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ORIGINAL ARTICLE

Synchronous BI-RADS Category 3 Lesions on Preoperative Ultrasonography in Patients with Breast Cancer: Is Short-Term Follow-Up Appropriate?

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Purpose: Breast ultrasonography (US) has been widely used in the preoperative examination of patients with breast cancer. Breast Imaging Reporting and Data System (BI-RADS) category 3 (C3) lesions (probably benign) are regarded as having a low probability of malignancy (≤2%). The purposes of this study were to verify the malignancy rates for synchronous BI-RADS C3 lesions in patients with breast cancer and consider appropriate management strategies for these lesions. **Methods:** Between January 2010 and January 2013, a total of 161 patients underwent surgery in our institute for breast cancer and synchronous BI-RADS C3 lesions. In the US reports, we found records of 219 synchronous BI-RADS C3 nodules in 161 patients. They were excised during surgery for breast cancer management. Stepwise logistic regression analysis was used to identify predictors of malignancy for synchronous BI-RADS C3 lesions. **Results:** The rate of malignancy among the 219 BI-RADS C3 lesions was 9.6%. In simple logistic regression analysis, the size of the primary tumor ($p<0.001$), pathologic T (pT) stage ($p=0.002$), and progesterone receptor (PR) status of the primary tumor ($p=0.029$) were significant predictive factors. In multiple logistic regression analysis, the pT stage and PR status of the primary tumor remained significant predictors ($p=0.004$ and $p=0.003$, respectively), and human epidermal growth factor receptor 2 (HER2) was identified as another significant factor ($p=0.006$). **Conclusion:** In patients with breast cancer who are scheduled for surgery, needle biopsy or excision should be considered for synchronous BI-RADS C3 lesions identified on preoperative US when the primary tumor has the following risk factors: large size, high PR expression, and HER2 positivity.

Key Words: *Breast diseases, Breast neoplasms, Multiple primary neoplasms, Predictive value of tests, Ultrasonography*

INTRODUCTION

Whole breast ultrasonography (US) has been widely used in the preoperative examination of patients with breast cancer [1-3]. This common use of breast US has resulted in the detection of many synchronous nonpalpable lesions. The American College of Radiology (ACR) has developed a Breast Imaging Reporting and Data System (BI-RADS) that can be used to classify breast lesions into categories 0–6 based on imaging findings [4-6]. The ACR has also proposed an appropriate management strategy for each category, and these strategies have become widely accepted. BI-RADS category 3 (C3) lesions, which are probably benign, are regarded as having a low probability of malignancy (< 2%); consequently, the ACR recommends short-term follow-up rather than needle biopsy or excision [5-22]. These follow-up examinations using imaging have a cost benefit, and they do not cause postoperative complications such as deformation or scarring of the breast.

However, if ipsilateral or contralateral synchronous BI-RADS C3 nodules are identified during preoperative US examinations in patients with breast cancer, surgeons may have difficulty in choosing between short-term follow-up after cancer surgery and histological confirmation by needle biopsy or excision before or during cancer surgery.

Although short-term follow-up has been commonly accepted for the management of such cases, based on our past clinical experience, the BI-RADS classification might be lacking, or there might be a discrepancy between the assessment and recommendations, especially in patients with known breast cancer [23].

The purposes of the present study were to verify the malig-

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nancy rate of synchronous BI-RADS C3 lesions in patients with breast cancer and suggest an appropriate management strategy for these lesions.

METHODS

Patients

Between January 2010 and January 2013, a total of 161 patients underwent surgery in our institute for breast cancer with synchronous BI-RADS C3 lesions located in the ipsilateral or contralateral breast. Data were retrospectively collected from medical records, imaging reports, and histological results. The patients were diagnosed as having *in situ* cancer or invasive cancer by means of needle, vacuum-assisted, or excisional biopsy. All patients underwent preoperative bilateral whole-breast US to evaluate the location, size, and extent of the primary tumor, multifocal malignancy, and axillary nodal status. In the US reports, we found records regarding 219 synchronous BI-RADS C3 nodules from 161 patients. Most nodules were nonpalpable and were detected incidentally. After localization using a skin marker or wire, the lesions were excised during surgery for breast cancer management. The surgical methods used for the treatment of the primary cancer lesions were breast-conserving surgery or mastectomy with or without reconstruction. In cases of synchronous nodules in the same quadrant of the ipsilateral breast, clinicians excised nodules easily with minimal extension of the surgical margin. Consequently, synchronous nodules in the same quadrant were usually excised along with the main tumor. Conversely, synchronous nodules in a different quadrant of the ipsilateral breast or in the contralateral breast were selectively excised using another incision. The Institutional Review Board of Pusan National University Hospital approved this study, and patient approval or informed consent was not required to review the patient images and records because the study was performed retrospectively using routinely acquired data (IRB approval number: E-2015025). However, information was provided to the patients, and they requested histological confirmation of the synchronous BI-RADS C3 lesions and their subsequent removal.

