# Value of the US BI-RADS final assessment following mastectomy: BI-RADS 4 and 5 lesions

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Original article

# Value of the US BI-RADS final assessment following mastectomy: BI-RADS 4 and 5 lesions

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## Abstract

**Background:** Clinical examination is not entirely sufficient for evaluation of the postoperative site for follow-up of patients with mastectomy. A few studies have reported that postoperative follow-up US evaluation allows early detection and proper management of local tumor recurrence.

**Purpose:** To evaluate the diagnostic performance of the American College of Radiology (ACR) ultrasonographic (US) Breast Imaging Reporting and Data System (BI-RADS) categories 4 and 5 breast lesions at the mastectomy site.

**Material and Methods:** Our institutional review board approved this study and waived the need for informed consent. We retrospectively reviewed the consecutive post-mastectomy US exams for palpable and non-palpable lesions in the post-mastectomy chest wall that were categorized as BI-RADS 4 (subcategorized 4a, 4b, and 4c) or 5 between January 2007 and April 2010. The positive predictive value (PPV) for final assessment was evaluated.

**Results:** From 2681 post-mastectomy US examinations, we obtained a study population of 50 patients with 50 lesions (20 palpable, 30 non-palpable). There were nine (45%) malignancies among the palpable lesions and six (20%) malignancies among the non-palpable lesions. The palpability showed no significant correlation with malignancy in overall subcategorization ($P > 0.05$). The PPVs of categories 4 and 5 were 14.3% for category 4a, 62.5% for category 4b, 100% for category 4c, and 100% for category 5.

**Conclusion:** The ACR US BI-RADS categorization of 4a, 4b, 4c, and 5 for breast lesions at the mastectomy site is a feasible method for predicting local recurrence. All lesions should be managed according to US characteristics during evaluation of local recurrence at the mastectomy site, regardless of palpability.

**Keywords:** Breast cancer, mastectomy, recurrence, ultrasonography, BI-RADS

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Early diagnosis and a combination of surgery, chemotherapy, and radiation therapy have led to a substantial decrease in breast cancer-related mortality and improved survival (1). However, local recurrence and distant metastasis remain a major problem in breast cancer management. Patients with local recurrence as a first site of failure are at higher risk for subsequent distant relapse than patients who are free of local recurrence, leading to lower survival (2–5).

Clinical examination is mandatory but not entirely sufficient for evaluation of the postoperative site for follow-up of patients with mastectomy. Ultrasound (US) evaluation of the chest wall is not routinely performed in the follow-up after mastectomy. A few studies have reported that postoperative follow-up US evaluation allows early detection and proper management of local tumor recurrence (6–8). To our knowledge, however, no studies have assessed the diagnostic accuracy of postmastectomy US according to the American College of Radiology (ACR) US Breast Imaging Reporting and Data System (BI-RADS) (9). Therefore, the purpose of our study was to evaluate the diagnostic performances of US BI-RADS categories for evaluation of chest wall lesions after mastectomy.

## Material and Methods

### *Surveillance protocol and study population*

At our institution, clinical examination after breast cancer surgery is performed by a surgeon every 6 months for the first 2 or 3 years and annually thereafter. In addition, all patients with a history of surgery for breast cancer are advised to undergo postoperative breast US every 6

months, along with annual mammography for the first 2 or 3 years after surgery and annual breast US and mammography thereafter. Also, our clinicians request US whenever a new palpable mass is detected.

Our institutional review board approved our retrospective study and waived the informed consent requirement. After review of the database, we collected 2681 consecutive US exams for chest wall after mastectomy (unilateral $n = 2599$; bilateral $n = 82$) performed between January 2007 and April 2010. Among these, we selected chest wall lesions assigned a BI-RADS final assessment category 4 or 5 at US. Chest wall lesions assigned to BI-RADS category 1, 2, or 3 or contralateral breast lesions assigned to BI-RADS category 4 or 5 were not included in this study. Chest wall lesions assigned to BI-RADS category 4 or 5 that were not confirmed pathologically were also excluded.

