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PERCENTAGE OF PATIENTS REQUIRED RE-EXCISSION OR MASTECTOMY FOLLOWING POST-BREAST CONSERVING SURGERY

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Abstract

Objective:
To evaluate the frequency, predictors, and outcomes of re-excision or mastectomy following BCS in patients with operable breast carcinoma.
Study design: Prospective observational study

Place and duration of study:
Department of general surgery, Surgical Unit 1, Ward 3, Jinnah post graduate medical Centre Karachi from August 2023 to August 2024.

Methods:
A total of 50 patients with operable breast carcinoma were enrolled who were on BCS. Both clinical and radiological parameters, intraoperative findings, and histopathological parameters were recorded prospectively. Intraoperative frozen-sectional evaluation of margins was performed in all patients and immediate re-excision/shaving of the cavity was performed if margins were involved.

Results:
A negative margin was obtained in 76% of patients, while 24% needed additional surgery. A total of 16% underwent re-excision lumpectomy and 8% completed mastectomy. Two patients by none other than their choice went for mastectomy when they were able to be offered more breast conservation techniques. Factors that were significantly associated with margin positivity were larger tumor size (>3cm, p = 0.02) and lobular histology (p = 0.04). Selected cases had a high risk for recurrent intervention due to previous close margins, poor radiotherapy compliance, and irregular follow up. During a mean follow-up of 12 months, no local recurrence was seen.

Conclusion:
Larger tumor size and lobular histology were associated with margin positivity. Careful surgical planning, intraoperative margin assessment, multidisciplinary

care, and adherence to adjuvant therapy may help reduce re-excision rates and improve outcomes following breast-conserving surgery.

Introduction

Breast cancer is the leading cancer type amongst women, with more than two million new cases reported every year and one of the biggest challenges for the global health system.1 Surgical resection is the key to curative management in early-stage disease, although advances in systemic therapy and screening have improved.2 In recent years, breast conserving surgery (BCS) combined with adjuvant radiotherapy has become the preferred choice for suitable patients, and has been shown to have equal survival, cosmetic and QOL advantages.3

The increasing implementation of screening programs has facilitated earlier detection of breast cancer and contributed to a greater utilization of BCS in clinical practice. 4 One of the most important factors for successful BCS is to reach negative surgical margins.5 Margin positivity (when tumor cells are found within or near the inked surgical margin) has been described as a robust risk factor for local recurrence and requirement for further surgery.6

The rates of positive margins reported are also highly variable, ranging from 20 to 30%, depending on the characteristics of the tumor, the level of surgical experience and the protocol followed in the institution.7 Repeat lumpectomy or completion mastectomy is sometimes required in case of positive margins, resulting in a greater likelihood of patient morbidity, psychological distress, rising health care costs, and potentially a delay in adjuvant therapy.8

Several clinicopathological factors have been identified as predictors of positive margins and subsequent re-excision. Larger tumor size, multifocal disease, and invasive lobular carcinoma have consistently been associated with higher rates of incomplete excision. 9The diffuse growth pattern of invasive lobular carcinoma presents a unique difficulty since preoperative imaging and clinical evaluation frequently underestimate the real extent of a disease.10 Although developments in breast imaging and intraoperative margin assessment techniques have improved surgical planning, a significant number of patients still require further surgery after their initial BCS .5These problems are especially relevant in low- and middle-income countries, where limited access to advanced imaging facilities and delayed presentation might have a negative impact on surgical results. 11

The current recommendations from the Society of Surgical Oncology and the American Society for Radiation Oncology advocate "no ink on tumor" as the conventional definition of an acceptable margin for invasive breast cancer; nonetheless, variability in local practice persist.12 Such variations may contribute to differences in re-excision rates across institutions and regions.

The evaluation of re-excision and complete mastectomy rates after BCS is critical for assessing surgical quality, refining institutional protocols, and improving patient counseling .13 Although there is extensive evidence from Western communities, data from South Asian contexts is limited. Identifying factors associated with inadequate margins and repeat surgery may facilitate better patient selection, improve surgical planning, reduce re-excision rates, and enhance overall oncological outcomes.

The current prospective study aims to investigate the frequency of re-excision and completion mastectomy following breast-conserving surgery, as well as the clinicopathological variables related with these outcomes in a tertiary care setting. The findings are intended to give region-specific data to help with evidence-based surgical decision-making and breast cancer treatment.