Imaging and interpretation

In the present study, we used ultrasonography units (iU22, Philips Healthcare, Best, The Netherlands; Logiq 9, GE Healthcare, Milwaukee, USA) equipped with 5–12-MHz linear-array transducers. All US examinations were performed or supervised by two experienced board-certified breast radiologists with experience in breast imaging. The breast radiologists routinely reviewed mammography and breast magnetic resonance imaging (MRI) findings before performing US. Therefore, they performed US with knowledge of the mammographic and MRI findings. They divided the lesions into categories according to the ultrasonographic BI-RADS classification [8,24,25]. Using US, the following lesions were classified as BI-RADS C3: a solid hypoechoic oval or gently lobulated mass with circumscribed margins; an oval- or round-shaped mass; a mass with slight or no lobulation; lesions with an abrupt interface and an orientation parallel to the skin; or complicated cysts or clustered microcysts [8,12,17,18,20,21]. The size of the nodules was measured on the initial US image.

Histological assessment

All histopathological results were evaluated by an experienced pathologist. The final diagnosis of synchronous lesions was obtained by examination of the excised specimen. Carcinoma *in situ*, including ductal carcinoma *in situ* and lobular carcinoma *in situ*, and invasive carcinoma were classified as malignancies. Atypical ductal hyperplasia (ADH), atypical lobular hyperplasia (ALH), and any lesions with atypia were classified as high-risk benign lesions.

Immunohistochemical staining of primary cancer was performed to identify the following indicators: estrogen receptor (ER), progesterone receptor (PR), human epidermal growth factor receptor 2 (HER2), and Ki-67. ER and PR status was determined by nuclear staining, which was graded from 0 to 8 using the Allred score [26]. The results were categorized as positive when the total score, expressed as the sum of the proportional score and immunointensity score, was 3 or higher. The PR expression level was classified as low or high according to the Allred score for statistical analysis (low: 0–3; high: 4–8). HER2 positivity was denoted by a score of 3+ on immunohistochemistry, as well as a score of 2+ but exhibiting amplification as demonstrated by fluorescence *in situ* hybridization or silver *in situ* hybridization, according to the guidelines of The American Society of Clinical Oncology and the College of American Pathologists [27]. Cancer was staged according to the American Joint Committee on Cancer Staging System seventh edition (2010) [28].

Statistical analysis

Continuous and categorical variables were presented as the mean ± standard deviation and frequency (%), respectively. Continuous variables were compared using the independent-samples t-test or Mann-Whitney U test, as appropriate. The chi-square test or Fisher exact test was used to determine the significance of differences in categorical variables. Stepwise logistic regression analysis was used to identify predictors of malignancy regarding the synchronous BI-RADS C3 lesions

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on US. Statistical analyses were performed using SAS version 9.3 (SAS Institute, Cary, USA). In all analyses, the significance level was set at 0.05.

RESULTS

The study included 219 synchronous BI-RADS C3 nodules identified in the US reports of 161 patients. In total, 195 of the 219 nodules (89.0%) were not palpable. Consequently, they were excised after US-guided skin marking or hook-wire localization during surgery for the primary cancer.

The final pathologic results for all 219 nodules that were classified as BI-RADS C3 lesions on preoperative US are detailed in Table 1. There were 21 malignant lesions, providing a rate of malignancy among the 219 BI-RADS C3 nodules of 9.6%. In addition, high-risk benign lesions (ADH, ALH, and any atypical lesions) were identified in 40 nodules (18.3%), which required histological diagnosis and treatment. Half of the benign lesions were confirmed by the presence of fibrocystic change and fibroadenoma (Table 1).