### *Imaging studies and interpretation*

US examination was performed with 7-12 MHz linear-array transducers (iU22 or HDI 5000, Philips-Advanced Technology Laboratories, Bothell, WA, USA) by one of three full-time, board-certified radiologists (authors HMG, EJS, JHY, who have 2, 11, and 5 years of experience with breast US, respectively). The radiologist performing the US had information of the patient's history and physical examination results from the clinician. When patients noted palpable lesions, the radiologists checked the lesions by means of a physical examination and US. The breast areas, chest walls, and bilateral axillary lymph node areas were routinely scanned. The lesion images were acquired in both the transverse and longitudinal projections with and without caliper measurement. The lesion size was measured in the maximal dimension.

ACR BI-RADS lexicon and final assessment were used in the radiologic interpretation. All lesions with low, intermediate, or moderate suspicion for malignancy were categorized as BI-RADS 4a, 4b, or 4c, respectively. Lesions categorized as BI-RADS 5 were considered to be highly suggestive of malignancy. Based on previous studies (10–12), suspicious findings were divided into major and minor, where major signs included irregular shape, spiculated margin, and microcalcification, and minor signs included round shape, microlobulated/indistinct/angular margins, non-parallel orientation, complex echogenicity, and posterior shadowing. BI-RADS category 4a was defined for lesions with one or more minor suspicious findings, category 4b for lesions showing more than three minor suspicious findings, and category 4c for lesions with one major suspicious finding with or without a minor suspicious finding. Category 5 lesions were defined for lesions showing two or more major suspicious findings. US-guided fine-needle aspiration biopsy (FNAB) or spring-loaded core needle biopsy (CNB) was recommended for all lesions categorized as BI-RADS 4 or 5.

### *US-guided FNAB or CNB*

Three radiologists were randomly assigned to each patient for US-guided FNAB or CNB. US-guided FNAB was performed at least twice using a 23-gauge needle (mean passage 2.3; range 2–3). US-guided CNB was performed using a freehand technique, and each procedure was performed with a 14- or 18-gauge dual-action semi-automatic core biopsy needle (Stericut with coaxial; TSK Laboratory, Tochigi, Japan). The throw of the biopsy needle was 2.2 cm. Our standard protocol included four or five core samples per lesion.

### *Data and statistical analysis*

The final diagnosis was based on pathologic results and clinical and imaging follow-up results from at least 12 months after the detection of lesion at mastectomy site. A positive for malignancy at FNAB or CNB examination was defined as a pathologic malignancy result. A negative for malignancy at FNAB or CNB examination was defined as no evidence of recurrence during follow-up for at least 12 months.

Diagnostic indexes such as positive predictive value (PPV) of US BI-RADS category for mastectomy site were calculated. Also, the PPVs were compared between palpable and non-palpable lesions. Statistical significance was assigned using a $\chi^2$ test with statistical software (SPSS 18.0 for Windows; SPSS, Chicago, IL, USA). A $P$ value of less than 0.05 was considered to indicate statistical significance.

## Results

### *Diagnostic performance of BI-RADS category in US for mastectomy site*

Of 2681 US examinations, 50 lesions (1.8%) in 50 patients (mean age 52 years, range 39–70 years) were categorized as BI-RADS 4 or 5. The sizes of the 50 lesions ranged from 3 to 28 mm (mean 10.2 mm). The assigned BI-RADS final assessment category of the 50 chest wall lesions was category 4a in 35 (70%), category 4b in eight (16%), category 4c in three (6%), and category 5 in four (8%). After US-guided FNAB ($n = 22$) or CNB ($n = 28$), 15 (30%) were diagnosed as malignant and 35 (70%) as benign. Table 1 summarizes the biopsy results and PPVs of each US BI-RADS category for chest wall lesions. Regarding palpability, 20 (40%) were palpable and 30 (60%) were non-palpable. There were nine (45%) malignancies in the palpable lesions and six (20%) malignancies in the non-palpable lesions ($P > 0.05$). The palpability showed no significant correlation with malignancy in overall subcategorization ($P > 0.05$).

