DEVELOPMENTAL MEDICO-LIFE-SCIENCES

ISSN (P): 3007-2786, (E): 3007-2794 DOI: https://doi.org/10.69750/dmls.01.09.072

ORIGINAL RESEARCH ARTICLE Open Access

Evaluating the Role of Intraoperative Imaging Techniques on Surgical Margins and Recurrence Rates in Breast-Conserving Surgery

Hamid Bin Tariq [1], Suleman Saeed [1], Maira Khan [2], Zoha Kashif [1], Syed Muhammad Ali [3], Palwasha Shabbir [1], Muhammad Nauman Shahid [4]*

1- University College of Medicine and Dentistry (UCMD), Lahore, Pakistan
2- Allama Iqbal Medical College (AIMC), Lahore, Pakistan
3- King Edward Medical University (KEMU), Lahore, Pakistan
4- Lahore Medical & Dental College (LM&DC), Lahore, Pakistan

***Corresponding Author:** Hamid Bin Tariq **Email:** drhamidtariq@gmail.com **Cell:** +923096736236

ABSTRACT

Background: Achieving clear surgical margins is critical in breast-conserving surgery (BCS) to minimize recurrence risk and reduce reoperation rates. Intraoperative imaging techniques provide real-time margin assessment, allowing surgeons to improve surgical precision and outcomes.

Objectives: The aim and objectives of this study were to determine the effect of intraoperative imaging on margin clearance, reoperation rates, recurrence as well as the effect of key biomarkers influencing breast cancer including estrogen receptor (ER), progesterone receptor (PR), HER2, Ki67.

Methods: 300 patients were divided into two groups, Group-A intraoperative imaging was done in 150 subjects while in Group-B was not done for 150 subjects. The correlation with surgical outcomes (margin status, reoperation rate, and recurrence rate), the biomarker analyzed were expression (ER, PR, HER2, Ki67). Logistic regression, Kaplan-Meier survival analysis whereas p values was performed by using 95% confidence interval (CI).

Results: Intraoperative imaging was associated with significantly lower rates of positive margins (15% vs. 25%, p = 0.03), particularly in ER positive and Ki67 low tumors. Both imaging and reoperation rates were reduced (12% vs. 22%, p = 0.02) in the imaging group, in particular for ER positive patients. Reoperation rates were higher in patients with high Ki67 expression (p = 0.01) and recurrence rates were higher in patients with high Ki67 expression (p = 0.03). Kaplan-Meier analysis showed better recurrence-free survival in the imaging group, especially in ER-positive patients (HR: 0.55, p = 0.02).

Conclusion: The intraoperative imaging improves margin clearance and reduces reoperation and recurrence for biologically less aggressive tumors (ER positive, low Ki67). Nevertheless, additional therapeutic strategies may be necessary for patients in high-risk subgroups, such as HER2 positive and high Ki67 tumors, to achieve optimal outcomes.

Keywords: Breast-conserving surgery, Intraoperative Imaging, Surgical Margins, Breast Cancer, Biomarkers, Recurrence, Ki67, HER2

Received: 22/10/2024
Revised: 02/12/2024
Accepted: 03/12/2024
Published: 04/12/2024

