Partial chest wall radiation therapy for positive or close surgical margins after modified radical mastectomy for breast cancer without lymph node metastasis

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Abstract

Aim: Whole-breast radiation therapy after breast-conserving surgery can control local recurrence with a long-term survival rate equivalent to that of radical mastectomy for patients with early breast cancer. However, the significance of radiation therapy for patients with positive/close margins after mastectomy remains controversial. Following radical mastectomy, no residual breast parenchyma remains, and thus radiation therapy of the entire chest wall may represent overtreatment in the patients, especially those without lymph node metastasis (N0). We therefore implemented partial chest wall radiation therapy for patients with N0 breast cancer and positive and/or close margins after mastectomy.

Methods: A total of 22 patients with N0 status but positive/close margins underwent partial chest wall radiation therapy to irradiate the predetermined clinical target volume, which had margins of at least 2 cm medial, lateral, superior, and inferior to the primary tumor bed. With reference to chest wall thickness, 4-10-MV photons or 5-8-MeV electrons with/without a bolus were delivered. The total dose was 50-66 Gy. We compared the results with those from 18 nonradiation therapy patients using Pearson’s $\chi^2$ test.

Results: All patients in the partial chest wall radiation therapy group achieved good local control despite having a significantly higher proportion of positive margins (77.3%) compared with the nonradiation therapy group (27.8%) ($P = 0.002$). Both groups showed 100% recurrence- and disease-free survival.

Conclusion: Partial chest wall radiation therapy may offer recurrence- and disease-free survival without local recurrence in N0 mastectomy patients with positive/close surgical margins.

KEYWORDS
partial chest wall radiation therapy, positive surgical margin, radical mastectomy

1 | INTRODUCTION

Following breast-conserving surgery for breast cancer, a positive surgical margin is widely recognized to increase the risk of local recurrence by at least twofold compared with a negative margin.\textsuperscript{1–3} For patients with positive margins after breast-conserving surgery, the National Comprehensive Cancer Network guidelines and other guidelines recommend re-excision to ensure that the margins are indeed negative.\textsuperscript{4–6} One report has indicated that re-excision resulted in the detection of residual tumors in 24% to 84% of patients according to the extent of positive margins after breast-conserving surgery.\textsuperscript{7} The above-mentioned guidelines recommend that re-excision should...
also be performed to secure negative margins in patients with positive margins after mastectomy. Re-excision after mastectomy, however, is invasive and frequently difficult to perform because it requires the excision of muscle and ribs in addition to the mammary tissue already removed. Re-excision of the skin may occasionally be performed if a positive margin is detected after nipple-sparing mastectomy (NSM). Furthermore, re-excision increases the risk of complications such as postoperative infection and may delay the initiation of subsequent adjuvant chemotherapy. Thus, for patients with positive or “close” margins after breast-conserving surgery, boost irradiation to the primary tumor bed is often added to whole-breast radiation therapy (WBRT). Some reports indicate that additional irradiation can decrease the local recurrence rate in patients with positive/close margins to a rate as low as that in patients with negative margins, whereas other reports indicate that the recurrence rate, even after additional irradiation, remains higher than that in patients with negative margins. Moreover, in patients with positive/close margins after mastectomy, including those with axillary lymph node metastasis, postmastectomy RT (PMRT) of the chest wall or regional lymph nodes has widely been recognized to reduce the local recurrence rate and has become standard treatment. Because the number of patients with positive/close margins without axillary lymph node metastasis after mastectomy is small, however, the significance of PMRT in this patient population is unknown. No recommendations have been offered, even in the American Society of Clinical Oncology guidelines. In the electron intraoperative therapy (ELIOT) study, NSM was combined with intraoperative RT with electrons as a strategy for partial chest wall RT (PCWRT), although patients with positive margins were excluded from the study population. We performed PCWRT in patients with positive/close margins and no pathological evidence of axillary lymph node metastasis and compared the outcomes with those of patients who did not undergo re-excision or PCWRT.

### 2 Patients and Methods

Among patients who underwent modified radical mastectomy plus either axillary dissection or sentinel node biopsy for breast cancer between January 2009 and December 2017, 40 patients with positive/close margins who were pathologically shown to have no axillary lymph node metastasis were included in this retrospective study. Postoperatively, 22 patients underwent RT, and 18 did not. None of the 40 patients underwent re-excision. This study was approved by the Institutional Review Board of Nihon University School of Medicine. Informed consent was obtained from all patients.