**Table 1** Positive predictive values of US BI-RADS categories for chest wall lesions after mastectomy

| BI-RADS category | *n* | Malignant | Benign | PPV |
|---|---|---|---|---|
| 4 | 46 | 11 | 35 | 23.9% (11/46) |
| 4a | 35 | 5 | 30 | 14.3% (5/35) |
| 4b | 8 | 3 | 5 | 62.5% (3/8) |
| 4c | 3 | 3 | 0 | 100% (3/3) |
| 5 | 4 | 4 | 0 | 100% (4/4) |
| Total | 50 | 15 | 35 | 30% (15/50) |

PPV = positive predictive value

Thirty-five lesions were categorized as BI-RADS 4a (Fig. 1). These patients had an average age of 51.5 years (age range 34–67 years) and an average lesion size of 8 mm (range 3–19 mm). Among the 35 BI-RADS category 4a lesions, five were malignant and 30 were benign lesions. Of these lesions, 12 (34.3%) were palpable: three of 12 (25%) were malignant (2 IDC and 1 DCIS) and nine (75%) were benign. The remaining 23 of 35 (65.7%) BI-RADS 4a lesions were non-palpable. Of these, two of 23 (8.7%) were malignant (1 DCIS, 1 mucinous carcinoma), and 21 (91.3%) were benign. In 30 patients with benign lesions, there was no evidence of local recurrence or distant metastasis by clinical findings or imaging study in the follow-up period (mean time 23 months, range 13–46 months).

Eight lesions were categorized as BI-RADS 4b (Fig. 2). These patients had an average age of 51.1 years (age range 35–66 years) and an average lesion size of 12.3 mm (range 5–21 mm). Of these lesions, five were palpable: three were malignant (3 IDC) and two were benign. The remaining three of eight BI-RADS 4b lesions were non-palpable, and all were benign. All benign lesions in five patients had no evidence of local recurrence or distant metastasis by clinical findings or imaging study in the follow-up period (mean time 21 months, range 14–39 months).

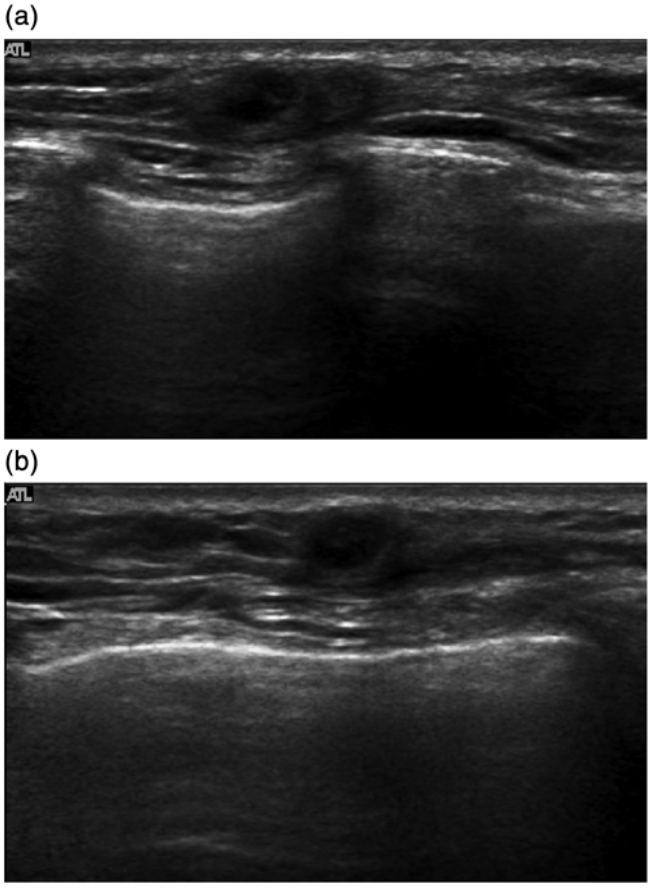


**Fig. 1** A 66-year-old woman with a palpable lesion after left mastectomy. (a) Transverse and (b) longitudinal sonography revealed a 15-mm-size complex echoic nodule at the left chest wall. This lesion was assessed as category 4a, and US-guided core-needle biopsy was performed. Pathology results showed fat necrosis