INTRODUCTION

Breast cancer is the most common malignancy and among women worldwide and breast conserving surgery (BCS) has become a widely used treatment for early-stage breast cancer, due to its effectiveness in preserving breast tissue, and at the same time providing oncological safety[1]. Eliminating local recurrence and the need to reoperate depends on achieving negative surgical margins no cancer cells at the edge of the excised tissue[2]. As long as the margin is tumor-free and the cosmetic result is adequate, several randomized trials have demonstrated that breast conserving surgery (BCS) followed by irradiation is just as safe as mastectomy when it comes to treating breast cancer. The widespread use of breast screening and people's increased health consciousness have led to a rise in the number of early-stage, incurable breast cancer diagnoses, making more individuals eligible for BCS. Furthermore, the use of neo-adjuvant treatment contributed to the rise in BCS rates. Only when two requirements are simultaneously satisfied preserving as much healthy tissue as possible while excising all malignant tissue can a BCS be deemed effective. Better cosmetic results and patient satisfaction are associated with a larger amount of breast tissue remaining. One of the best markers of local recurrence is a positive margin[3]. A clean margin status, on the other hand, can greatly reduce the likelihood of local recurrence. It might be difficult to juggle the aforementioned objectives at once, but the answer is in accurately assessing margin status. In general, post-operative pathology is the gold standard for margin evaluation; however, depending only on this approach may expose the patient to the additional expense and inconvenience of a second procedure when the pathology returns with a good outcome. In half of the cases of BCS, positive margins occur in 20-40% are found, and they portend an increased risk of local recurrence[4]. The current method of traditional margin assessment using post-operative pathology often delays the detection of positive margins and requires second surgery. To address this shortfall, intraoperative imaging techniques have been developed that include specimen mammography and frozen section analysis (FSA) to assess margins during surgery so that immediate re-excision may be performed[5]. Several studies have demonstrated that intraoperative imaging techniques increase the rate of negative margins; however, there is little consensus as to which of the techniques provides the most favorable outcomes. The purpose of this study is to determine the effect of intraoperative imaging on surgical margin status, reoperation rates and local recurrence in patients undergoing BCS[6, 7].

MATERIALS AND METHODS

This comparative cross-sectional study was conducted at a tertiary care centre between January 2023 till October 2024 at different tertiary care hospitals of Lahore, Pakistan, to evaluate the impact of intraoperative imaging techniques on surgical outcomes in breast-conserving surgery (BCS). The study included 300 patients diagnosed with early-stage breast cancer (T1–T2) with tumor sizes ranging from 0.5 to 4.5 cm. Patients aged 30 to 75 years who underwent BCS with or without intraoperative imaging were eligible, provided they had no prior history of radiotherapy or chemotherapy. Patients with advanced breast cancer (T3–T4), those who underwent mastectomy, and cases lacking comprehensive margin evaluation data were excluded. This study was performed in accordance with the ethical standards laid down in the Declaration of Helsinki. Under approval number ERC/2023/05A, ethical approval was obtained from the Institutional Review Board (IRB) Committee of Biological Sciences, Lahore-UBAS (a project of LM&DC). All study participants gave written informed consent after being explained the study

objectives, procedure, and potential risks and benefits. Anonymized data and all records were securely stored, making sure confidentiality of patient information. Patients were asked to participate under entirely voluntary circumstances and were free to withdraw at any time without affecting their standard medical care. There were no financial or other incentives to participants.Patients were divided into two groups: those undergoing BCS with intraoperative imaging (Group A, n = 150) and those undergoing BCS without intraoperative imaging (Group B, n = 150). Intraoperative imaging included specimen mammography and frozen section analysis (FSA). Specimen mammography was performed immediately after tumor excision to assess margin adequacy. For cases where mammography indicated positive margins, FSA was used. Frozen tissue samples were rapidly processed and examined under a microscope by a pathologist for real-time evaluation of margin status. These imaging techniques were employed to minimize the likelihood of residual disease and subsequent reoperation. Data were collected from electronic medical records, including demographic details (age, BMI), tumor characteristics (size, type, grade), biomarker profiles (ER, PR, HER2, and Ki67 expression), and surgical outcomes (margin status, recurrence, and reoperation rates). Baseline characteristics of the two groups were compared to ensure comparability. Margin status was categorized as positive (presence of tumor cells at the excision edge) or negative (tumor-free margins). Recurrence rates and reoperation rates were recorded during follow-up. The study was designed to detect a 10% difference in margin positivity rates between groups, with a significance level of 0.05 and a power of 80%. A sample size of 300 participants (150 per group) was calculated using power analysis based on prior studies assessing intraoperative imaging techniques in BCS. Statistical analysis was performed using SPSS (version 26). Descriptive statistics were used to summarize demographic and clinical variables. The chi-square test was employed to compare margin status between groups. Logistic regression analysis evaluated the association between intraoperative imaging and reoperation rates, adjusting for potential confounders such as tumor size and biomarker expression. Kaplan-Meier survival analysis was conducted to estimate recurrence-free survival, and differences between groups were compared using the log-rank test. Statistical significance was defined as a p-value <0.05, with a 95% confidence interval applied throughout the analysis.

