

Evaluating the pectoralis nerve blocks I & II for mastectomy patients at an academic hospital: A prospective observational cohort study.

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Abstract

Background:

Poorly managed perioperative mastectomy pain increases the incidence of chronic pain. The aim of this study was to compare PEC I & II blocks versus the administration of local anaesthesia (LA) via a surgical drain in female patients presenting for unilateral mastectomy. These techniques were compared with regard to postoperative pain scores, satisfaction, time to first request for systemic opioids postoperatively, opioid consumption, the incidence of postoperative nausea and vomiting (PONV), and complications.

Methods:

A prospective, cohort, observational, single-centre study with 33 female participants who were recruited via purposive sampling; three were excluded from the study. Participants were assigned to PEC blocks (Group P, n=15) or LA via surgical drain (Group S, n=15). Group S received the standard of care, which was administration of 2mg/kg of 0.5% bupivacaine with adrenaline (1:200,000) via the surgical drain. Group P received 0.2ml/kg of 0.5% bupivacaine plus adrenaline (1:200,000) in each fascial plane.

Results:

There were no significant differences in participants' characteristics in the groups. The study showed no statistically significant difference between the pain scores of the groups at 30 minutes, 3, 6, and 24 hours postoperatively ($p=0.660$, $p=0.160$, $p=0.894$, $p=0.931$). The differences in patient satisfaction scores and morphine consumption were statistically insignificant. No complications were noted in either of the groups. No statistically significant relationship with the occurrence of vomiting and nausea and the specific technique.

Conclusion:

This study showed no difference between PEC I & II blocks and the administration of LA via a surgical drain in the management of postoperative pain in mastectomy patients. The techniques can be considered safe, as there was a low incidence of the described complications, including the incidence of PONV.

Recommendations:

The author recommends further research in the form of randomised controlled trials with larger sample sizes comparing all breast regional modalities.

Keywords: breast cancer, chronic pain, mastectomy, pain, pectoralis nerve block, surgical drain, bupivacaine.

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Introduction

The most prevalent cancer amongst women worldwide is breast cancer, with 1.7 million estimated diagnoses yearly. These patients undergo either a wide local excision, total mastectomy (unilateral or bilateral), or oncoplastic breast reduction with or without axillary lymph node dissections.¹ Post-mastectomy patients experience a significant amount of acute pain, and the evidence suggests that these patients are at a higher risk for chronic pain syndrome.² Senapathi et al. in 2014 reported a 41.8% incidence of chronic pain in breast surgery patients who experienced severe postoperative pain.³ Fitzgerald et al reported a prevalence of 30-50% severe postoperative pain in mastectomies.¹ Several perioperative risk factors have been identified in the development of chronic pain after breast surgery. The postoperative risk factor for developing chronic pain identified was severe acute postoperative pain.⁴⁻⁶ This presents the perioperative team with a variable that can be modified with regional anaesthesia to improve outcomes. The recommendation by the Enhanced Recovery After Surgery (ERAS) Society guidelines for breast surgery advocates for the use of a multimodal analgesic strategy including local anaesthetics to alleviate the pain intensity and reduce opioid consumption, as supported by the current evidence.⁷

Regional anaesthetic techniques have been shown to reduce the incidence of chronic post-surgical pain and may mitigate one of the factors involved in cancer recurrence.^{1, 8, 9} Several regional techniques for breast surgery have since been described, namely, the serratus anterior plane block, the pecto-intercostal fascial block, serratus intercostal fascial block, rhomboid intercostal and sub-serratus plane block, erector spinae plane block, retrolaminar block, the mid-point transverse process to pleura block, and the pectoralis nerve block (PEC).¹