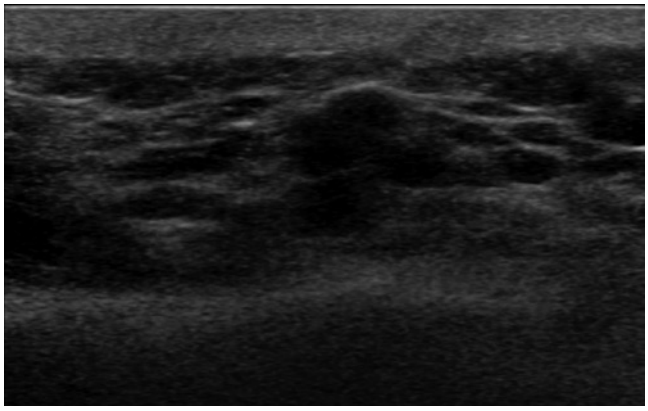

**Fig. 2** A 43-year-old woman with a palpable lesion after right mastectomy. Transverse sonography revealed a 12-mm-size hypoechoic nodule with round shape, indistinct margin and nonparallel orientation at the right chest wall. This lesion was assessed as category 4b, and US-guided fine-needle aspiration biopsy was performed. Pathology results were positive for malignancy. Surgical excision also revealed recurred invasive ductal carcinoma

Three lesions were categorized as BI-RADS 4c (Fig. 3). These patients had an average age of 51.7 years (age range 39–67 years) and an average lesion size of 12.3 mm (range 6–25 mm). Of these three masses, all were malignant

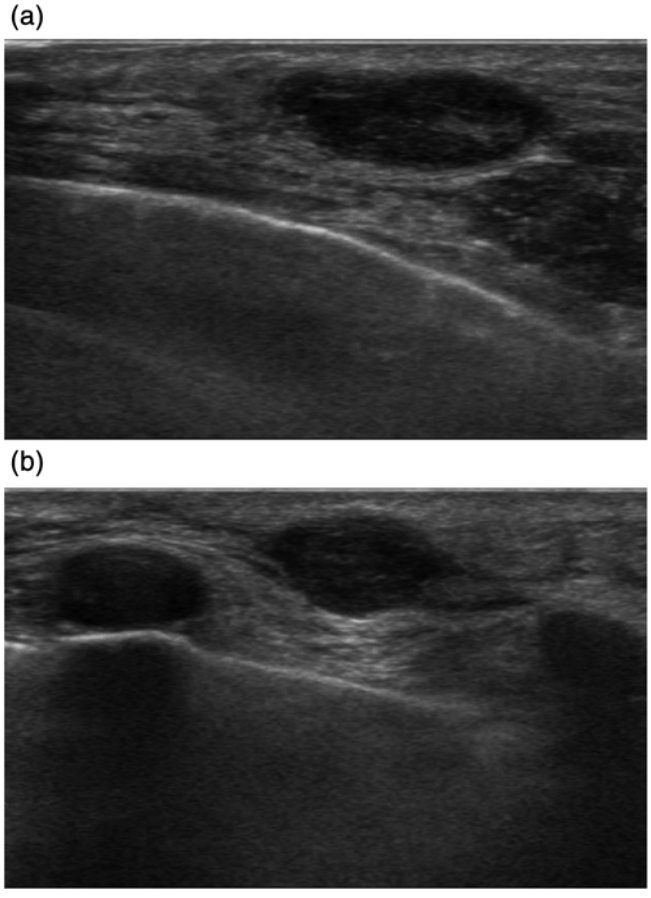


**Fig. 3** A 58-year-old woman with a palpable lesion after right mastectomy. (a) Transverse and (b) longitudinal sonography revealed a 16-mm-size hypoechoic nodule with focal areas of speculated margin at the right chest wall. This lesion was assessed as category 4c, and US-guided core-needle biopsy was performed. Pathology results showed recurred invasive ductal carcinoma in both core biopsy and surgical excision

(2 IDC, 1 mucinous carcinoma): two were palpable and one was non-palpable. Surgical excision was performed in all three cases. In two patients, there was no evidence of additional local recurrence or distant metastasis after surgical excision (mean follow-up time 35 months). In one patient, bone metastasis was detected on whole-body PET 6 months after surgical excision of the recurred lesion.

Four lesions were categorized as BI-RADS 5 (Fig. 4). These patients had an average age of 59 years (age range 54–64 years) and an average lesion size of 18.8 mm (range 9–28 mm). Of these lesions, all were malignant (4 IDC): one was palpable and three were non-palpable. In one patient, only local recurrence at the mastectomy site was seen using imaging studies including breast US, chest CT, abdomen CT, and whole body PET. Surgical excision was performed in this case, and there was no evidence of another local recurrence or distant metastasis after surgery (follow-up time 21 months). In the remaining three patients, distant metastasis was detected by whole body PET or CT within 1 month, and chemotherapy was performed in these cases.