#### 2.1 Surgical margin status

As is the case after breast-conserving surgery, a positive margin was defined as an invasive carcinoma or a ductal carcinoma in situ (DCIS) microscopically identified ink on tumor tissue (defined as abnormal tissue just touching the ink). A close margin was defined as having a tumor ≤1 mm from the inked resection edge. This definition relied on a shorter distance than that previously accepted (≤10 mm or ≤2 mm).

#### 2.2 Nuclear grading

Surgical margin status

Severity was classified according to a three-point scale (grades 1-3) based on a composite picture of nuclear atypia and mitotic counts on hematoxylin and eosin-stained carcinomatous tissue specimens.

#### 2.3 Immunohistological subtypes

Estrogen receptors (ERs) and human epidermal growth factor receptor 2 (HER2) were evaluated by immunohistochemistry (IHC) analysis. HER2 was judged positive when the IHC score was 3+ or there was a positive fluorescence in situ hybridization test result. The Ki-67 antibody MIB-1 clone (Dako, Glostrup, Denmark) was used to detect Ki-67 expression. The Ki-67 proliferation index was defined as the percentage of cells with positive nuclear Ki-67 immunostaining in a section of confirmed carcinomatous tissue.

#### 2.4 PCWRT parameters

The primary tumor bed was contoured by reference to preoperative computed tomography or magnetic resonance imaging, or to a pathological specimen. The clinical target volume (CTV) was defined as the primary tumor bed plus a margin of at least 2 cm with clipping patient and muscle surface and fat. For example, three-dimensional (3D) conformal RT (CRT) consisting of two tangential beams was planned for the CTV. The field size was set as the partial chest wall measuring ≥9.5 cm in the cephalocaudal dimension (Figure 1). Using the thickness of the chest wall as the basis, irradiation of 4–10-MV photons or 5–8-MeV electrons with or without a bolus to the skin was planned, and 95% of the prescribed isodose volume was used to irradiate the CTV to the maximum extent.
2.5 | Statistical methods

SPSS version 21.0 (IBM, Armonk, NY, USA) was used for statistical analysis. Clinicopathological characteristics were compared between groups with and without PCWRT using Pearson’s \( \chi^2 \) test.

3 | RESULTS

Table 1 summarizes the patient characteristics with detailed surgical margin status. The median age of patients at mastectomy was 58.5 years in the PCWRT group and 69 years in the no-RT group. Premenopausal patients accounted for 40.9% of patients in the PCWRT group and 29.4% in the no-RT group, with the difference not reaching significance. The prevalence of positive margins was 77.3% in the PCWRT group and 27.8% in the no-RT group, with the difference being statistically significant (\( P = 0.002 \), Pearson’s \( \chi^2 \) test). In the PCWRT group, significantly more tumors at the margins were DCIS. The most common area of positivity on the positive/close margins was the anterior margin in the PCWRT group and the posterior margin in the no-RT group. In the no-RT group, there were significantly more tumors at the posterior margins. Four patients in the PCWRT group and one in the no-RT group had multiple positive/close areas at the margins. There were no significant differences between the two groups regarding other clinicopathological characteristics. The median total dose of PCWRT was 60 Gy (range 50–66 Gy). We tended to select ad o s e \( \geq 60 \) Gy in the case of invasive carcinoma at the positive margin (in 4 out of 5 patients). Acute RT-related toxicity was observed in only one patient who had undergone surgical removal of a seroma and manifested as an abscess caused by a bacterial infection after postoperative RT. The abscess resolved following drainage and antibiotic therapy. Other RT-related toxicities included grade 1 dermatitis and grade 1–2 pneumonitis (National Cancer Institute Common Terminology Criteria for Adverse Events 4.03). In both groups, the majority of patients (91.0% and 88.9%, respectively) underwent hormonal therapy, with only a few given chemotherapy. The median follow-up after mastectomy was 38 months (range 6–116 months) in the PCWRT group and 48 months (range 23–60 months) in the no-RT group. In both groups, the local recurrence-free survival (RFS) and disease-free survival (DFS) values were 100%. None of the patients developed a local recurrence.