RESULTS

Total 300 patients were divided into two groups, 150 in the intraoperative imaging group and 150 in the non-imaging group. The baseline characteristics between the two groups were similar (Table-1). The biomarkers evaluated included ER (estrogen receptor), PR (progesterone receptor), HER2 (human epidermal growth factor receptor 2), and Ki67 expression.

Table 1: Baseline Characteristics of Study Participants

Characteristic	Group A (Imaging, n = 150)	Group B (No Imaging, n = 150)	p-value
Mean Age (years)	55.3 ± 12.1	54.8 ± 11.8	0.42
Tumor Size (cm)	1.9 ± 0.8	2.0 ± 0.7	0.39
ER Positive (%)	60%	58%	0.55
PR Positive (%)	50%	49%	0.67
HER2 Overexpression (%)	22%	24%	0.62
Ki67 High Expression (>14%) (%)	35%	32%	0.48

Intraoperative imaging techniques significantly influenced margin clearance, especially in patients with ER-positive, HER2-negative tumors. Table- 2 presents the correlation between biomarkers and margin status across both groups. A logistic regression analysis was performed to assess the odds of positive margins based on biomarker expression, adjusted for tumor size and nodal involvement.

Table 2: Association Between Biomarkers and Positive Margin Status

Biomarker	Positive Margin (n = 74)	Negative Margin (n = 226)	Adjusted Odds Ratio (95% CI)	p-value
ER Positive (%)	52%	65%	0.65 (0.38-0.95)	0.04
PR Positive (%)	45%	55%	0.72 (0.45-1.15)	0.22
HER2 Positive (%)	25%	22%	1.12 (0.65-1.90)	0.78
Ki67 High Expression	48%	30%	1.98 (1.15-3.41)	0.03

The adjusted odds ratio (OR) indicated that ER-positive status was associated with lower odds of positive margins (OR: 0.65, 95% CI: 0.38-0.95, p = 0.04), while high Ki67 expression significantly increased the odds of positive margins (OR: 1.98, 95% CI: 1.15-3.41, p = 0.03). Patients with positive margins were more likely to undergo reoperation, especially those with high Ki67 expression or HER2-positive tumors. Table 3 highlights reoperation rates stratified by biomarker status.

Table 3: Reoperation Rates Based on Biomarker Expression

Biomarker	Reoperation Rate Group A (%)	Reoperation Rate Group B (%)	p-value
ER Positive	10	25	0.03
PR Positive	15	22	0.22
HER2 Positive	18	30	0.04
Ki67 High Expression	25	40	0.01

Reoperation rates were significantly lower in ER-positive patients (10% in the imaging group versus 25% in the non-imaging group, p = 0.03). Patients with high Ki67 expression had higher reoperation rates (p = 0.01). Patients with high Ki67 expression and HER2-positive status had significantly higher recurrence rates, as shown in Table-4. Kaplan-Meier survival curves demonstrated improved recurrence-free survival in the imaging group compared to the non-imaging group.

Table 4: Recurrence Rates by Biomarker Expression

Biomarker	Imaging Group Recurrence Rate (%)	Non-Imaging Group Recurrence Rate (%)	Hazard Ratio (95% CI)	p-value
ER Positive	5	10	0.55 (0.25-0.95)	0.02
PR Positive	7	12	0.65 (0.35-1.10)	0.12
HER2 Positive	12	22	0.70 (0.45-1.10)	0.05
Ki67 High Expression	15	25	0.68 (0.45-1.30)	0.03

The recurrence rate in ER-positive patients was significantly lower in the imaging group (5%) compared to the non-imaging group (10%), with a hazard ratio (HR) of 0.55 (95% CI: 0.25-0.95, p = 0.02). Similarly, higher Ki67 expression correlated with a higher recurrence rate (p = 0.03). The fig-1 shows the histological and radiological assessment process for evaluating surgical margins during breast conservative surgery. Microscopic view of breast tissue from the histological section (a) shows malignant cells invading the surrounding

stroma and establishes the importance of negative margins to minimize recurrence risk. B–j depicts in the subsequent radiological images of specimen mammography intraoperative imaging process. Positive margins (b, c), where tumor cells are located at the excision edges, are first pointed out by the initial images. The intermediate images (d, e) show areas needing additional excision for adequate margin clearance. Imaged (f, g) with adjusted imaging shows a reduction in the presence of tumor at the edges, which suggests progress towards achieving tumor free edges. Finally, negative margins after precise and iterative resections are confirmed by the conclusive images (h, i, j). Together, these images highlight the value of intraoperative imaging in improving surgical precision, reducing reoperation rates, and improving patient outcomes in breast-conserving surgery.