### *Characteristics of 15 patients with local recurrence at the mastectomy site*

Fifteen lesions in 15 patients aged 34–64 years (mean 51.4 years) were diagnosed with local recurrence at postoperative follow-up US (Table 2). Of these 15 patients, nine (60%) had palpable lesions. The mean diameter of the recurred lesions was 14.9 mm (range 4–28 mm). The median interval time after mastectomy was 54.5 months (range 6–183 months). The pathology results of the 15 lesions of local recurrence included 11 IDC, two DCIS and two mucinous carcinomas. Four of the 15 patients (26.7%) with local recurrence at the mastectomy site had subsequent distant metastases during follow-up.

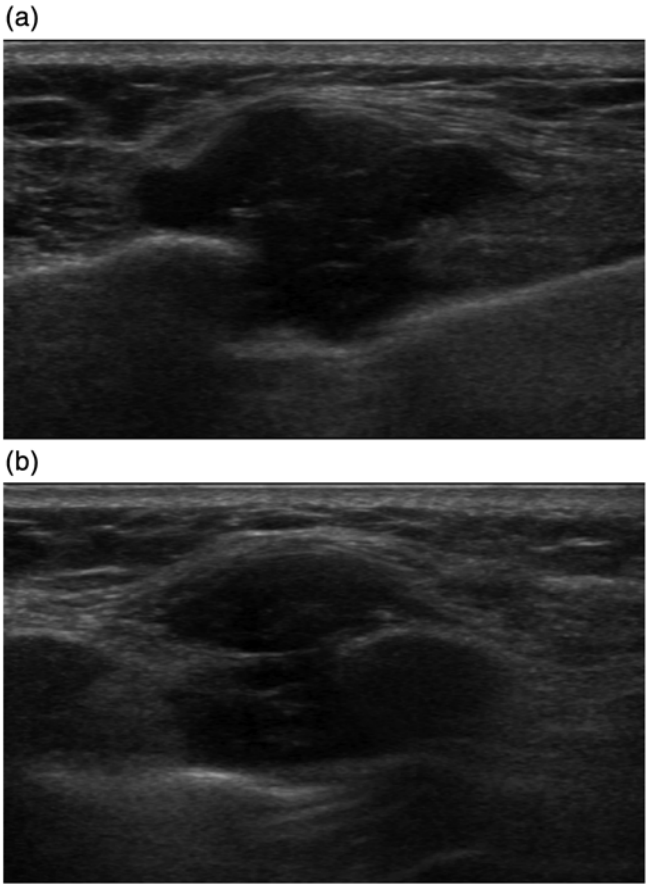


**Fig. 4** A 58-year-old woman with a palpable lesion after left mastectomy. (a) Transverse and (b) longitudinal sonography revealed a 28-mm-size hypoechoic nodule with irregular shape and speculated margin. This lesion was assessed as category 5, and US-guided core-needle biopsy was performed. Pathology results showed recurred invasive ductal carcinoma in both core biopsy and surgical excision

## Discussion

A standardized lexicon for breast US was developed in 2003 by the ACR in light of the increasing use of US in clinical practice. Many studies found the US BI-RADS lexicon and categorization useful for predicting malignancy of a breast mass (13–16). However, to our knowledge, the usefulness of US BI-RADS categories for chest wall lesions at mastectomy sites after breast surgery has not been widely studied.

**Table 2** Findings in 15 patients with local recurrence after mastectomy

| Patient age (years) | BI-RADS | Interval (months) | Palpability | Lesion size (mm) | Pathology |
|---|---|---|---|---|---|
| 39 | 4a | 35 | Non-palpable | 7 | Mucinous ca. |
| 34 | 4a | 18 | Palpable | 4 | IDC |
| 59 | 4a | 29 | Non-palpable | 18 | DCIS |
| 55 | 4a | 53 | Palpable | 8 | DCIS |
| 40 | 4a | 17 | Palpable | 18 | IDC |
| 43 | 4b | 14 | Palpable | 12 | IDC |
| 58 | 4b | 95 | Palpable | 21 | IDC |
| 52 | 4b | 174 | Palpable | 21 | IDC |
| 49 | 4c | 12 | Palpable | 6 | Mucinous ca. |
| 67 | 4c | 24 | Non-palpable | 25 | IDC |
| 39 | 4c | 6 | Palpable | 8 | IDC |
| 60 | 5 | 75 | Non-palpable | 24 | IDC |
| 64 | 5 | 36 | Non-palpable | 9 | IDC |
| 54 | 5 | 46 | Non-palpable | 14 | IDC |
| 58 | 5 | 183 | Palpable | 28 | IDC |

ca. = carcinoma, IDC = invasive ductal carcinoma, DCIS = ductal carcinoma *in situ*

