

Ultrasound-Guided Erector Spinae Plane Block Versus Local Wound Infiltration in Breast Conservative Surgery: A Randomized Double-Blinded Comparative Study

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ABSTRACT

Background: Postoperative pain management is an important component of care following breast-conserving surgery. Regional analgesic techniques like ultrasound-guided erector spinae plane block (ESPB) may provide broad dermatomal coverage but require ultrasound equipment and procedural expertise. Local wound infiltration (LWI) is a simpler technique that delivers local anesthetic directly to the surgical site. The comparative effectiveness of these approaches in limited breast-conserving procedures remains insufficiently characterized.

Objective: To compare the analgesic effectiveness and safety of ultrasound-guided ESPB against LWI in cases undergoing breast-conserving surgery.

Design: Prospective, randomized, controlled clinical trial with patient and postoperative outcome-assessor blinding.

Setting: National Cancer Institute, Cairo University, Major Operating Room Unit, Cairo, Egypt.

Patients: Sixty-six adult female patients aged 17–78 years and classified as ASA physical status II, scheduled for elective breast-conserving operation.

Interventions: Patients were randomly allocated to ultrasound-guided ESPB with twenty-five milliliters levobupivacaine 0.25% at T5 (ESPB group, n=33) or subcutaneous LWI with bupivacaine 0.5% at the surgical site (LWI group, n=33), administered under general anesthesia before skin incision.

Measurements: The 1st outcome was total postoperative intravenous morphine consumption during the 1st twenty-four hours. 2nd outcomes involved intraoperative fentanyl consumption, hemodynamic parameters, time to 1st rescue analgesia, Numerical Rating Scale (NRS) pain scores, postoperative nausea and vomiting (PONV), and case satisfaction.

Main Outcomes: A statistically insignificant between-group variance has been reported in 24-hour postoperative morphine consumption (ESPB: 4.00 ± 1.40 ; LWI: 3.60 ± 1.34 ; $P=0.659$), intraoperative fentanyl consumption (ESPB: 106.06 ± 20.76 ; LWI: 104.69 ± 19.51 ; $P=0.784$), NRS pain scores, hemodynamic parameters, PONV, or patient satisfaction.

Conclusions: In this study of breast-conserving surgery with limited incisions, statistically insignificant variances have been observed among LWI and ultrasound-guided ESPB in the reported postoperative analgesic outcomes. LWI may be a practical option when a simple wound-directed analgesic technique is appropriate. **Clinical trial registration:** ClinicalTrials.gov NCT07301840.

Keywords: Erector spinae plane block; postoperative analgesia; local wound infiltration; breast-conserving surgery; regional anesthesia; opioid-sparing

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INTRODUCTION

Breast cancer is the most commonly identified neoplasm and a primary contributor to cancer-associated fatalities among women globally [1]. While multimodal treatment strategies—including surgery, radiotherapy, chemotherapy, immunotherapy, and endocrine therapy—are employed, surgical resection remains an important component of treatment [2,3]. Breast-conserving surgery (BCS) has become standard care for eligible cases, preserving breast tissue whereas achieving comparable oncological results to mastectomy.

Despite its relatively limited extent, BCS may be related to acute postoperative pain. Inadequately treated acute pain is a recognized risk factor for persistent postoperative pain, which has been stated in a substantial proportion of patients following breast surgery [4,5]. Persistent pain may impair functional recovery and quality of life and may be associated with prolonged opioid exposure [6].

Regional analgesic techniques can diminish postoperative pain and opioid requirements and may decrease PONV and other consequences of acute postoperative pain [7,8]. Among these techniques, ultrasound-guided ESPB, 1st described by Forero et al. in 2016, has gained widespread

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use [9]. The block includes deposition of local anesthetic deep to the erector spinae muscle at the level of the thoracic transverse processes and may provide broad craniocaudal spread [9–11].