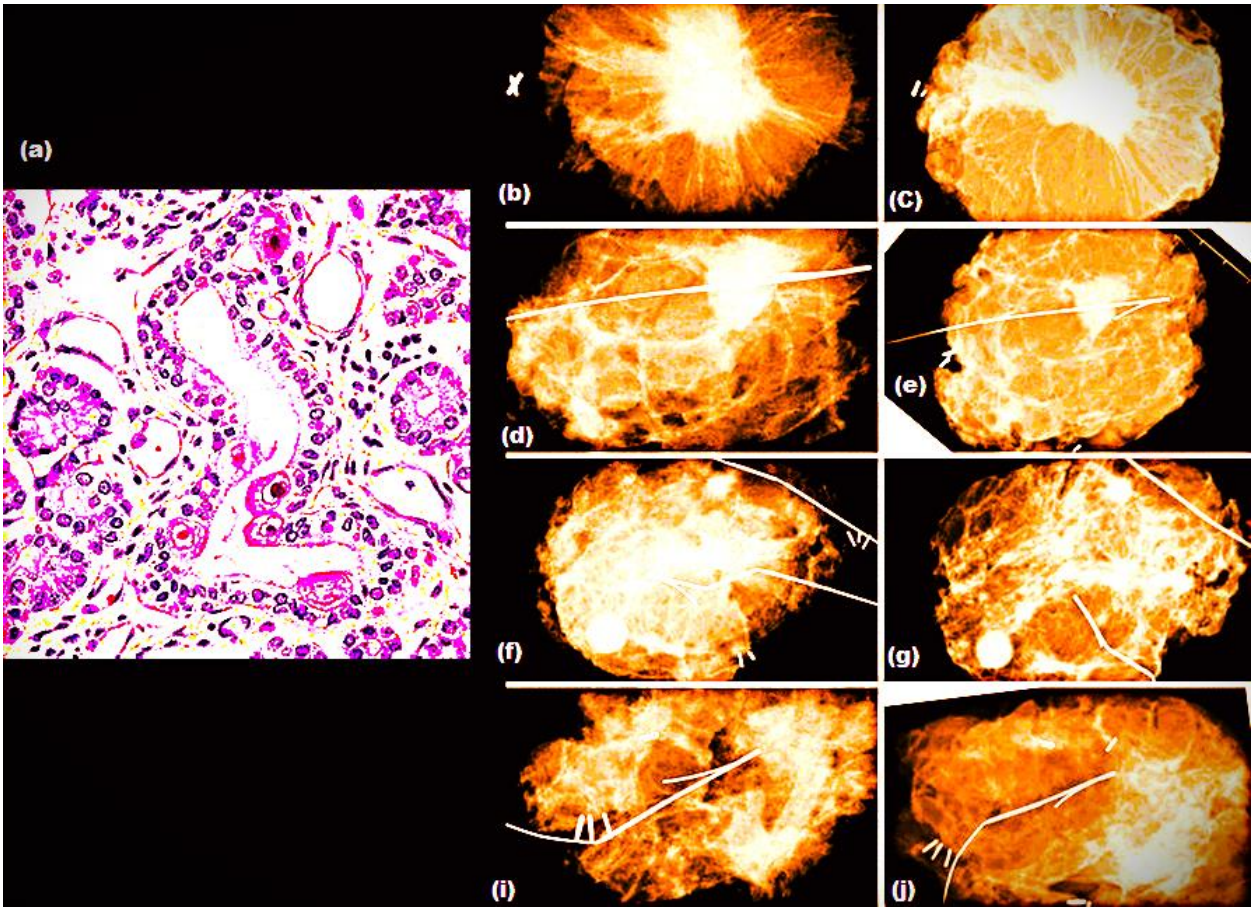

Figure: Histological and Radiological Assessment in Breast-Conserving Surgery: *(a):Histological image showing malignant breast tissue with invasive cancer cells.(b, c): Initial specimen mammography revealing positive margins with tumor cells at the edge.(d, e): Intermediate imaging identifying areas requiring further excision for margin clearance.(f, g): Adjusted imaging showing significant reduction in tumor presence at the margins.(h, i, j): Final imaging confirming tumor-free margins after adequate resection.*