The characteristics of the 219 BI-RADS C3 synchronous nodules are detailed in Table 2. All of the 161 patients were women, and their mean age was 47.95 ± 8.66 years (range, 29–72 years). In total, 57 of these patients (26.0%) were postmenopausal. Simple logistic regression analysis was performed to identify the factors that could predict malignancy in the synchronous lesions. There was no significant difference between the two groups (benign vs. malignant) in terms of age, menopausal status, surgical procedure, and the location of the synchronous nodules. Of the 219 nodules, 60 (27.4%) were located in the ipsilateral breast, and 159 (72.6%) were located in the contralateral breast. In the ipsilateral breast, 31 nodules (14.2%) were situated in the same quadrant, and 29 nodules (13.2%) were located in other quadrants. Additionally, the size and number of synchronous nodules (multiplicity) identified on preoperative US did not differ sig-

Table 1. Histopathologic results for 219 BI-RADS C3 synchronous nodules on ultrasonography

Histopathologic result	No. (%)
Benign	158 (72.1)
Fibrocystic change	73 (33.3)
Fibroadenoma	49 (22.4)
Sclerosing adenosis	20 (9.1)
Intraductal papilloma	5 (2.3)
Intraductal hyperplasia	11 (5.0)
High risk benign	40 (18.3)
ADH	35 (16.0)
ALH	3 (1.4)
Atypical apocrine metaplasia	2 (0.9)
Malignant	21 (9.6)
DCIS	8 (3.7)
LCIS	9 (4.1)
IDC	4 (1.8)
Total	219 (100.0)

BI-RADS = Breast Imaging Reporting and Data System; ADH = atypical ductal hyperplasia; ALH = atypical lobular hyperplasia; DCIS = ductal carcinoma *in situ*; LCIS = lobular carcinoma *in situ*; IDC = invasive ductal carcinoma.

Table 2. Baseline characteristics of 219 BI-RADS C3 lesions and simple logistic regression analysis

Characteristic	Total (n = 219) No. (%)	Benign (n = 198) No. (%)	Malignant (n = 21) No. (%)	*p*-value	OR (95% CI)
Age (yr)*	47.95 ± 8.66	47.93 ± 8.54	48.05 ± 8.90	0.954	1.0 (1.0–1.1)
Menopausal status				0.808	
Premenopause	162 (74.0)	146 (73.7)	16 (76.2)		1.0 (reference)
Postmenopause	57 (26.0)	52 (26.3)	5 (23.8)		0.9 (0.3–2.5)
Surgical treatment				0.952	
Breast conserving	168 (76.7)	152 (76.8)	16 (76.2)		1.0 (reference)
Mastectomy	51 (23.3)	46 (23.2)	5 (23.8)		1.0 (0.4–3.0)
Location				0.699	
Ipsilateral breast	60 (27.4)	55 (27.8)	5 (23.8)		1.0 (reference)
Same quadrant	31 (14.2)	28 (14.1)	3 (14.3)		
Different quadrant	29 (13.2)	27 (13.6)	2 (9.5)		
Contralateral breast	159 (72.6)	143 (72.2)	16 (76.2)		1.2 (0.4–3.5)
Tumor size on US (cm)*	0.60 ± 0.44	0.58 ± 0.44	0.62 ± 0.39	0.695	1.2 (0.5–2.9)
No. of nodules*	1.66 ± 0.80	1.65 ± 0.79	1.71 ± 0.90	0.732	1.1 (0.6–1.9)
Multiplicity of nodules				0.687	
Single	116 (53.0)	104 (52.5)	12 (57.1)		1.0 (reference)
Multiple	103 (47.0)	94 (47.5)	9 (42.9)		0.8 (0.3–2.1)

BI-RADS = Breast Imaging Reporting and Data System; OR = odds ratio; CI = confidence interval; US = ultrasonography.
*Mean ± SD.

nificantly between the two groups. The mean size of the nodules measured on US was 0.6±0.44 cm (range, 0.2–4.3 cm) (Table 2).

When the results of imaging studies other than US were compared between the two groups, there was no difference in mammographic and positron emission tomography findings; most of the cases were categorized as BI-RADS category 1. The preoperative MRI findings did reveal a significant difference between the two groups; however, the BI-RADS category was found to be rather low in the malignant group (Table 3). Because of the small number of nodules in the malignant group, there was a limitation in analyzing the results, and it was more difficult to determine clinical significance.