The pectoralis nerve I (PEC I) block was initially described by Blanco et al. in 2011 as a technique in which local anaesthesia was injected between the pectoralis major and minor muscles to block the medial and lateral pectoral nerves.^{10, 11} The pectoralis nerve II (PEC II) block was also described by Blanco et al. in 2012 as requiring the injection of local anaesthesia between the pectoralis major and minor muscles as well as between the pectoralis minor and serratus muscle with the intention to block the intercostobrachial, three to four intercostal, and long thoracic nerves.^{10, 12} The medial and lateral pectoral nerves, which innervate the pectoralis major and minor muscles, run between the clavipectoral fascia and the pectoral fascia. These nerves arise from C5-7 and C8-T1, respectively, of the brachial plexus. The PEC I block requires the deposition of a local

anaesthetic volume of 0.2-0.4 ml/kg in that inter-fascial plane. The PEC II block requires the deposition of 0.2-0.4 ml/kg of local anaesthetic between the clavipectoral fascia and the superior border of the serratus anterior muscle. The PEC blocks are ultrasound-guided regional anaesthetic techniques as the fascial planes must be identified for the administration of the local anaesthetic into the planes.¹⁰

The complications associated with the PEC blocks include potential local anaesthetic systemic toxicity due to the large volume, arterial puncture of the thoracoacromial artery, hematoma formation, and pneumothorax.^{1, 6} However, there are reports of intraoperative hypotension with PEC blocks. There is scarce literature that reports of other complications with ultrasound-guided PEC blocks.⁶

The administration of a local anaesthetic via the surgical drain in mastectomy patients has also been investigated. Talbot et al. found that the difference in pain scores and morphine consumption was not significant.¹³ Beguinot et al. found a decrease in visual analogue scale (VAS) scores in the local anaesthetic group.¹⁴ Khpal et al. demonstrated a statistically significant decrease in pain scores, but the morphine consumption difference was not statistically significant.¹⁵ None of these studies suggest a distinct mechanism for the demonstrated analgesic efficacy.¹³⁻¹⁵ The authors propose that the mechanism is the local anaesthetic effect on the cutaneous branches of the intercostal nerves in the region.

Inadequate management of the post-mastectomy pain results in several short- and long-term sequelae. Breast cancer's 5-year survival after surgery is 85%, and thus the associated sequelae need to be recognised and managed.¹ Poorly managed perioperative mastectomy pain increases the incidence of chronic pain. Achieving effective perioperative pain management is the recommended strategy. This can be accomplished with regional anaesthetic techniques.² PEC blocks are a regional technique with a favourable risk profile, demonstrated good efficacy, and an uncomplicated administration technique.¹ PEC blocks confer numerous benefits aligned to enhanced recovery after surgery (ERAS) for post-mastectomy pain management guidelines.⁷ The current practice at Chris Hani Baragwanath Academic Hospital (CHBAH) as part of analgesia is the administration of local anaesthesia via a surgical drain as standard care.

At CHBAH, it is not known whether the analgesic benefit outweighs standard care in post-mastectomy patients. The aim of this study was to compare PEC I & II blocks versus the administration of local anaesthesia (LA) via a surgical drain in female patients presenting for unilateral mastectomy.

The primary objective of this study was to:

- compare post-operative pain utilising the Universal Pain Assessment Tool questionnaire between the two groups at 30 minutes, 3, 6, and 24 hours.

The secondary objectives of the study were to:

- compare patient satisfaction using a numerical rating scale
- compare the time to first request for systemic opioid post-operatively
- compare the systemic opioid consumption in morphine equivalents at 24 hours
- describe complications of PEC blocks
- compare the incidence of postoperative nausea and vomiting (PONV) postoperatively.

Methods

Study design

This study utilised a prospective, contextual, cohort, observational research design. The reporting guideline followed was the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guideline.

Study setting

The study was conducted in the theatre complex of CHBAH affiliated to the Department of Anaesthesiology at the University of the Witwatersrand. CHBAH is a 3200-bed central hospital with 25 theatres, of which 3 are general surgery theatres. The breast theatres perform an average of 480 mastectomies annually in theatres 15,16, and St. John's breast theatre. The study was conducted from 01 February 2023 to 28 February 2024.

Participants

The study population consisted of patients presenting for one-sided radical mastectomy surgery under general anaesthesia at CHBAH theatres.

Inclusion criteria

- ASA I-III
- elective one-sided radical mastectomy patients
- patients 18 years and older
- patients who consent to the study
- patients undergoing mastectomy between 07h00 and 13h00 on weekdays.

Exclusion criteria

- allergy to local anaesthetics and opioids
- previous diagnosis of chronic pain syndromes
- previous breast surgery on the same side

- contraindication to regional anaesthesia
- male patients
- patients who choose an analgesic modality other than the PEC block or the standard management

Sampling method

Purposive sampling method was utilised. Eligible patients booked for a radical mastectomy were identified at the preoperative visit the day before surgery and invited to participate in the study.