Methods

Study design, Place and duration of study:

This was a prospective observational study conducted in Department of general surgery, Surgical Unit 1, Ward 3, Jinnah post graduate medical Centre Karachi from August 2023 to August 2024

Ethical consideration:
The Jinnah Postgraduate Medical Centre (JPMC), Karachi's Institutional Review Board (IRB) granted ethical approval (IRB No.F.2-79/2024-GENL/260/JPMC). Prior to participation, each participant provided written informed consent. patient information was kept private and anonymous throughout the study.

Inclusion Criteria:
Female patients aged ≥18 years.
Histopathological examination confirmed operable, non-metastatic breast cancer.
The multidisciplinary tumor board determined that the patients were suitable candidates for breast-conserving surgery.
Patients agree to offer written informed consent.

Exclusion criteria
Locally advanced breast cancer.
Metastatic breast cancer.
Recurrent breast cancer.
Previous breast radiation.
Patients refused to participate or give informed consent.

Sample Size Estimation
The sample size was determined using the WHO sample size calculator. Using the estimated frequency of re-excision following breast-conserving surgery of 24%, a confidence level of 95%, and an absolute accuracy of 12%, a sample size of 50 patients was computed.

Study protocol
After receiving ethical approval and informed consent, a total of 50 eligible female patients with operable, non-metastatic breast cancer were considered appropriate candidates for BCS by the multidisciplinary tumor board. Clinical, radiological, and histological data were collected. All patients undergoing BCS had intraoperative frozen section assessment of surgical margins. When margin positivity was recognized, immediate re-excision of the cavity with "shaving," was done; depending on the involvement of the margin, in the same operative setting Patients were followed up on a regular basis in the outpatient department to examine their margin condition, the necessity for re-excision or complete mastectomy, and disease recurrence. Data were gathered prospectively and examined to determine the parameters related with additional surgical intervention.

Statistical Analysis
The data were entered and analyzed with SPSS version 26. Variables (age and tumor size) were given as mean ± SD, whereas categorical variables (margin status, histological type, and necessity for re-excision or mastectomy) were provided as frequencies and percentages. The Chi-square test or Fisher's exact test were used to investigate associations between clinicopathological factors and margin positive, if applicable. A p-value of ≤0.05 indicated statistical significance.

Results
The total number of 50 female patients undergoing breast-conserving surgery (BCS) were included in this study. The mean age was 49.3 ± 10.6 years. Most of the patients (62%) had the stage II disease; and 10% had stage III disease with 28% being stage I. The majority of cancers were invasive ductal (82%), 12% were invasive lobular and the remaining 6% were of other, less common histogram. The mean tumor size was 2.7 ± 1.1 cm as shown in table 1.

Table 1. Baseline Characteristics of Patients (n = 50)

Variable	n (%) or Mean ± SD
Age (years)	49.3 ± 10.6
Age <50 years	27 (54%)
Age ≥50 years	23 (46%)
Stage I	14 (28%)
Stage II	31 (62%)

Stage III	5 (10%)
Histology – Ductal	41 (82%)
Histology – Lobular	6 (12%)
Others	3 (6%)
Mean tumor size (cm)	2.7 ± 1.1

Negative surgical margins were achieved in 38 (76%) individuals after the first BCS. Positive or near margins that required further surgery were seen in 12 (24%) individuals. Of them, 8 (16%) had re-excision lumpectomy and 4 (8%) had complete mastectomy. Of the patients who had complete mastectomy, two had extensive margin involvement and two chose mastectomy while they were eligible for additional breast-conserving surgery (Table 2).

Table 2. Margin Status and Surgical Outcomes

Surgical Outcome	n	%
Negative margins (no further surgery)	38	76%
Positive/close margins (further surgery)	12	24%
Re-excision lumpectomy	8	16%
Completion mastectomy	4	8%
Extensive margin involvement	2	4%
Patient preference despite eligibility for BCS	2	4%

Analysis of features associated with margin positivity revealed a significant connection with tumor size >3cm (58.3% vs. 21.1%, p=0.02) and lobular histology (25.0% vs 7.9%, p=0.04). There was no significant relationship between margin positivity and age ≥50 years (p=0.71) or high tumor grade (p=0.52) (Table 3).

Table 3. Factors Associated with Margin Positivity

Factor	Margin Positive (n = 12)	Margin Negative (n = 38)	p-value
Tumor size >3 cm	7 (58.3%)	8 (21.1%)	0.02*
Lobular histology	3 (25.0%)	3 (7.9%)	0.04*
Age ≥50 years	5 (41.7%)	18 (47.4%)	0.71
High tumor grade	6 (50.0%)	15 (39.5%)	0.52

*Statistically significant

The patients were followed clinically and radiologically for a mean of 12 months (range 6–18 months). Patients requiring further operations frequently had close margins (<0.5 cm) previously. Some cases had poor compliance to adjuvant radiation and follow-up. However, there was no local recurrence during the follow-up period.