LWI is an alternative analgesic approach that is technically simple, inexpensive, and does not need ultrasound equipment or specialized regional anesthesia expertise. By delivering local anesthetic directly to the surgical site, LWI acts at the source of nociceptive input [12,13].

Although ESPB and LWI have each been evaluated in breast operation, the present research has been designed to compare the two techniques specifically in patients undergoing BCS. We hypothesized that LWI would provide postoperative analgesia comparable in measured outcomes to ESPB in this surgical population.

METHODS

Study design and ethical considerations

This was a forward-looking, randomized, controlled clinical study carried out at the National Cancer Institute, Cairo University, Cairo, Egypt. The research received approval from the institutional review board and has been executed in line with the Declaration of Helsinki. Informed permission in writing has been secured from all participants prior to their enrolment. The research is documented in Clinical trials.gov (NCT07301840).

Participants

Eligible patients were adult females aged 17–78 years, classified as ASA physical status II, and scheduled for elective BCS under general anesthesia. Exclusion criteria involved patient refusal, inability to provide informed consent, ASA physical status III–IV, known allergy or contraindication to local anesthetics or opioids, pregnancy or lactation, history of chronic pain or psychiatric disorders, contraindications to regional anesthesia like local sepsis, coagulopathy, or pre-existing peripheral neuropathy, severe cardiorespiratory disease, and advanced hepatic or renal impairment.

IMPORTANT DATA CHECK: The source Table 1 reports age ranges of 33–76 years in the ESPB group & 17–78 years in the LWI group, consistent with the stated eligibility range of 17–78 years.

Randomization and blinding

Cases have randomly been assigned to either the ESPB or LWI group by computer-generated random numbers contained in sealed opaque envelopes, that were prepared by a statistician not otherwise engaged in the research. Patients and the anesthesiologist assessing postoperative pain were blinded to group allocation. The anesthesiologist performing the intervention was aware of the assigned technique and did not participate in postoperative outcome assessment.

Interventions

ESPB group

After the administration of general anaesthesia and prior to the skin incision, cases have been arranged in the lateral decubitus posture. A linear ultrasound transducer (six to thirteen Megahertz; Fujifilm SonoSite M-Turbo) has been positioned in a parasagittal alignment 2.5–3 centimetres from the midline to locate the T5 transverse process & the adjacent erector spinae muscle. An echogenic

needle was positioned in-plane from cranial to caudal until its tip made contact with the T5 transverse process, beneath the erector spinae muscle. Accurate positioning within the fascial plane was validated with the injection of 0.5–1 millilitres of normal saline, which allowed for the observation of fluid dispersion elevating the muscle from the transverse process. Following negative aspiration, twenty-five millilitres of 0.25% levobupivacaine was administered progressively.

LWI group

Following induction of general anesthesia, patients remained supine. Using a 22-gauge needle under aseptic conditions, bupivacaine 0.5% was administered by subcutaneous infiltration at the proposed incision site 15 minutes before skin incision. The maximum local anesthetic dose was individualized according to body weight (2–2.5 mg/kg); when required, the solution was diluted with preservative-free normal saline to provide sufficient volume to cover the planned incision.

Anesthetic management

All cases have been administered intravenous midazolam at a dosage of 0.01–0.02 milligram per kilogram as premedication 30 minutes before to induction. General anaesthesia was initiated with intravenous fentanyl at a dosage of two micrograms per kilogram and propofol at two milligrams per kilogram; tracheal intubation has been assisted with rocuronium at 0.5 mg/kg. Anaesthesia has been sustained with sevoflurane at two percent concentration in oxygen-enriched air (FiO₂=0.5) alongside rocuronium administered at 0.1 mg/kg every half hour. Multimodal analgesia comprised 500 mg of intravenous paracetamol and 30 mg of intraoperative ketorolac. Intraoperative rescue analgesia (intravenous fentanyl 0.5 micrograms per kilogram) has been provided whenever the mean arterial pressure or heart rate rose more than twenty percent over baseline, with a ceiling of 3 micrograms per kilogram.