Study size

Stata statistical software was utilised for the calculation of the sample size. Based on a median pain score of 1.3 ($\pm$ 0.5 as SD) at 3 hours postoperatively obtained from a previous study³ in which PEC blocks were administered to mastectomy patients, a decrease of 60% in the pain score is needed to detect a significant difference in the PEC group. Thus, according to these parameters, a sample size of 30 patients (15 per group) was required at an alpha of 5% and power of 80%.

Bias

To minimise bias, the researcher used a standardised data collection sheet and ensured an appropriate sample size as guided by a biostatistician. The principal researcher's technique for PEC blocks was taught by a senior anaesthesiologist who has a postgraduate diploma in regional anaesthesia from the University of Montpellier. Ultrasound-guided PEC I & II blocks performed by the researcher were validated by a trained sonographer from the Department of Radiology affiliated with the University of the Witwatersrand. Utilising a Sonosite or GE ultrasound machine, which is standardised to depict the required images. A clear explanation of the universal pain assessment tool was provided to participants. Ensuring data was collected by the researcher. Appropriate data analysis with the guidance of a biostatistician.

Data collection

The participants were then allocated into study groups based on the anaesthetic regional technique they selected preoperatively. If the participant selected a PEC block, they were allocated to the PEC group (Group P), and if they selected the local anaesthesia via the surgical drain, they were allocated to the standard of care group (Group S). Participants who selected any of the other described anaesthetic regional techniques for breast surgery were excluded from the study.

All participants were transferred to the theatre table and monitored intraoperatively as per ASA standards. All participants received general anaesthesia and were maintained with oxygen, air, and sevoflurane. They received 20mg/kg paracetamol and 0.15mg/kg dexamethasone. Morphine 0.5mg - 0.1 mg/kg was administered as rescue analgesia when necessary. The attending anaesthetist managed any subsequent intraoperative analgesic requirements per their discretion. The additional morphine administered was taken into consideration for the data analysis.

Group P: The PEC block was placed according to the South African Society of Anaesthesiologists Guidelines for Regional Anaesthesia.¹⁶ Either a Fujifilm Sonosite, Sonoscape, or GE ultrasound machines with comparable efficacies were used to do the PEC blocks with a linear transducer (± 5.0 -15 MHz). The probe was placed at the midclavicular line in the sagittal plane, and the thoracoacromial artery was identified. The probe was then moved laterally till the pectoralis major, pectoralis minor, and serratus anterior were visible. The needle was then advanced into the inter-fascial plane between the pectoralis minor and the serratus anterior muscles, in which 0.2ml/kg of 0.5% bupivacaine plus adrenaline (1:200,000) was administered (PEC II). The needle was then retracted into the inter-fascial plane between the pectoralis major and the pectoralis minor, in which 0.2ml/kg of 0.5% bupivacaine plus adrenaline (1:200,000) was administered (PEC I). A toxic dose of 2mg/kg was calculated and not exceeded.¹⁰

Group S: Participants received the standard of care, which was administration of 2mg/kg of 0.5% bupivacaine with adrenaline (1:200,000) via the surgical drain. The clamp on the surgical drain was removed in the post-anaesthetic care unit 30 minutes after the instillation of the local anaesthetic. The following time intervals were used in this study:

Time 0 (T0): 30 minutes postoperatively in the post-anaesthetic care unit.

Time 1 (T1): 3 hours postoperatively.

Time 2 (T2): 6 hours postoperatively.

Time 3 (T3): 24 hours postoperatively.

Data measurement

All data were captured on a collection sheet. The pain severity was assessed with the UPAT in all participants at all time intervals. Complications, PONV, and total systemic opioid analgesic requirements post a PEC block or anaesthetic via drain were determined in morphine equivalent doses at T3. Overall patient satisfaction using a numerical rating scale was noted at T3. The data were then consolidated into a single Microsoft Excel[®] sheet.

Variables

Variables included age, weight, and duration of surgery. In the intraoperative period, additional analgesia and PONV prophylaxis were indicated in the anaesthetic charts. Pain scores using UPAT and satisfaction score using NRS were also recorded. Time to first opioid request, the opioid given, route of administration, and total dose given in 24 hours were recorded.