Discussion

Breast-conserving surgery (BCS) has become the preferred surgical treatment for appropriately selected women with early-stage breast cancer. However, attaining negative surgical margins is still a challenging process. In the current study, negative margins were attained in 76% of patients, whereas 24% required further surgical interventions. These findings are consistent with previously reported rates of positive margins and

reoperations following BCS, highlighting the ongoing issue of balancing oncologic safety with breast conservation.7

Positive surgical margins are linked to a higher risk of local recurrences and are frequently associated with further surgical treatments. Despite advancements in surgical methods and pathological assessment, re-excision is still a typical part of breast conservation treatment.14Additional surgery after BCS can increase patient morbidity, psychological suffering, treatment expenses, and postpone adjuvant therapy. As a result, reducing the need for reoperation remains an important goal for breast cancer treatment .15

In the current study, tumor size was found to be a key predictor of margin positive. Patients with tumors larger than 3 cm were more likely to require further surgery. Kumar et al. observed similar findings, demonstrating that increasing tumor burden is associated with a higher likelihood of microscopic disease persistence along the surgical margin.16 Similarly, Chauhan et al. found that larger tumor size was a significant clinicopathological predictor of positive margins following breast-conserving surgery.17

Histologic subtype was also a significant influence in surgical outcomes. Patients with invasive lobular carcinoma showed more positive margins than those with invasive ductal carcinoma. Invasive lobular carcinoma is frequently associated with an underestimate of disease area on imaging, increasing the risk of partial excision .18 Furthermore, breast tumors are multicentric and histologically varied, which may make it more difficult to achieve adequate surgical clearance.19 The diffuse infiltrative growth pattern of invasive lobular carcinoma frequently makes it difficult to precisely detect the tumor before surgery in accordance with Perezlucha et al.20

In addition to tumor-related concerns, the characteristics of breast tissue might influence the margin status. Dense breast tissue and residual glandular tissue have been proven to be factors that may complicate surgical planning and result in insufficient excision in certain patients.21

All patients in this study had regular intraoperative frozen-section examination. The good margin clearance rate might be attributable to prompt cavity shaving when margin involvement was detected. Previous research has demonstrated that intraoperative margin evaluation procedures aid to minimize delayed reoperations and improve surgical outcomes by allowing for real-time decision making.22

During the follow-up period, no local recurrence was detected. Because the follow-up period was brief, the findings on long-term oncological safety are restricted yet promising. Adherence to adjuvant therapy and thorough monitoring is critical, particularly in low- and middle-income countries where delays in treatment and follow-up might have a detrimental impact on outcomes.23

The current study has several distinguishing features, including a prospective design, standardized surgical method, frequent intraoperative margin evaluation, and a detailed analysis of clinicopathological factors associated with margin positivity. These findings provide important regional information on the outcomes of breast conserving surgery at a tertiary care facility.

Limitations

The study was conducted at a single tertiary care hospital with a limited sample size and a short follow-up time, which may limit the generalizability of the findings. Larger multicenter studies with longer follow-up periods are required to validate these findings and assess the long-term oncological implications.

Conclusion

In this study, 24% of patients underwent a re-excision lumpectomy or complete a mastectomy following breast-conserving surgery. Tumor size and invasive lobular histology were strongly associated with positive margins. Intraoperative frozen-section screening can help assure margin clearance and perhaps reduce the need for additional operative procedures. Careful pre-operative evaluation, appropriate patient selection, and multidisciplinary therapy are critical for optimizing outcomes following breast conserving surgery.

Author Contributions

Dr. Qandeel Fatima: Conceived and designed the study, collected data, performed statistical analysis, interpreted results, drafted the manuscript, and served as the corresponding author.

Dr. Tanweer ahmed: Contributed to study design, supervised data collection, critically reviewed the manuscript, and approved the final version.

Prof. Dr. Zahid Mehmood: Supervised the research project, contributed to study methodology, critically revised the manuscript for intellectual content, and approved the final version.

Dr. kanwal gadit: Assisted in study design, patient recruitment, data interpretation, manuscript review, and final approval.

Dr. rafia: Participated in data collection, literature review, manuscript drafting, and final approval.

Dr. isha: Assisted in data collection, data entry.

All authors read and approved the final manuscript and agree to be accountable for all aspects of the work.

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