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Outcomes Following Breast-Conserving Surgery for Positive Radial Margins: A Five-Year Longitudinal Study

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Abstract

Introduction

Breast-conserving surgery (BCS) is the treatment of choice for ductal carcinoma in situ (DCIS) and early-stage invasive carcinoma. BCS is associated with a re-excision rate of 17-20%. The aim of this study is to determine the incidence of residual disease in patients requiring re-excision of margins following BCS, assess margin positivity towards the nipple, and evaluate long-term oncological outcomes.

Methods

This was a single-centre retrospective study that included all patients who had involved or close margins following BCS between July 2013 and November 2018. Data on histology, treatment following subsequent surgery, and follow-up information were collected from medical records.

Results

Out of the 1,779 patients, 190 (10.6%) underwent further surgery for positive margins; 49 had DCIS, 141 patients had invasive carcinoma; and 73 (38.6%) patients had residual disease in the re-excised margin(s). The incidence of residual disease in the excised specimen was significantly higher for DCIS (36/49) than for invasive disease (37/141) ($p < 0.0001$). Overall, 32 (17%) needed a second re-excision for positive margins. Radial margin involvement towards the nipple was more commonly seen in DCIS than in invasive cancers ($p = 0.0044$). The overall mastectomy rate for the entire cohort was 7.3%. During a median follow-up of 47 months, seven (3.7%) local, one (0.5%) regional, and five (2.6%) distant recurrences were observed. Local recurrence was significantly higher in patients with pure DCIS (10.2%) with positive margins ($p = 0.00278$).

Conclusion

The rates of second re-excision, margin positivity towards the nipple, and local recurrence were significantly higher in patients with pure DCIS. Patients should be counselled pre-operatively regarding these outcomes when undergoing breast-conserving procedures.

Categories: General Surgery, Oncology
Keywords: breast conserving surgery, dcis, invasive carcinoma, margins, recurrence, re-excision

Introduction

Breast-conserving surgery (BCS) involves removing only the affected part of a breast and is often combined with radiotherapy when treating ductal carcinoma in situ (DCIS) or early-stage breast cancer. The decision for BCS is made on the extent of disease in relation to the size of the breast, location of tumour, and patient's preference. BCS is widely offered as the treatment of choice due to the adoption of an oncoplastic approach and having advanced localisation techniques.

Whilst BCS has numerous advantages over mastectomy, including shorter anaesthetic time, quicker recovery, fewer post-operative complications, psychological well-being, and an overall survival benefit [1-3], it is associated with the risk of requiring further surgery to achieve clear margins. Pursuing excessively wide margins at the time of primary surgery has a detrimental effect on the cosmetic outcome, which is further exacerbated by radiotherapy and secondary procedures to improve cosmetic outcomes, adding a burden on health resources.

The national (UK) re-excision rates following BCS for either DCIS or invasive carcinoma vary from 17% to

20%, with some studies suggesting that the re-excision rates are twice as high in DCIS as compared to invasive cancers [4]. The need for re-operation is associated with several adverse consequences, such as requiring a second general anaesthesia and a higher risk of wound complications. It can negatively impact patients' satisfaction and cosmetic outcome, whether the second operation is a margin re-excision or a mastectomy [5]. Furthermore, it prolongs the cancer treatment pathway, may potentially cause a delay in adjuvant treatment, and adds to the burden on the health service [6].

Achieving clear margins for a successful BCS is based on evidence showing an increased rate of local and distant recurrences in patients with involved or close margins as compared to patients with negative margins in patients with DCIS and invasive cancers [7,8]. There is inconsistent data on the incidence of finding residual disease in the re-excised specimens. The aim of this study is to determine the incidence of residual disease in patients requiring re-excision of margins following BCS, assess margin positivity towards the nipple, and evaluate long-term oncological outcomes.

Materials And Methods

Study design and setting

This was a retrospective study carried out at a university teaching hospital. Both screening and symptomatic breast cancer patients are treated at this centre with provision of the full spectrum of BCS using oncoplastic techniques, including volume displacement and replacement techniques.

Study duration

The study included consecutive patients who underwent BCS from July 2013 to November 2018.

Inclusion and exclusion criteria

All patients who underwent BCS and had involved or close margins were included in the study. Patients with bilateral cancers, phyllodes tumours, previous history of breast cancer, or who underwent BCS with negative margins were excluded from the study.

Data collection

Data for this study were obtained from electronic medical records and included demographic, clinical, operative, and pathological information. Demographic variables encompassed patients' age and mode of presentation. Operative details included the type of breast-conserving procedure performed, use of oncoplastic techniques, incision site, and whether additional radial margin shavings were taken at the index operation.