Statistical analysis

The data collected were entered into the Statistical Package for Social Science (SPSS) software. The qualitative data were subsequently presented in frequency tables, and comparisons were done with Chi-square tests and Fisher's exact tests. A z-test was applied for the normality test using skewness and kurtosis. The quantitative data comparisons were performed with the independent t-test. The confidence interval was 95%, the margin of error accepted was set to 5%, and a p-value of < 0.05 was considered significant.

Ethical considerations

Approval was obtained from the Human Research Ethics Committee (Medical) Clearance certificate number: M220856 on the 16th of November 2022, the Postgraduate Committee (Medical) of the University of the Witwatersrand and other relevant authorities, the CHBAH Medical Advisory Committee, and National Health Research database study number (GP_202208_073).

The participants were then allocated into study groups based on the anaesthetic regional technique they selected preoperatively. Participants were assigned a study number. A list correlating the patient-identifying details with the patient number was kept electronically and separately from the data analysed for the study. The list of patient details, study numbers and raw data remain confidential, with access provided only to the study researcher and supervisors for paper-based and electronic information. Data is stored securely after completion of the study in a locked cupboard for paper-based information, including the signed consent forms and data collection sheets; and for electronic data is kept on a password-protected database.

Informed consent

Eligible patients booked for a radical unilateral mastectomy were identified at the preoperative visit the day before surgery and invited to participate in the study. The participants were offered the different regional anaesthetic modalities by the primary anaesthetic team for breast surgery commonly used in current practice and the standard of care at CHBAH. Patients who chose standard care or PEC block were invited to participate in the study. Information

regarding the study aims and objectives, the study intervention, potential benefits, possible complications, voluntariness, and the right to decline participation in the study was explained. This information was shared verbally, and an information sheet was provided for them to read. The researcher answered any questions. If the patient agreed to participate in the study, they signed a consent form and kept the information sheet.

Thirty-three participants were recruited (Figure 1); three were excluded from the study. The exclusions were two participants who were postponed for surgery and one who received an erector spinae plane block (ESPB). The participants' characteristics are demonstrated in Tables I and II. The data indicate that there was no significant difference between the groups. Most participants had an ASA classification of two and demonstrated no significant difference ($p=0.682$).