Simple logistic regression analysis was performed to identify the factors regarding the primary tumor that could be used to predict whether a synchronous BI-RADS C3 nodule was malignant (Table 4). The results of the analysis illustrated that the histological size ($p<0.001$), pathologic T (pT) stage ($p=0.002$), and PR status of the primary tumor ($p=0.029$) had statistical significance. In particular, the odds ratio (OR) for stage pT3 (>5 cm) was 4.3 (95% confidence interval [CI], 1.5–12.2) as compared with stage pT1 (≤2 cm); the OR for nodules with a high PR status (Allred score 4–8) was 3.2 (95% CI, 1.1–9.1) compared with nodules with low PR status (Allred score 0–3) (Table 4).

In multiple logistic regression analysis, the pT stage and PR

Table 3. Preoperative imaging findings for 219 synchronous BI-RADS C3 lesions on ultrasonography

BI-RADS category	Benign (n=198) No. (%)	Malignant (n=21) No. (%)	*p*-value
Mammography			0.605
0	7 (3.5)	0	
1	172 (86.9)	20 (95.2)	
2	6 (3.0)	1 (4.8)	
3	13 (6.6)	0	
MRI			<0.001
0	10 (5.1)	6 (28.6)	
1	106 (53.5)	4 (19.0)	
2	26 (13.1)	6 (28.6)	
3	47 (23.7)	4 (19.0)	
4	6 (3.0)	1 (4.8)	
5	3 (1.5)	0	
PET			0.074
1	195 (98.5)	19 (90.5)	
5	3 (1.5)	2 (9.5)	

BI-RADS=Breast Imaging Reporting and Data System; MRI=magnetic resonance imaging; PET=positron emission tomography.

Table 4. Simple logistic regression analysis of the characteristics of the primary cancer predictive of malignancy

Histologic characteristics of primary cancer	Total (n=219) No. (%)	Benign (n=198) No. (%)	Malignant (n=21) No. (%)	*p*-value	OR (95% CI)
Histologic tumor size (cm)*	2.83±2.22	2.65±1.82	4.54±4.24	<0.001	1.3 (1.1–1.5)
pT stage				0.002	
1	111 (50.7)	101 (51.0)	10 (47.6)		1.0 (reference)
2	81 (37.0)	78 (39.4)	3 (14.3)		0.4 (0.1–1.5)
3	27 (12.3)	19 (9.6)	8 (38.1)		4.3 (1.5–12.2)
pN stage	-	-	-	0.627	-
Histologic type	-	-	-	0.062	-
Histologic differentiation	-	-	-	0.846	-
Nuclear grade	-	-	-	0.515	-
Lymphovascular invasion	-	-	-	0.513	-
Necrosis	-	-	-	0.514	-
ER (Allred score)				0.474	
Negative (0–2)	56 (25.6)	52 (26.3)	4 (19.0)		1.0 (reference)
Positive (3–8)	163 (74.4)	146 (73.7)	17 (81.0)		1.5 (0.49–4.7)
PR (Allred score)				0.029	
Low (0–3)	104 (47.5)	99 (50.0)	5 (23.8)		1.0 (reference)
High (4–8)	115 (52.5)	99 (50.0)	16 (76.2)		3.2 (1.1–9.1)
HER2				0.086	
Negative†	169 (77.2)	156 (78.8)	13 (61.9)		1.0 (reference)
Positive‡	50 (22.8)	42 (21.2)	8 (38.1)		2.3 (0.9–5.9)
Ki-67 (%)*	15.67±21.01	16.07±21.40	11.95±16.86	0.398	1.0 (1.0–1.0)

OR=odds ratio; CI=confidence interval; pT stage=pathologic T stage; pN stage=pathologic N stage; ER=estrogen receptor; PR=progesterone receptor; HER2=human epidermal growth factor receptor 2.
*Mean±SD; †0–2 Positive immunohistochemistry (IHC) or not amplified by fluorescence *in situ* hybridization (FISH) or silver *in situ* hybridization (SISH); ‡3 Positive in IHC or amplified by FISH or SISH.