Histopathological data were extracted from formal pathology reports and included tumour size, presence of in situ or invasive disease, histological subtype, and receptor status (oestrogen receptor, progesterone receptor, and human epidermal growth factor receptor 2 (HER2)). Radial margin status, including direction towards the nipple, was recorded for all specimens. Margin involvement was defined as the presence of in situ or invasive carcinoma at the inked margin, and margins were considered close when tumour was present within 1 mm of the resection edge, in accordance with the Association of Breast Surgery (ABS), UK guidelines [9].

For patients undergoing subsequent surgical procedures, data were collected on the type of re-operation (margin re-excision or mastectomy), the number and anatomical location of radial margins re-excised, and the presence or absence of residual disease in the re-excised specimen. The status of the new margins following re-excision was also documented.

Follow-up data included details of adjuvant treatment (radiotherapy, endocrine therapy, chemotherapy), as well as oncological outcomes. Recurrence data captured both local and distant events, and survival outcomes were also recorded.

Statistical analysis

Statistical analysis was performed using Statistical Product and Service Solutions (SPSS, version 29; IBM SPSS Statistics for Windows, Armonk, NY) and a p-value of < 0.05 was considered statistically significant. Differences in proportions between groups were calculated using the two-sample Z-test. Differences in recurrence-free survival were calculated using the log-rank test.

Ethical considerations

The study was registered with the local governance department (Registration number CA22926).

Results

During the study period, 1,779 patients underwent BCS for in situ or invasive carcinoma, of whom 190 patients (10.6%) had close or involved margins. All patients were females with a median age of 61 (range: 34-85) years. The majority of the patients had screen-detected disease (58.4%), followed by symptomatic presentation (37.9%), and a small proportion (3.7%) had an incidental finding on other radiological investigations. Median follow-up duration was 47 (range: 17-85) months (Table *1*).

Parameters		n (%)
Gender	Female	190 (100)
	Male	0 (0)
Mode of diagnosis	Screen	111 (58.4)
	Symptomatic	72 (37.9)
	Incidental	7 (3.7)
Age (years)		34-85 (median: 61)
Follow-up (months)		17-85 (median: 47)

TABLE 1: Demographic details

One hundred and twenty-six (66.3%) patients had unifocal disease, and 138 (72.6%) patients required wire-guided tumour localisation for BCS. Tumour was located in the upper outer quadrant in 89 (46.8%) patients, and the central quadrant was the second most common site of disease in 32 (16.8%) patients. One hundred and seventy patients (90%) had standard wide local excision, and volume replacement or displacement technique was used in 17 (8.9%) patients. Surgery was commonly performed using an incision over the site of disease in 134 (70.5%) patients, and additional margins were taken at the time of the index procedure in 95 (50%) cases (Table *2*).

Focality of disease	**Unifocal**	**126 (66.3)**
	Multifocal	39 (20.5)
	Unknown	25 (13.2)
Tumour quadrant	UOQ	89 (46.8)
	Central	32 (16.8)
	UIQ	30 (15.8)
	LOQ	24 (12.6)
	LIQ	13 (6.8)
	Unknown	2 (1.1)
Localised BCS	Yes	138 (72.6)
	No	51 (26.8)
	Unknown	1 (0.5)
Incision used	Above the tumour	134 (70.5)
	Away from tumour	51 (26.8)
	Unknown	5 (2.6)
Operation performed	Standard wide local excision	171 (90)
	Therapeutic mammoplasty	11 (5.8)
	Perforator flaps	6 (3.1)
	Unknown	2 (1.1)
Extra margins taken	Not taken	82 (43.2)
	Taken	95 (50)
	Unknown	13 (6.8)

TABLE 2: Presentation and operative details

LIQ: Lower inner quadrant; LOQ: Lower outer quadrant; UIQ: Upper inner quadrant; UOQ: Upper outer quadrant

Out of 190 patients with close or involved margins, 49 (25.8%) had DCIS, and 141 (74.2%) had invasive disease on presentation. One hundred and eight (76.6%) of the invasive cancers were of ductal/no special type, followed by invasive lobular carcinoma in 19 (13.5%) patients. One hundred and four (73.7%) were HR+ HER 2-, 17 (12%) triple-positive, and 8 (5.6%) triple-negative cancers. One hundred and thirty-six (71.6%) had involved margins, and 54 (28.4%) had close margins (Table *3*). The median size of DCIS was 36 (range: 3-100) mm and 21 (range: 1.5-75) mm for invasive tumours (Table *4*).