Results

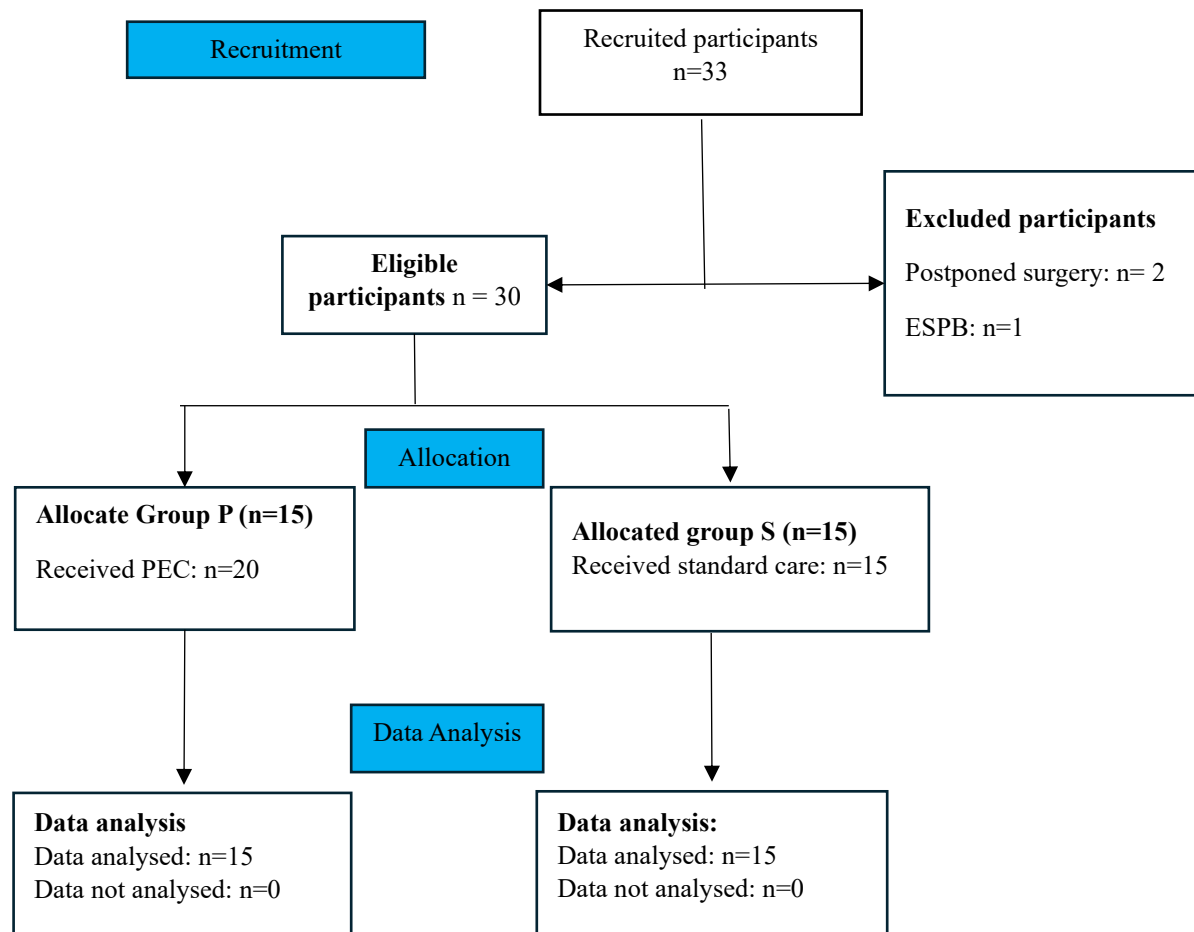


Figure 1: Case selection flow diagram.

Table I. Patient Characteristics

Patient Characteristics	Group S Mean (SD)	Group P Mean (SD)	p value
Age (years)	53.47 (10.288)	58.80 (15.694)	.280*
Weight (kg)	77.27 (16.757)	80.47 (12.609)	.559*

* *Independent samples t-test*

Table II. Surgical duration

	Category	Group S	Group P	p value
Duration of surgery- n (%)	<2 hr	13 (46.4%)	15 (53.6%)	.483 [†]
	2-3 hr	2 (100%)	0	

[†] *Fisher's exact test*

Participants' post-operative pain scores utilising the UPAT at different time intervals are shown in Figure 2. The significance level of 5% demonstrates that the differences are not statistically significant. The 3-hour pain scores showed a slight increase among the Group P participants but were statistically insignificant.