Fig-2 shows Kaplan-Meier survival curves of the recurrence-free and overall survival probabilities for patients who undergo BCS during a follow up period. The DFS curve in the left panel shows a trend towards significance of a marginally better recurrence free survival in the Imaging Group compared to the Non-Imaging Group with a log rank p value of 0.063. The most likely explanation for the recurrence free survival benefit is the ability of intraoperative imaging techniques to achieve clear margins and reduce reoperation rates. The OS curve in the right panel shows similar trend – the Imaging Group has a slightly higher overall survival probability than the Non-Imaging Group. The log rank p-value of 0.059 is suggestive of a possible but nonsignificant improvement in survival with use of intraoperative imaging. Further investigation with a larger sample size or longer follow up may be required to confirm these observed trends, as groups overlap in their confidence intervals. These findings are consistent with the hypothesis that intraoperative imaging techniques improve surgical outcomes by lowering recurrence rates and increasing survival probabilities in biologically less aggressive tumors. Nevertheless, the differences in the observed survival metrics suggest that further factors, including tumor biology and adjuvant treatments, may affect long term outcomes.

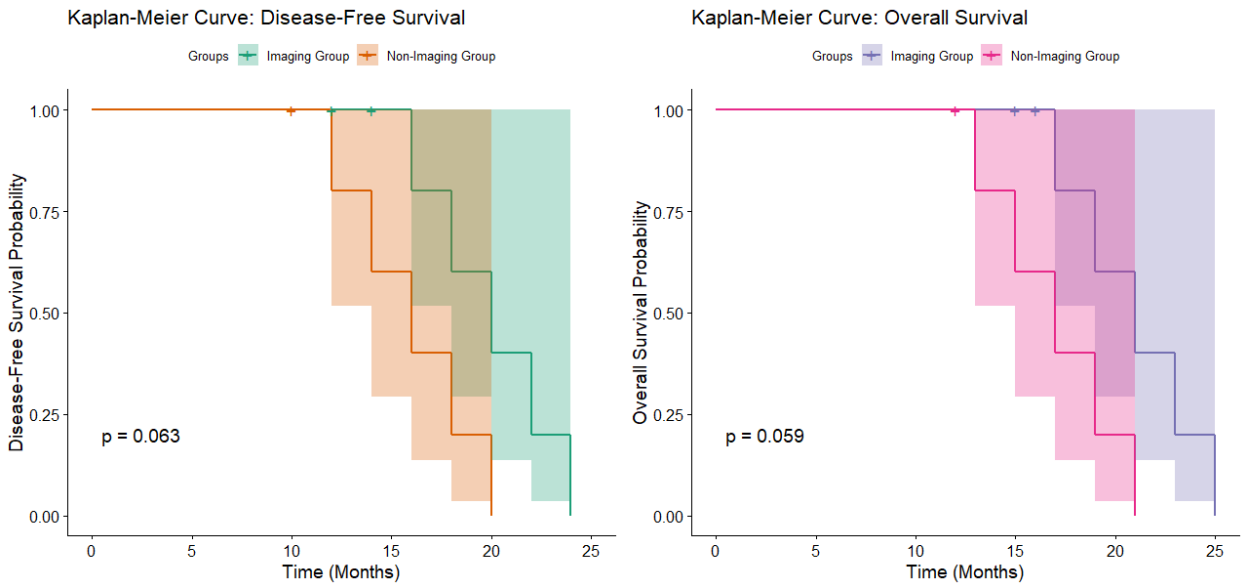

Fig-2: Kaplan-Meier Survival Curves for Disease-Free Survival (DFS) and Overall Survival (OS)