Parameters		n (%)
Tumour type (n=190)	DCIS	49 (25.8)
	Invasive carcinoma with DCIS	99 (52.1)
	Invasive carcinoma	42 (22.1)
Type of invasive carcinoma (n=141)	No special type	108 (76.6)
	Invasive lobular	19 (13.5)
	Mixed	8 (5.6)
	Other	6 (4.2)
Receptor status (n=141)	HR+, HER 2-	104 (73.7)
	HR+, HER 2+	17 (12.0)
	HR-, HER 2+	7 (4.9)
	HR-, HER 2-	8 (5.6)
	Unknown	5 (3.5)
Margin status (n=190)	Involved	136 (71.6)
	Close	54 (28.4)
Number of margins involved (n=190)	Single margin	112 (58.9)
	Multiple margins	78 (41.1)

TABLE 3: Histopathology results

DCIS: Ductal carcinoma in situ

Tumour type	Number	Median size (mm, largest dimension)	Minimum size (mm, largest dimension)	Maximum size (mm, largest dimension)
DCIS	49	36.02	3	100
Ductal	108	21.87	1.5	75
Lobular	19	23.16	2	54
Mixed	8	25.75	12	40
Other	6	12.17	3	30
Total	190	25.35	1.5	100

TABLE 4: Tumour size

DCIS: Ductal carcinoma in situ

Residual disease in re-excised specimen

All patients in this cohort were offered re-excision of margins. The median time to re-operation was 33 (range: 11-45) days. One patient with invasive cancer opted for completion mastectomy (0.6%), and the rest of the patients in this cohort (n=189) underwent re-excision of margins (99.4%).

Following re-excision, residual disease was found in 73 (38.6%) cases, and 116 (61.4%) cases did not have residual disease in the specimen. Out of 49 patients with DCIS, residual disease was found in 36 (73.5%), while 13 (26.5%) did not have residual disease. In the group of invasive cancer (n=140), 37 (26.4%) had residual disease, and 103 (73.6%) did not have residual disease. The incidence of residual disease in resected

specimens was significantly higher in DCIS (36/49, 73.5%) when compared to invasive disease (37/140, 26.4%) (p < 0.0001) (Table 5).

Parameters	Residual disease n (%)	No residual disease n(%)	P-value
Total (n=189)	73 (38.6)	116 (61.4)	
DCIS (n=49)	36 (73.5)	13 (26.5)	p<0.0001
Invasive cancer (n=140)	37 (26.4)	103 (73.6)	

TABLE 5: Residual disease in re-excised specimen

DCIS: Ductal carcinoma in situ

Margin status

One patient had a completion mastectomy, and 189 (99.4%) underwent margin re-excision. Margins were deemed clear following discussion in a multidisciplinary team meeting for 157 (83%) patients (116 had no residual disease, 38 had residual disease with clear margins, and no further tissue left to remove in three patients), and 32 (17%) patients had positive margins.

All 32 patients with positive margins were offered further surgery (28 for involved margins and 4 for close margins). Four patients with close margins declined further surgery. Out of the 28 patients with positive radial margins, 12 (42%) had pure DCIS, and 16 (58%) had invasive disease. The rate of second re-excision was significantly higher in patients with pure DCIS (12/49 versus 16/141, p=0.035).

In this group of 28 patients, 19 (67.9%) patients had further re-excision of margins, and nine (32.1%) had completion mastectomy. Out of the 19 patients who underwent further re-excision, clear margins were achieved in 15 patients (78.9%), and four (21.1%) had close or involved margins. Out of the other four patients who needed further surgery, three (75%) had a mastectomy, and one (25%) had further excision, which showed close or involved margins and subsequently underwent a completion mastectomy (Table 6). Overall, the mastectomy rate was 7.3% (14/190) in this cohort. The details are summarised in Figure 1.