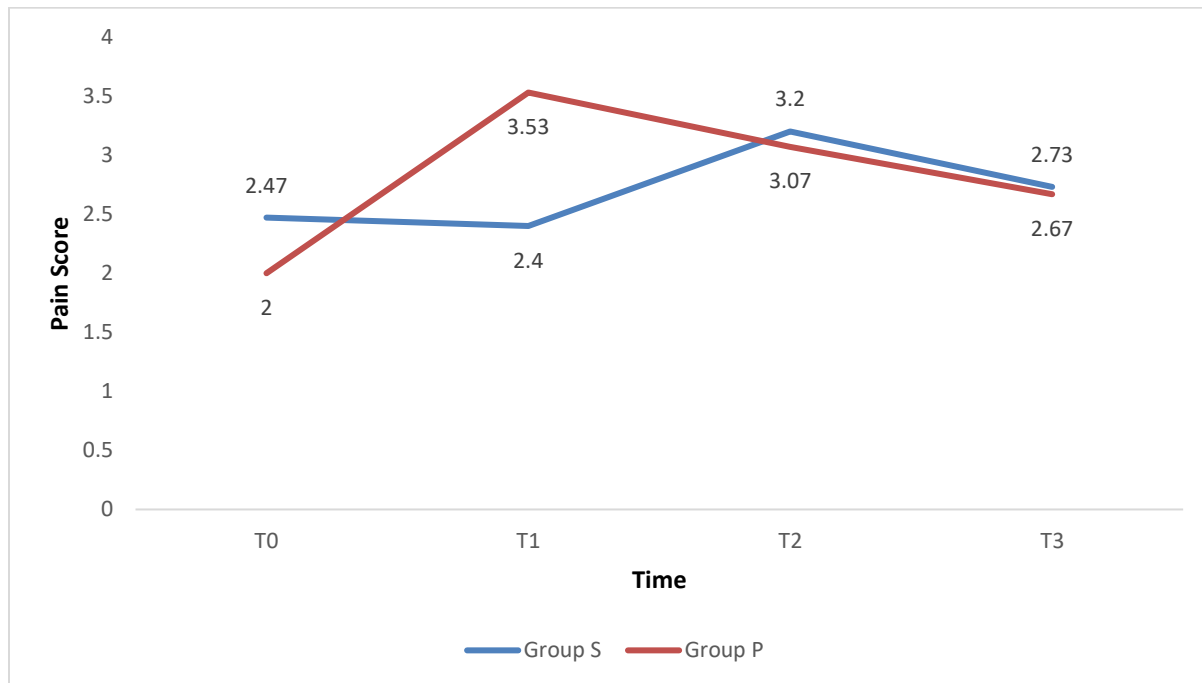


Figure 2. Pain Scores

Table III compares the participants' overall satisfaction score with their pain management.

Table III. Satisfaction score

	Group P Mean $\pm$ SD	Group S Mean $\pm$ SD	p value
Numerical rating scale	7.33 $\pm$ 1.589	8.13 $\pm$ 1.727	.197*

* *Independent samples t-test*

Time to first request for systemic opioid postoperatively was not assessed as the data were not collected.

Table IV. Morphine consumption

	Group P Mean $\pm$ SD	Group S Mean $\pm$ SD	<i>p</i> value
Morphine consumption (mg)	23.33 $\pm$ 7.237	21.33 $\pm$ 5.164	.392*

** Independent samples t-test*

Table IV compares the two groups' morphine consumption postoperatively and notes that both groups received a similar amount.

No complications were noted in either of the groups. No statistically significant relationship with the occurrence of vomiting and nausea and the specific technique. Fisher's exact test demonstrated this lack of association with a *p*-value = 1.000.

Discussion

The participants in this study demonstrated similar characteristics between the two groups, including the duration of the surgery. This provided a homogeneous group of study subjects for comparisons to be made even though the data were collected over one year. The results of this study demonstrated that the participants in Group P and Group S reported similar postoperative pain scores at all the time intervals (Figure 2). The greatest difference between the reported pain scores noted was at T1, with Group P demonstrating a mean and SD of 3.53 ± 2.200 and Group S 2.40 ± 2.098 ; however, the difference remained statistically insignificant *p* = .160. A recent review article looked at 15 different PEC block studies that were compared to placebos or other regional techniques and demonstrated better analgesic efficacy in 13 of the studies. Local anaesthetic via the surgical drain has also been compared to placebos and showed analgesic superiority.^{6, 17} However, no studies have evaluated and compared specifically PEC blocks and local anaesthetic via the drain after extensive literature review. A study by Barrington et al. compared PEC II blocks to local anaesthetic infiltration into the subcutaneous and cutaneous tissue at the completion of surgery by the surgeon. This study is the closest in similarity to this study that can be used to compare. They demonstrated no statistically significant difference in the quality of recovery (QoR) questionnaire between the techniques. It is worth noting that the pain scores in the QoR were also statistically insignificant.¹⁸ This seems to support this study's results.

The satisfaction scores between the groups assessed with a numerical rating scale were similar between the groups (Table III, *p* = .197). This suggests that the two techniques have similar efficacy. It should be noted that the satisfaction score may be influenced by other aspects of the participants' overall care, as noted by McNeill et al., such as cognitive and behavioural factors.¹⁹

This study did not demonstrate any difference in time to first request for systemic opioid administration, as no data were collected and thus no comment can be made regarding this objective. However, a meta-analysis of PEC blocks demonstrated significant prolongation in the time to first request of postoperative analgesia by 296.69 minutes.⁶

Morphine consumption in this study was the same between the groups, which is in keeping with a previous study by Khpal et al. that compared local anaesthetic via a surgical drain and direct infiltration.¹⁵ This was further supported by a similar study by Beguinot et al. that noted that the morphine consumption difference was almost statistically significant postoperatively.¹⁴ However, a review by Bin Ghali et al. comparing PEC blocks to other regional anaesthetic techniques or placebos showed a statistically significant decrease in the postoperative opioid consumption in the PEC block group except for two studies.¹⁷ It should be noted that this study's cumulative opioid consumption was confounded by the protocolised postoperative analgesic regimen of the institution.