Ongoing surveillance encompassed electrocardiography, non-invasive blood pressure assessment, peripheral oxygen saturation measurement, and end-tidal CO₂ monitoring (target range 30–35 mmHg).

Postoperative management

Cases have been moved to the PACU for at least two hours before to discharge to the ward. Postoperative multimodal analgesia included intravenous paracetamol one gram administered every eight hours and ketorolac 30 mg given every 8 hours. Rescue analgesia has been administered via intravenous morphine in three milligrams boluses for a Numeric Rating Scale (NRS) of 4 or above, with a maximum limit of 0.5 mg/kg/day during a 24-hour period. Ondansetron 0.1 milligrams per kilogram intravenously has been given for moderate to severe postoperative nausea and vomiting.

Outcome measures

The 1st outcome was total intravenous morphine consumption during the first 24 postoperative hours. 2nd results included total intraoperative fentanyl consumption; NRS pain scores at rest and during movement at 0, 2, 4, 8, 12, 16, 20, and 24 hours postoperatively; MAP and HR at baseline, at incision, and at 30-minute intraoperative

intervals; time to first rescue analgesia; PONV severity; patient satisfaction; and complications including local anesthetic systemic toxicity, pneumothorax, arterial puncture, respiratory depression, urinary retention, and pruritus.

Sample size calculation

Sample size has been calculated utilizing G*Power version 3.1.9.2 with $\alpha=0.05$ and eighty percent power. Based on a mean 24-hour morphine consumption of 1.95 ± 2.01 milligrams in the ESPB group and an expected 50% variance between groups, 29 patients per group have been required. Four additional cases per group were recruited to account for potential dropout, yielding a planned total of 66 participants.

Statistical analysis

Statistical evaluation has been conducted utilizing SPSS version 26.0 (IBM Inc., Chicago, IL, USA). The Shapiro–

Wilk test and histograms have been utilized to estimate data distribution. Continuous variables that follow a normal distribution have been expressed as mean $\pm$ SD and analyzed utilizing the independent-samples t-test. Non-parametric data have been expressed as median (interquartile range) and analyzed with the Mann–Whitney U test. Categorical parameters have been represented as frequency (%) and examined via the chi-square test or Fisher's exact test, if suitable. All assessments were bilateral, and a P-value of less than 0.05 has been deemed statistically significant.

RESULTS

Sixty-six cases have been enrolled and completed the research without reported protocol deviations. No patients were excluded after randomization.

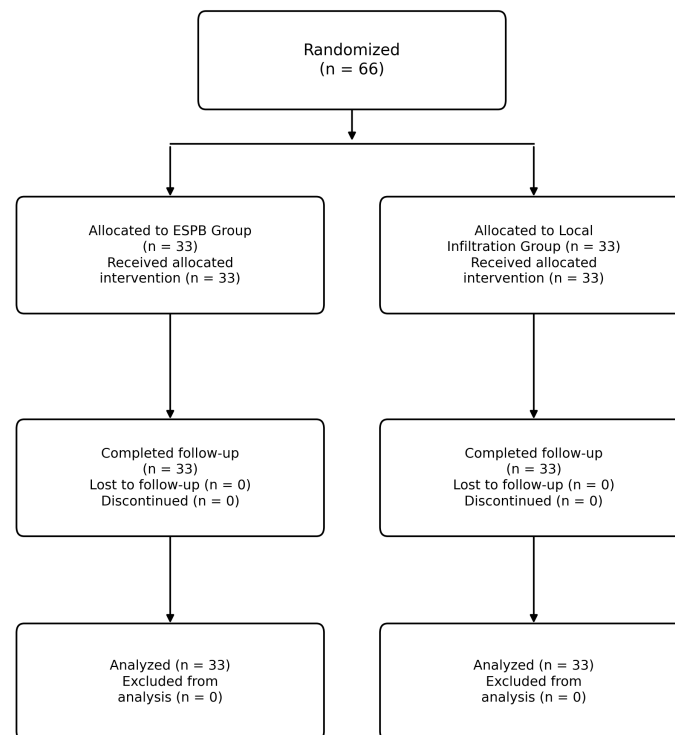


Fig. 1. CONSORT flow diagram of case randomization, monitoring, allocation, and analysis. No cases have been lost to monitoring or excluded from analysis in either group. Records of cases evaluated for eligibility and excluded before randomization were not separately retained for this study.