Total	Completion mastectomy	Re-excision		Margin status after re-excision	
				Clear Margins	Involved/Close margins
n (%)	n (%)	n (%)		n (%)	n (%)
190 (100)	1 (0.6)	First	189 (99.4)	157 (83)	32 (17)
28 (100)	9 (32.1)	Second	19 (67.9)	15 (78.9)	4 (21.1)
4 (100)	3 (75)	Third	1 (25)	0 (0.0)	1 (100)

TABLE 6: Margin status

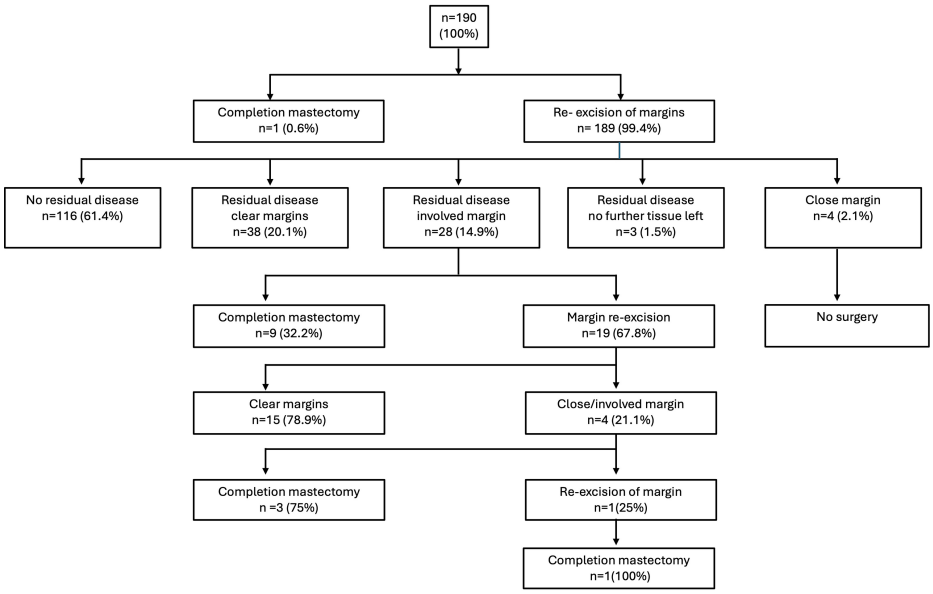


FIGURE 1: Margin status following BCS

BCS: Breast-conserving surgery

Radial margin towards the nipple

The radial margin towards the nipple was positive for malignancy in 63.2% (120/190) of the cohort. The incidence of finding a positive margin towards the nipple was significantly higher in pure DCIS (38/49,77.5%) compared to patients with invasive carcinoma (82/141,58.2%) (p=0.015) (Table *7*).

Parameters	Positive towards the nipple n(%)	Negative towards the nipple n(%)	P-value
DCIS (n=49)	38 (77.5)	11 (22.5)	
Invasive carcinoma (n=141)	82 (58.2)	59 (41.8)	p=0.015
Total (n=190)	120 (63.2)	70 (36.8)	

TABLE 7: Radial margin towards the nipple

DCIS: Ductal carcinoma in situ

Adjuvant treatment

Adjuvant treatment (systemic therapy and radiotherapy) was offered to all patients based on the standard UK guidelines after multi-disciplinary team discussion. Whole breast and chest wall radiotherapy was given to 168 (88.4%) breasts and 3 (1.6%) patients. Out of 141 patients with invasive cancer, adjuvant chemotherapy was given to 51 (36.2%) patients, and hormone therapy was offered to 124 (87.9%) patients (Table *8*).

Parameters		n (%)
Radiotherapy	Breast	168 (88.4)
	Chest wall	3 (1.6)
	No radiotherapy	17 (9.0)
	Unknown	2 (1)
	Total	190 (100)
Chemotherapy	Yes	51 (36.2)
	No	90 (63.8)
	Total	141 (100)
Hormone therapy	Tamoxifen	44 (31.2)
	Aromatase inhibitors	80 (56.7)
	None	15 (10.6)
	Unknown	2 (1.4)
	Total	141 (100)

TABLE 8: Adjuvant treatment

Follow-up data

During a median follow-up of 47 (range: 17-85) months, 13 (6.8%) patients developed recurrence, of which seven (3.7%) were local, one (0.5%) regional, and five (2.6%) distant metastases. Median time to local and distant recurrences were 37 and 17 months, respectively.

Of the seven cases with local recurrence, five patients had pure DCIS on initial presentation, and two patients had invasive disease with DCIS. Margins on initial resection for all seven cases were positive for DCIS, and all cases recurred within the original tumour bed. Local recurrence was significantly higher in patients with pure DCIS (10.2%) compared with invasive cancer (1.4%) (p=0.00278). Nine (4.7%) deaths were observed during the follow-up period, including two patients with distant metastases (Table 9).