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Table 5. Multiple logistic regression analysis of the characteristics of the primary cancer predictive of malignancy

Variable	*p*-value	OR (95% CI)
pT stage	0.004	
1		1.0 (reference)
2		0.149 (0.022–1.024)
3		6.734 (1.522–29.801)
Lymphovascular invasion	0.069	
Negative		1.0 (reference)
Positive		0.232 (0.05–1.1)
NA		
PR (Allred score)	0.003	
Low (0–3)		1.0 (reference)
High (4–8)		9.225 (2.1–40.1)
HER2	0.006	
Negative*		
Positive†		8.993 (1.9–43.2)

OR = odds ratio; CI = confidence interval; pT stage = pathologic T stage; NA = not accessed; PR = progesterone receptor; HER2 = human epidermal growth factor receptor 2.
*0–2 Positive immunohistochemistry (IHC) or not amplified by fluorescence *in situ* hybridization (FISH) or silver *in situ* hybridization (SISH); †3 Positive in IHC or amplified by FISH or SISH.

status remained significant factors that could predict malignancy in synchronous BI-RADS C3 lesions ($p = 0.004$ and $p = 0.003$, respectively). HER2 was identified as another significant predictive factor of malignancy in multiple logistic regression analysis ($p = 0.006$), which was a different result from those of the simple logistic regression analysis (Table 5).

DISCUSSION

To date, several studies involving BI-RADS C3 lesions reported that the malignancy rate of this lesion type is ≤2%. Thus, short-term follow-up for 2–3 years is recommended for BI-RADS C3 lesions [5-22]. However, most patients with breast cancer who know that they have an ipsilateral or contralateral synchronous nodule in their breasts are worried that the lesion may have the potential to become cancerous or that it is another cancer. These patients usually want to be given an accurate histological diagnosis.

Physicians may also feel a great deal of pressure because of the presence of a BI-RADS C3 lesion during the postoperative follow-up period. If these lesions have changed in size or shape, needle biopsy or excision should be performed for the histological diagnosis. If the histological report reveals that the lesion is malignant, then patients should undergo additional surgery, and they may experience psychological and economic damage because of the failure of the early diagnosis and treatment.

However, if the BI-RADS C3 lesion is not located near the primary cancer lesion, especially if it is located in a different quadrant or in the contralateral breast, it is technically difficult to remove the C3 lesion together with the primary lesion. There may be adverse effects regarding cosmesis and problems associated with an unnecessary additional procedure.

In the current study, we found that the malignancy rate of synchronous BI-RADS C3 lesions on US was much higher than those previously reported in other studies. We also identified significant factors associated with malignancy in synchronous BI-RADS C3 lesions such as the size (pT stage), PR status, and HER2 status of the primary tumor. Additionally, the rate of occurrence of high-risk benign lesions such as ADH, ALH, or any lesion with atypia was 18.3%. These lesions require wide excision to confirm the pathologic diagnosis. Conclusively, 61 (27.9%) of 219 synchronous BI-RADS C3 nodules on US were lesions requiring immediate surgical excision. In patients with breast cancer, if BI-RADS C3 lesions are identified on preoperative US, we suggest that aggressive work-up such as needle or excisional biopsy should be undertaken before or during cancer surgery. Furthermore, the size (pT stage), PR status, and HER2 status of the primary cancer lesion should be considered as risk factors for synchronous malignant tumors.

A limitation of the present study was the small number of patients involved. In the future, it will be possible to obtain results that are more accurate and reliable by evaluating a larger number of patients. In addition, comparison of the malignancy rate of newly discovered BI-RADS C3 lesions after curative resection for breast cancer with the results of our study will be meaningful. We will need to wait and determine whether long-term follow-up confirms our current findings.

In conclusion, the present study demonstrated that the malignancy rate of ipsilateral or contralateral synchronous BI-RADS C3 lesions in patients with breast cancer on preoperative US was 9.6%. This rate is considerably higher than those reported in several previous studies. We also identified a number of significant predictive factors associated with malignancy in synchronous BI-RADS C3 lesions such as the size (pT stage), PR status, and HER2 status of the primary tumor. In patients with breast cancer who are scheduled for surgery, ipsilateral or contralateral synchronous BI-RADS C3 lesions identified on preoperative US should be treated using a more aggressive strategy than routine follow-up.

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CONFLICT OF INTEREST

The authors declare that they have no competing interests.

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