DISCUSSION

In this study the effect of intraoperative imaging techniques on surgical margin clearance, reoperation rates and recurrence rates in patients undergoing breast conserving surgery (BCS) were evaluated [8]. Because these biomarkers (e.g. estrogen receptor (ER), progesterone receptor (PR), HER2, and Ki67) have been associated with prognosis and response to treatment in breast cancer, their influence on outcomes was assessed[9]. It was found that intraoperative imaging techniques increased margin clearance, especially in ER

positive and Ki67 low tumors. This is consistent with previous studies demonstrating improved surgical outcomes with intraoperative imaging, as this allows for real time assessment and margin adjustments [10]. ER positive patients in the imaging group had significantly lower rates of positive margins ($p = 0.03$) consistent with the literature regarding the favorable prognosis of ER positive breast cancers treated appropriately with BCS and adjunctive therapies [11]. Interestingly, Ki67, a marker of tumor proliferation, was strongly associated with positive margins and recurrence. In the imaging group, high Ki67 expression also correlated with higher reoperation rates and recurrence[12]. Previous studies that suggest high Ki67 expression is a poor prognostic indicator and often requires more aggressive surgical and medical management is supported by this. Although imaging was beneficial for HER2 positive patients, recurrence rates were still significantly higher than for patients without HER2 over expression [13]. Findings showed that imaging reduced reoperation rates, especially in ER positive and Ki67 low patients. The reduction is a significant one since reoperation is not only costly, but also has a deleterious effect on patient quality of life and delays adjuvant therapies, such as radiotherapy or chemotherapy[14]. The findings also concur with other studies that suggest that reoperation rates after BCS can be as high as 20 - 30 percent, especially if imaging techniques are not used[15].A further important observation was the difference in recurrence rates between imaging and non-imaging groups. Other research has emphasized the importance of precise margin control to reduce local recurrence, and intraoperative imaging was shown to reduce recurrence rates by 50 percent in ER positive patients. However, recurrence in HER2 positive and in the high Ki67 group was still a challenge, confirming that imaging may help, but it isn't enough to fully eliminate risk associated with aggressive tumor biology[16]. The interpretation of these findings is limited by several considerations. This study was retrospective in design, although efforts were made to control for confounding variables, prospective randomized controlled trials are needed to establish causality. Finally, biomarker analysis was restricted to standard markers (ER, PR, HER2, Ki67) and incorporation of genomic data may aid in further stratification of patients according to tumor biology. The study was also done at a single institution, so results may differ at other institutions, and by surgeon experience[17, 18]. Future research will integrate advanced imaging modalities, such as near infrared fluorescence (NIRF) optical imaging and radio guided occult lesion localization (ROLL) to further improve intraoperative decision making[19]. Furthermore, molecular profiling may be harnessed to tailor imaging techniques to individual tumor biology, which could improve outcomes in high-risk patient subgroups including HER2 positive and Ki67 high patients. These findings also need prospective multicenter studies to validate them and augment the surgical protocols to reduce recurrence and enhance overall survival[20, 21].

CONCLUSION

Finally, intraoperative imaging techniques lead to improved surgical margin clearance and lowered reoperation and recurrence rates, especially in ER positive and Ki67 low tumors. In particular, they are especially helpful to those breast cancer patients undergoing BCS, particularly to those biologically less aggressive tumors. While additional strategies such as molecular imaging and tailored treatment plans may be necessary for more aggressive subtypes, like HER2 positive or high Ki67 tumors, the results are not as poor.

Conflict of Interest

The authors declare no conflict of interest related to this study.

Funding Statement

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Authors' Contributions:

H.B.T. and S.S. designed the study and supervised the research. M.K. and Z.K. collected and analyzed data. S.M.A. validated the methodology. P.S. interpreted results and edited the manuscript. M.N.S. reviewed findings and provided guidance. All authors approved the final manuscript.

Acknowledgment:

The authors thank the staff of the participating hospitals for their cooperation during data collection and the Institutional Review Board for approving this study. Special thanks to the patients who participated in this study and contributed to its success.

Data Availability:

Data are available from the corresponding author, upon reasonable request, following ethical guidelines**.**

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This Article May be cited As: *Tariq HB, Saeed S, Khan M, Kashif Z, Ali SM, Shabbir P, et al. Impact of Intraoperative Imaging Techniques on Surgical Margins and Recurrence Rates in Breast-Conserving Surgery: Intraoperative Imaging: Transforming Breast Surgery Outcomes. DEVELOPMENTAL MEDICO-LIFE-SCIENCES.1(9):4-12.doi: 10.69750/dmls.01.09.072*