Rissanen *et al.* (17) evaluated the efficacy of breast US for the diagnosis of local breast cancer recurrence after mastectomy, which is the first published report on the use of US at the mastectomy site. The sensitivity of US was 91%, whereas the sensitivities of clinical examination and mammography were 79% and 45%. Mammography in a mastectomy breast is less sensitive since it is difficult to perform in this circumstance, and there is poor visibility of the lesions situated deep in the muscle layer. Kanso *et al.* (8) assessed the value of US at the mastectomy site according to the BI-RADS category and found seven malignant lesions among 11 BI-RADS category 4 lesions. However, there was no diagnostic index of subcategorization for BI-RADS category 4, and there were no BI-RADS 5 lesions.

In our study, the PPVs of category 4 and 5 were 14.3% in category 4a, 62.5% in category 4b, 100% of category 4c, and 100% of category 5. This classification showed good performance and supports the feasibility of using US BI-RADS categories to predict the local breast cancer recurrence at the mastectomy site. These results are consistent with those of previous reports on PPVs of US BI-RADS categories for breast masses from untreated breasts (12, 16). Lee e*t al*. (16) reported that the US BI-RADS categories have a PPV of 26% for category 4a, 83% for category 4b, 91% for category 4c, and 96% for category 5. Yoon *et al.* (12) reported that the PPVs for subcategorization of US BI-RADS 4 are 7.6% for category 4a, 37.8% for category 4b, and 81.9% for category 4c.

The presence of palpability showed no significant correlation with malignancy in overall subcategorization in this study. In contrast to our study, one previous study showed that the PPV was 54.0% for palpable BI-RADS 4 lesions and 16.8% for non-palpable BI-RADS 4 lesions (11). Baek *et al.* (18) also found that the clinical information for risk factors of breast cancer and palpability can affect the diagnostic performance and the BI-RADS final assessment and allow radiologists to search for subtle but suspicious findings in the interpretation of lesions on US. However, similar to our results, Raza *et al.* (19) reported that only 9.4% of palpable BI-RADS 4 lesions were malignant compared with 16.5% of non-palpable lesions. They suggested that even when a lesion is palpable, if the characteristics at US are benign, the likelihood is that it is benign and may be managed without biopsy. Whether palpable or not, overall, lesions of BI-RADS 4c and 5 were malignant in our study. This may be because BI-RADS 4c and 5 lesions have many suspicious US findings suggesting malignancy. Based on this, we suggest that lesions be managed according to US characteristics during evaluation of local recurrence at mastectomy site, regardless of palpability.

There are limitations to our study. First, this study only included biopsy-proven BI-RADS category 4 and 5 lesions at the mastectomy site. Therefore, patient selection bias might possibly result in an overestimation of PPVs. Furthermore, this study did not address the diagnostic index of BI-RADS features in more benign-appearing lesions. In clinical practice, probably benign lesions (BI-RADS 3) may be malignant and their management is difficult, especially in patients who have undergone breast cancer surgery. Second, we did not analyze the specific US features that contribute to the diagnosis of local recurrence at the mastectomy site. Further evaluation of the US BI-RADS lexicon, including probably benign lesions with prospective analysis of breast lesions at the mastectomy site would be useful to assess local recurrence in patients with mastectomy. Third, the study population was too small to generalize the results in all patients with mastectomy.

In conclusion, the ACR US BI-RADS categorization of 4a, 4b, 4c, and 5 for breast lesions at the post-mastectomy site was successful as a predictor for local recurrence. Proper classification according to US characteristics are helpful in the evaluation of local recurrence at the mastectomy site, regardless of palpability.

**Conflict of interest:** None.

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