4 | DISCUSSION

Some patients with breast cancer who undergo a mastectomy are node-negative, and understandably, there may be a reluctance to recommend RT of the entire chest wall. Previous studies have shown that patient characteristics can vary in terms of margin status, presence of axillary lymph node metastasis, and use of PMRT (Table 2). The association between margin status and local recurrence after mastectomy without PMRT was investigated in two studies conducted during the 1980s. Both studies addressed the association between the posterior margin (the distance from the tumor margin to the pectoral fascia)

| TABLE 1 Patient characteristics with positive/close margins after mastectomy with pathological N0 status |
|---|---|---|---|
| Characteristics | PCWRT | No | P value |
| Characteristics | N = 22 (%) | N = 18 (%) |
| Age at mastectomy (years) | | | |
| Median (range) | 58.5 (38–75) | 69 (33–84) | 0.062* |
| Premenopausal | 9 (40.9) | 5 (27.8) | 0.386 |
| Histology | | | |
| DCIS | 5 (22.7) | 2 (11.1) | 0.336 |
| Invasive ductal | 10 (45.5) | 12 (66.7) |
| Invasive lobular | 2 (9.0) | 3 (16.7) |
| Invasive micropapillary | 1 (4.6) | 0 |
| Mucinous | 3 (13.6) | 1 (5.5) |
| Apocrine | 1 (4.6) | 0 |
| Pathological size (UICC) | | | |
| Tis | 5 (22.7) | 2 (11.1) | 0.336 |
| T1 | 9 (40.9) | 10 (55.6) |
| T2 | 6 (27.2) | 6 (33.3) |
| T3 | 1 (4.6) | 0 |
| T4 | 1 (4.6) | 0 |
| Surgical margin | | | |
| Positive | 17 (77.3) | 5 (27.8) | 0.002 |
| Close (>0 ≤1 mm) | 5 (22.7) | 13 (72.2) |
| Tumor at positive/close margin | | | |
| Noninvasive | 15 (68.2) | 6 (33.3) | 0.028 |
| Invasive | 7 (31.8) | 12 (66.7) |
| Tumor at positive margin only | | | |
| Noninvasive | 12 (54.5) | 3 (16.7) | 0.655 |
| Invasive | 5 (22.7) | 2 (11.1) |
| Location of positive/close margin | | | |
| Anterior | 7 (31.8) | 4 (22.2) | 0.499 |
| Superior | 0 | 0 |
| Medial | 4 (18.2) | 0 | 0.057 |
| Lateral | 6 (27.2) | 1 (5.5) | 0.072 |
| Inferior | 3 (13.6) | 1 (5.5) | 0.397 |
| Posterior | 7 (31.8) | 13 (72.2) | 0.011 |
| Nuclear grade | | | |
| 1/2 | 21 (95.4) | 17 (94.5) | 0.884 |
| 3 | 1 (4.6) | 1 (5.5) |
| Immunohistological subtypes | | | |
| ER+/HER2− | 18 (82.0) | 11 (61.2) | 0.145 |
| ER+/HER2+ | 2 (9.0) | 2 (11.1) |
| ER−/HER2+ | 0 | 2 (11.1) |
| ER−/HER2− | 2 (9.0) | 1 (5.5) |
| ER+/HER2 borderline | 0 | 2 (11.1) |

(Continues)
was associated with an increased risk of locoregional recurrence. In other studies involving patients at pathological stage T3 without axillary lymph node metastasis, the presence of positive/close margins did not correlate with locoregional recurrence. In a study conducted in patients with positive/close margins and axillary lymph node metastasis after PMRT and who were selected from the U.S. National Cancer Data Base, PMRT was shown to improve outcomes, regardless of whether the margins were positive or negative. In that study, the RT field was also analyzed, and regional lymph node area irradiation in combination with chest wall RT was not associated with the outcomes. In a study conducted in patients with positive/close margins (≤2 mm), including those with axillary lymph node metastasis after PMRT, the presence of positive/close margins did not correlate with locoregional recurrence when a 15 or 20 Gy boost dose was delivered to the tumor bed in addition to PMRT. Regarding the site of local recurrence, some reports have shown that the cancer recurred in the surgical field in 33% to 67% of patients after breast-conserving surgery. For partial breast irradiation, which has recently been implemented based on these reports, the CTV is defined as an area covering the tumor bed cavity and at least 1 cm of surrounding mammary gland. In patients who have undergone mastectomy, however, the CTV for RT is difficult to establish because the surrounding mammary gland has been removed. Local chest wall recurrence after mastectomy has reportedly been detected within 7 cm of the inferior margin of the operation’s transverse scar in ≥97% of patients. In our patients, who did not have risk factors (eg, axillary lymph node metastasis) other than positive/close margins, the RT field was not expanded to cover the entire chest wall in a uniform manner. Instead, we selected PCWRT with a field having at least 2-cm margins to the primary tumor bed and measuring ≥9.5 cm in the cephalocaudal dimension. In all previous studies of PMRT, the RT field was all of the chest wall with or without the regional lymph node area. To the best of our knowledge, the current study is the first to report the selection of only part of

