bias in the assignment.

Implementation

The random allocation sequence was generated by a research assistant not involved in participant enrollment. Participants were enrolled by a study coordinator, who was blinded to the group assignments. The interventions were assigned by a third-party administrator who was also blinded to the allocation sequence.

Blinding

Both the participants and the outcome assessors were blinded to the group assignment. The anesthesia team and surgical staff were also blinded to the treatment allocation. This ensured that patient care and outcome assessments were unbiased.

Statistical Analysis

Data analysis was done in SPSS. An independent t-test was used to obtain significance. Less than 0.05 was the cutoff point for statistical significance.

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Results

Participant screening

A total of 60 patients were assessed for eligibility. Ten patients were excluded (6 did not meet the inclusion criteria, and 4 declined to participate). Fifty patients were randomized equally into two groups: 25 received the deep ESP block, and 25 received the superficial ESP block. All participants received the assigned interventions and were analyzed for both primary and secondary outcomes. No participants were lost to follow-up or excluded from the final analysis.

Baseline Data

The demographic and baseline clinical parameters, including age, BMI, ASA physical status, and relevant socioeconomic indicators, were comparable between the two groups, confirming adequate randomization. Fifty women in all had participated in the study, and the average age was 54. The baseline clinical parameters and socioeconomic data were evenly distributed throughout the study groups (Table 1).

Table 1. Baseline Characteristics of Participants

Parameter	Deep ESP Group (n=25)	Superficial ESP Group (n=25)	P-value
Mean Age (years)	53.8 ± 6.2	54.1 ± 5.9	>0.05
BMI (kg/m²)	26.2 ± 3.1	25.8 ± 2.9	>0.05
ASA I/II/III (n)	5/15/5	6/14/5	>0.05
Urban/Rural Residence (n)	10/15	9/16	>0.05
Education Level (High/Low)	12/13	11/14	>0.05

Notably, six hours following the procedure, the average VAS score of superficial ESP was 4.7, whereas the deep ESP block groups were 2.4. With a p-value less than 0.05, this difference was statistically significant.

Furthermore, during the first 24 hours following surgery, the group that had the deep ESP block used 10 mg of morphine, indicating a significant reduction in opioid utilization. This was significantly less than the group of superficial ESP block, which took 20 mg of morphine, with a p-value less than 0.05. Furthermore, with 90% of participants reporting excellent satisfaction, the deep ESP block group had considerably higher patient satisfaction ratings than the superficial ESP block group, with a p-value less than 0.05. The shallow ESP block group only lasted four hours with a p-value less than 0.05, however, the median time until the initial need for rescue analgesia was 10 hours longer for the profound ESP block group. Table 2 depicts outcome measures of both primary and secondary measures.

Table 2. Outcome measures of both primary and secondary measures

Outcome	Deep ESP Block Group	Superficial ESP Block Group	P-value
Mean Vas score at 6 hours	2.4	4.7	<0.05
Opioid Consumption (mg ME)	10	20	<0.05
Patient Satisfaction (%)	90%	66%	<0.05
Time to first Analgesia (in hours)	10	4	<0.05
Complications (%)	Minor, Similar	Minor, Similar	-

Discussion

In terms of reducing postoperative pain after a modified radical mastectomy, the outcomes of this preliminary study indicate that the deep ESP block was effective comparative to superficial ESP block [9, 10]. Notably, at different points in time after the treatment, those who received the deep ESP block reported significantly less discomfort. This finding suggests that the provided pain relief was more effective [11].

The deeper administration of the local anesthetic, which permits a greater dispersion and effective suppression of the particular sensory nerves, may be one explanation for this phenomenon [12]. Additionally, the deep ESP block cohort's decreased opioid use highlights the block's effectiveness in managing pain. This is especially important given the current emphasis on reducing opioid use because of its potential risks and adverse effects. This decrease promotes patient safety and rehabilitation by indicating improved pain management as well as a decrease in opioid-related problems and side effects [13,14].

Less pain and thus, a decreased need for further pain-killers were associated with a significant increase in patient

satisfaction in the ESP block group [15]. Patients' evaluations of their surgical experience and the complete recuperation process are greatly impacted by the higher degree of satisfaction. Its ability to extend comfort and reduce the burden on patients and medical personnel further supports the considerable time between the deep ESP block's efficacy and the initial need for pain relief [16,17]. Numerous studies have demonstrated the function of ESP in individuals undergoing mastectomy. These have all made use of deep method. Because it is located outside of the spinal canal, erector spinae block is regarded as a safer substitute for paravertebral block. Additionally, administering the block is made simple by its surface form. We found no negative side effects in any of the subjects. Blocking the spinal cord's ventral rami is the goal of ESP block for individuals who have had mastectomy. In contrast to superficial block, the medication can seep into the paravertebral region when it is deposited deeply into the ESP muscle. Therefore, the deep method is the usual procedure for patients undergoing mastectomy and is superior in terms of analgesia.

Conclusion

The study concluded that deep ESP blocks were more effective at lowering post-operative pain in patients having modified radical mastectomy than shallow ESP blocks. The deep ESP block effectively reduces pain scores and opiate use, maintains pain relief for longer, and enhances patient satisfaction without raising risk. According to the evidence, administering the local anesthetic deeper into the ESP might offer a safer and more effective way to manage pain during breast surgery.

Generalizability

The results of this pilot study apply to adult female patients undergoing modified radical mastectomy in tertiary care centers. However, due to the small sample size and single-center design, caution should be taken when extending these findings to broader populations. Further multicentric studies with larger cohorts are needed to confirm external validity.

Limitations

The study's limitations encompass its narrow focus and limited participant pool; thus, it is essential to conduct larger research to validate these findings and potentially impact current pain treatment guidelines in breast surgery.

Recommendations

Additional studies with larger cohorts are essential to validate these findings and potentially revise treatment guidelines recommended mastectomy procedures to consider ESP block as a standard technique in managing pain post-operatively.

Abbreviations

- ASA: American Society of Anesthesiologists
- ESP: Erector Spinae Plane
- VAS: Visual Analog Scale
- SPSS: Statistical Package for the Social Sciences

Source of Funding

No external funding was received for this study.

Conflict of Interest

The authors declare no conflicts of interest.

Author Contributions

All authors contributed to the study design, data collection, analysis, and manuscript preparation.

Data Availability

Data are available from the corresponding author upon reasonable request.

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