Baseline characteristics

Demographic characteristics were reported as similar between groups. Mean age was 52.67 ± 10.97 years in the

ESPB group versus 49.52 ± 14.66 years in the LWI group ($P=0.326$), and mean body weight was 84.85 ± 11.22 kg versus 82.53 ± 10.76 kg ($P=0.407$), respectively.

Table 1. Baseline demographic characteristics. ESPB, erector spinae plane block; SD, standard deviation; LWI, local wound infiltration.

Variable	ESPB Group (num.=thirty-three)	LWI Group (num.=thirty-three)
Age (years), mean $\pm$ SD	52.67 ± 10.97	49.52 ± 14.66
Age range (years)	33–76	17–78
Weight (kg), mean $\pm$ SD	84.85 ± 11.22	82.53 ± 10.76
Weight range (kg)	65–109	60–106

Primary outcome: 24-hour morphine consumption

Mean 24-hour postoperative morphine consumption was reported as 4.00 ± 1.40 in the ESPB group and 3.60 ± 1.34 in the LWI group ($P=0.659$).

Table 2. Primary and secondary analgesic outcomes.

Outcome	ESPB Group	LWI Group	P-value
24-h morphine consumption, mean $\pm$ SD	4.00 ± 1.40	3.60 ± 1.34	0.659
Range	2–5	2–5	—

Secondary outcomes**Intraoperative fentanyl consumption**

Intraoperative fentanyl consumption was comparable between groups (ESPB: 106.06 ± 20.76 $\mu\text{g/kg}$; LWI: 104.69 ± 19.51 $\mu\text{g/kg}$; $P=0.784$).

Hemodynamic parameters

Intraoperative MAP and HR values showed similar trends in both groups across the reported time points. Although the ESPB group exhibited slightly higher MAP and HR values at some time points, these variances were not statistically significant (all P above 0.05).

Postoperative pain scores

NRS pain scores at rest and during movement were similar between groups at all reported time points from immediate postoperative recovery through 24 hours (all P above 0.05). Median NRS scores remained low in both groups throughout the observation period.

Postoperative complications and patient satisfaction

PONV occurred in 3 cases (9.1%) in the ESPB group and 1 patient (3.0%) in the LWI group ($P=0.302$). Case satisfaction has been reported as high in both groups (93.9% vs. 90.9%; $P=0.642$). No episodes of local anesthetic systemic toxicity, pneumothorax, arterial puncture, respiratory depression, urinary retention, or pruritus were recorded in either group.

Table 3. Postoperative complications and patient satisfaction. LAST, local anesthetic systemic toxicity; LWI, local wound infiltration; PONV, postoperative nausea and vomiting.

Variable	ESPB Group (n=33)	LWI Group (n=33)	P-value
PONV – mild, n (%)	3 (9.1%)	1 (3.0%)	0.302
PONV – none, n (%)	30 (90.9%)	32 (97.0%)	—
Patient satisfied, n (%)	31 (93.9%)	30 (90.9%)	0.642
LAST / pneumothorax / other complications	0 (0%)	0 (0%)	—

DISCUSSION

The principal finding of this randomized controlled trial is that statistically insignificant variances have been observed between LWI and ultrasound-guided ESPB in the reported analgesic outcomes among patients undergoing BCS. The groups did not differ significantly in the reported primary outcome of 24-hour morphine consumption, intraoperative fentanyl requirements, postoperative NRS pain scores, hemodynamic parameters, PONV, or patient satisfaction. No study-related complications were recorded.