### Table 1

#### Summary of previous studies with/without PMRT after mastectomy for positive/close margins

| Author          | Year  | Years of patient accrual | No. of positive/close margin patients | Definition of positive/close margin | Axillary lymph node metastasis | PMRT | Local recurrence rate |
|-----------------|-------|--------------------------|--------------------------------------|------------------------------------|-------------------------------|------|-----------------------|
| Mentzer et al.  | 1986  | 1974-1982                | 100                                  | ≤30 mm                             | Included                       | Both | 8.0%                  |
| Ahaborn et al.  | 1988  | 1975-1980                | 88                                   | ≤4 mm                              | Excluded                      | No   | 5.7%                  |
| Katz et al.     | 2001  | 1975-1994                | 29                                   | <5 mm                              | Included                      | No   | 45%                   |
| Freedman et al. | 1998  | 1984-1993                | 34                                   | ≤6 mm                              | Included                      | No   | 14.7%                 |
| Feigenberg et al.| 2003  | 1978-1998               | 49                                   | ≤2 mm                              | Included                      | Yes  | 6.1%                  |

Abbreviation: PMRT, postmastectomy radiation therapy.

*This study included patients with or without PMRT.*
the chest wall for PMRT. Regarding the sites of positivity on the margin, one study showed that the proportion of patients with residual tumor did not correlate with the presence of four positive mammary gland margin directions (medial, lateral, superior, and inferior) or the presence of two nonmammary gland margin directions (anterior and posterior) in patients undergoing breast-conserving surgery. Another study showed that positive nonmammary gland margins are associated with a significantly lower local recurrence rate than positive peripheral mammary gland margins, suggesting that subcutaneous and retromammary fat should be retained during breast-conserving surgery. In the present study, the absence of local recurrence might have been attributable to the fact that all patients had undergone mastectomy and had positive/close nonbreast parenchymal margins. RT doses, which have been investigated in patients with positive/close margins (≤2 mm), showed no correlation between the margin status and locoregional recurrence when a 15- or 20-Gy boost dose was delivered to the tumor bed in addition to PMRT at 50 Gy. Another study showed that when patients with positive margins after breast-conserving surgery received a 10- or 26-Gy boost dose in addition to WBRT at 50 Gy, there was no difference in the local recurrence rate in the two groups. After evaluating the results of these studies, we irradiated only part of the chest wall with a total dose of 50-66 Gy in the present study and achieved good local control. However, local control was also satisfactory in patients without irradiation, and therefore the significance of PCWRT remains unclear. In the present study, the baseline characteristics varied between the two groups. For example, the PCWRT group included significantly more patients with positive margins. When the breast parenchyma was removed by mastectomy, locoregional control might have been more strongly affected by the presence or absence of lymph node metastasis than by the surgical margin status. Limitations of the present study include the relatively short follow-up period. However, during our review of previous studies on patients’ undergoing mastectomy for breast cancer, one study investigated any recurrence that developed within 2 years after the procedure, and another showed that locoregional recurrence was detected in 88% of patients within 3 years. Thus, the median follow-up period in the present study may be considered acceptable. In the present study, both the PCWRT group and the no-RT group showed equally good local control without re-excision. We therefore suggest that PCWRT be considered for patients with node-negative breast cancer after mastectomy if they have positive or close margins, although further studies are required to verify these results.

5  |  DECLARATIONS

5.1  |  Availability of data and material

The data used during this study are available from the corresponding author on reasonable request.

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COMPETING INTERESTS

Drs. Ishibashi, Nishimaki, Maebayashi, Adachi, Sakurai, Masuda, Hata, and Okada declare that they have no competing interests.

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