No complications were reported in this study, which is consistent with other studies.^{1, 6, 20} The reported complications in the other studies appeared to arise not from the PEC blocks or local anaesthetic via the drain techniques but rather from paravertebral blocks or thoracic epidurals.^{1, 21} A meta-analysis of PEC block studies reported hematoma formation in one study; however, no other complications were related to the PEC block technique.⁶

This study had one participant report the experience of postoperative nausea. The 2023 Bin Ghali et al. meta-analysis supports the results from this study. This meta-analysis showed 5 studies that demonstrated a statistically

significant decrease in the incidence of postoperative nausea and vomiting (PONV) in post-mastectomy participants who received regional anaesthetic techniques.¹⁷ The proposed reduction in PONV is most likely due to the opioid sparing effects of these regional techniques.²²

Generizability

The results of this prospective cohort observational study are mainly relevant to adult female patients a PEC block for unilateral radical mastectomy in similar urban public-sector central tertiary hospitals in South Africa. As the research was conducted at a single hospital in central Johannesburg, the findings are most applicable to populations with comparable public healthcare systems, referral patterns, availability, and perioperative practices.

Conclusion

The techniques evaluated in this study demonstrate a similar analgesic benefit in the management of postoperative pain in mastectomy patients. Patients' similar overall satisfaction and postoperative opioid consumption may be because of the equivalent pain scores across the two techniques. The techniques can be considered safe, as there is a low incidence of the described complications, including the incidence of PONV.

Limitations

This study, however, has several limitations that may have affected the results. The inherent disadvantages of an observational study design. These disadvantages include the potential presence of confounding factors, the presence of bias, and the inability to control variables. The purposive sampling method may have introduced selection bias. The study's contextual nature needs to be considered when extrapolating the results and applying them at different sites. Thus, the results of the study may not translate to other breast surgery units at different sites. The different participants' cancer stages were not considered and may have affected the pain scores. A further confounding factor of the study was the protocolised nature of systemic opioid administration postoperatively to the participants in the ward at the institution.

Recommendations

The authors recommend that further research in the form of randomised controlled trials with larger sample sizes is necessary. Involvement of the institution's ward to avoid a regimented postoperative analgesic plan. The inclusion of an opioid only control group to compare with the regional

anaesthetic groups. Comparisons of local anaesthetic via the surgical drain and other regional techniques like the erector spinae plane block may elucidate further knowledge that would improve our understanding and management of postoperative pain in breast surgery.

Conflict of interest

The authors declare no conflict of interest.

Funding statement

No funding was received to complete this study.

Data availability

Data are available from the corresponding author upon request.

List of abbreviations

ASA	American society of anaesthesiology
CHBAH	Chris Hani Baragwanath Academic Hospital
ERAS	Enhanced recovery after surgery
ESPB	Erector spinae plane block
LA	Local anaesthesia
PEC	Pectoral nerve block
PIFB	Pecto-intercostal fascial block
PONV	Postoperative nausea and vomiting
QoR	Quality of Recovery
SPSS	Statistical Package for Social Science
STOBE	Strengthening the Reporting of Observational Studies in Epidemiology
UPAT	Universal Pain Assessment Tool
VAS	Visual Analog Scale

Author contributions

Pablo Samuel Tshiteta: Conceptualisation, literature search, study design, methodology, protocol drafting, data collection, manuscript drafting.

Lunganga Toms Lushiku: Supervision, conceptualisation, methodology, validation, review, revising based on feedback, editing, and ensuring the work is accurate and properly cited.

Mathabe Sehlapelo: Supervision, conceptualisation, methodology, validation, review, editing, revising based on feedback, ensuring the work is accurate and properly cited. Ensuring adherence to ethical considerations. All authors have read and approved the final version of the manuscript.

Author biography

Pablo Samuel Tshiteta is a dedicated anaesthesiologist with a strong passion for perioperative medicine, critical care,

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