These findings are relevant to the selection of analgesic techniques for limited breast procedures. ESPB requires ultrasound equipment and an operator familiar with ultrasound-guided regional anesthesia, whereas LWI can be performed with standard equipment at the surgical site. The present findings should therefore be interpreted within the specific surgical context studied rather than generalized to all breast operations.

Our results are consistent with the literature demonstrating analgesic efficacy of ESPB in breast surgery [14]. Gürkan et al. reported diminished postoperative opioid consumption with ESPB than control. In contrast, the present study compared ESPB directly with LWI in BCS, and statistically insignificant variance has been detected between the two techniques.

A systematic review and network meta-analysis by Wong et al. [15] stated differences among local and regional

analgesic modalities in breast operation, particularly across procedures of differing extent. The present study focused on BCS and therefore should not be extrapolated to larger breast operations without further evidence.

Previous studies have also described the role of wound infiltration in postoperative pain management [16,17]. The influence of wound infiltration may depend on the extent of tissue dissection, incision characteristics, local anesthetic concentration and volume, and timing of administration. The findings of Syal and Chandel [18], who compared regional techniques with local infiltration in modified radical mastectomy, further illustrate the importance of surgical context. Modified radical mastectomy involves greater tissue dissection than the limited BCS procedures described in the present study. Differences among studies may therefore reflect differences in surgical extent and analgesic requirements.

An intraoperative observation of possible interference with diathermy coagulation after LWI was noted by the surgical team. Because this observation was not prospectively quantified, it should be regarded as exploratory and hypothesis-generating rather than as a study outcome.

Limitations

- This was a single-center research, that may limit generalizability to other patient populations and surgical settings.

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- The sample size has been calculated for the primary result and may not have been sufficient to detect modest variances in secondary outcomes.
 - BCS encompasses procedures that may differ in incision size, location, and extent of axillary surgery; the absence of detailed stratification may introduce heterogeneity.
 - Long-term outcomes, including chronic postoperative pain at 3 and 6 months, were not assessed.
 - The reported observation regarding diathermy interference was not systematically recorded.
 - The manuscript requires verification of the reported opioid units, the primary-outcome P value, and the age-range discrepancy before submission.
- Future multicenter trials with standardized BCS classification, adequate sample size, detailed surgical characterization, and longer follow-up would help clarify the comparative role of LWI and ESPB.

CONCLUSION

In cases undergoing breast-conserving operation with limited incisions, statistically insignificant variances have been detected between local wound infiltration and ultrasound-guided ESPB in the reported postoperative analgesic outcomes. LWI may represent a practical wound-directed analgesic option when its use is appropriate for the surgical procedure and patient. Selection of analgesic technique should consider surgical extent, patient characteristics, local anesthetic dosing, available expertise, and available resources.

Author Contributions (CRediT)

Conceptualization: T.H.K.A., K.M.K. Data curation: T.H.K.A. Formal analysis: T.H.K.A. Investigation: T.H.K.A., K.M.K. Methodology: T.H.K.A., W.S., K.M.K. Project administration: T.H.K.A. Supervision: M.E.M.A., W.S., K.M.K. Writing – original draft: T.H.K.A. Writing – review & editing: M.E.M.A., W.S., K.M.K.

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Highlights

- No statistically significant difference was observed in postoperative analgesic outcomes between ultrasound-guided ESPB and local wound infiltration in cases undergoing breast-conserving surgery with limited incisions.
- The two groups showed similar reported 24-hour morphine consumption, intraoperative fentanyl use, postoperative pain scores, and hemodynamic parameters.
- PONV and case satisfaction were also similar between groups.
- Local wound infiltration is technically simple and does not require ultrasound equipment or a dedicated regional anesthesia procedure.
- The analgesic technique should be considered in relation to the extent and characteristics of breast surgery.

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