Parameters	Total (n=190), n(%)	DCIS (n=49), n(%)	Invasive cancer (n=141), n(%)	P-value
Local recurrence	7 (3.7)	5 (10.2)	2 (1.4)	p=0.0027
Regional recurrence	1 (0.5)	0 (0.0)	1 (0.7)	p=0.5545
Distant recurrence	5 (2.6)	0 (0.0)	5 (3.5)	p=0.1816
Death	9 (4.7)	0 (0.0)	9 (6.4)	p=0.0700

TABLE 9: Follow-up data

DCIS: Ductal carcinoma in situ

Discussion

Our re-excision rate for positive margins of 10.6% following initial BCS for DCIS or early-stage invasive breast carcinoma is lower than the national standard re-excision rate [10]. In our series, 38% of patients who underwent re-excision of margins were found to have residual disease in the excised specimen, but some studies have reported a lower rate [11-13]. Interestingly, our study demonstrated that the presence of residual disease (73.5%) in the re-excised specimen was significantly higher in patients with pure DCIS.

Our study showed a 17% second re-excision rate, which is similar to previously reported studies [13]. We also found a significantly higher rate of second re-excision in patients with pure DCIS as compared to those with

invasive disease [4,13]. A possible explanation for this is the underestimation of the size on mammograms in cases of pure DCIS [14-16]. Studies have also reported that extensive intraductal component, size of DCIS, number of involved margins, and Van Nuy's score have a predictive value in finding residual disease on re-excision sample [11,17]. Considering the higher further re-excision rates in pure DCIS, patients should be appropriately counselled prior to surgery.

In our series, 77% of pure DCIS cases had margin positivity towards the nipple. This could be explained by the contiguous pattern of growth via ducts and acini, as evident by studies showing that DCIS grossly follows the distribution of the main lactiferous ducts [18,19]. Studies have also shown that the growth of DCIS appears to be faster in the radial direction when compared to the perpendicular direction [20]. Considering the higher incidence of finding residual disease in pure DCIS (73.5%) and the significantly increased rate of margin positivity towards the nipple (77%), taking additional intraoperative margins in the direction towards the nipple during surgery could potentially reduce re-excision rates.

In our unit, the overall five-year local recurrence rate for both invasive cancer and pure DCIS is around 1.9% [21]. In this study, we found a higher rate of recurrence in patients with positive margins, which is consistent with previous studies [22]. Our local ipsilateral recurrence rate for pure DCIS (10.2%) is slightly higher than the rates reported in the national Sloane Project (7%). This may be due to our cohort having a median size of 36 mm when compared to the Sloane Project, in which more than 80% of patients had DCIS of < 20 mm [23]. The Sloane Project also reported a lower risk of recurrence in patients with 2 mm clearance margins, and this has been recommended in the current international guidelines [24,25]. This change in practice is likely to have an impact on reducing recurrence rates.

Limitations

The data for the study were collected retrospectively from the hospital records and therefore have their limitations. There was minimal missing data, which is unlikely to have an impact on the outcomes. The potential selection bias has been minimised as decisions on the type of surgery for individual patients were made in multidisciplinary meetings. The sample size was small and therefore will have an impact on the generalizability of the results. The median follow-up for this study was 47 months; a longer follow-up would have been effective in identifying late recurrences, considering the long natural history of the disease and the impact of heterogeneous breast cancer biology.

Conclusions

The results of this study have shown that, in patients with pure DCIS, there is significantly higher residual disease in the resection specimen and, in corroboration, significantly higher second re-excision rates. With study evidence showing that there is a higher rate of margin positivity towards the nipple in this cohort, re-excision rates can potentially be reduced by excising additional margins towards the nipple during the primary BCS. In addition, the current American Board of Surgery (ABS) and American Society of Clinical Oncology (ASCO) guideline recommendation of 2 mm margin clearance for pure DCIS could potentially have a positive impact on lowering re-excision rates in the future.

This study showed a higher risk of local recurrence in patients with positive margins following BCS for both invasive cancer and pure DCIS. This information could be used for optimising stratified follow-up planning for patients with high risk of recurrence. The findings in this study are valuable additions to the counselling process prior to surgery.

Additional Information

Author Contributions

All authors have reviewed the final version to be published and agreed to be accountable for all aspects of the work.

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Disclosures

Human subjects: Informed consent for treatment and open access publication was obtained or waived by all participants in this study. University Hospitals of North Midlands issued approval CA22926. **Animal subjects:** All authors have confirmed that this study did not involve animal subjects or tissue. **Conflicts of interest:** In compliance with the ICMJE uniform disclosure form, all authors declare the following: **Payment/services info:** All authors have declared that no financial support was received from any organization for the submitted work. **Financial relationships:** All authors have declared that they have no financial relationships at present or within the previous three years with any organizations that might have an interest in the submitted work. **Other relationships:** All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

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