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ORIGINAL ARTICLE

Predictors of invasive disease in patients preoperatively diagnosed with ductal carcinoma without stromal invasion, with breast magnetic resonance imaging (MRI) and ultrasound (US)

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Abstract

Background A preoperative diagnosis of ductal carcinoma in situ (DCIS) is sometimes upstaged to invasive disease postoperatively. Our objective was to clarify the predictive factors of invasive disease using preoperative imaging and to investigate the positive ratio of sentinel lymph nodes (SLN) and the incidence of invasive disease.

Methods The subjects were 402 patients with preoperatively diagnosed ductal carcinoma without stromal invasion who underwent breast surgery with concomitant SLN surgery in January 2007 to December 2016. Of the 306 included patients, all 306 patients underwent preoperative MRI and US assessment. Outcomes were analyzed for significance using univariate and multivariate analyses.

Results Of the 306 patients, 115 (37.6%) had invasive disease and 191 (62.4%) had DCIS only. Of the 115 patients with invasive disease, 5 (4.4%) and 4 (3.5%) had macro- and micrometastases in SLN. On the other hand, of the 191 patients with DCIS, only 1 (0.5%) had a micrometastasis. Predictors of invasive disease in the univariate analysis included having a palpable mass, were varied by biopsy method, having a US hypoechoic mass, MRI enhancement, or MRI large enhanced lesion; the size of the mass enhancement ≥ 1.1 cm or a spread of non-mass enhancement ≥ 3.1 cm ($P = 0.003$). Predictors of invasive disease in the multivariate analysis included US hypoechoic mass and MRI large enhanced lesion.

Conclusion We need to perform SLN biopsy for preoperatively diagnosed DCIS when patients have predictors of invasive disease, but SLN biopsy will no longer be essential for patients when they have no predictors of invasive disease.

Keywords DCIS · Predictive factors · MRI · US · SLN biopsy

Introduction

Ductal carcinoma in situ (DCIS) accounts for 20–25% of newly diagnosed breast cancer cases annually [1]. By definition, DCIS is a non-invasive lesion with malignant cells bound by the basement membrane [2]; therefore, sentinel lymph node (SLN) surgery is typically not advised.

However, lesions initially diagnosed as DCIS on needle biopsy are occasionally upstaged to invasive cancer after the final pathology report of the completely excised specimen. This is due to the inherent limitations of biopsy sampling techniques, by which a small invasive lesion may fail to be detected in a large area of intraductal lesions. Today, this upstaging occurs in 8–38% of patients with a needle-biopsy diagnosis of DCIS [3–9]. In these cases, previous studies reported SLN metastasis rates of 1.3–13% [10–14]. On the other hand, in patients who had no invasive disease on reevaluation of the primary tumor, SLN metastasis rates were reported to be only 2% and the metastases were almost all classified as micrometastases [2].

SLN surgery is not a risk-free procedure [16–19]. Although the complication rates are lower with an SLN biopsy than with axillary lymph node dissection, there remains a risk of complications such as lymphedema, arm pain, and numbness [20, 21]. Forgoing SLN sampling in

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cases, where it is not necessary would avoid the risk of these complications.

Multiple studies have identified the factors associated with the upstaging of DCIS to invasive disease [3–9]. The results of previous studies have reported that the predictive factors of invasive disease are age, palpable lesion, mammography (MMG) and MRI imaging, pathological factors, and so on [22–24]; however, no consensus has been reached regarding the factors that should be used.

This study was designed to determine the positive ratio of SLN and the incidence of biopsy diagnoses of ductal carcinoma without stromal invasion that were upstaged to invasive carcinoma at the time of definitive resection. In addition, prognostic factors were evaluated to determine if selective SLN surgery could be recommended in patients with a biopsy diagnosis of DCIS who have no risk of being upstaged to invasive carcinoma by preoperative imaging studies.

Materials and methods

Patient collection

The study consisted of 402 patients who were diagnosed with ductal carcinoma without stromal invasion by a preoperative needle or excisional biopsy and who underwent breast surgery with concomitant SLN surgery between January 2007 and December 2016 at Keio University Hospital (Tokyo, Japan) as identified retrospectively from a medical record database. The exclusion criteria were as follows: (i) 64 patients were not performed MRI; (ii) 32 patients were obvious suspected stromal invasion by imaging (i.e., spiculated mass); (iii) No one received neoadjuvant drug therapy; and (iv) No one had heterochronous ipsilateral breast cancer recurrence. After applying the exclusion criteria, a total of 306 patients were included in our study (Fig. 1).

Data collection

The patients' clinical characteristics, pathologic data, treatment methods, and imaging data (e.g., MMG, US, and MRI) were prospectively recorded, and a retrospective review was then performed. All patients underwent lumpectomy or mastectomy. Prognostic factors such as age, palpable mass, hormone receptor, biopsy technique [stereotactically guided Mammotome biopsy (ST-MMT) by 8 G access, a core needle biopsy (CNB) by 14 G access, a vacuum-assisted CNB (VACNB) by 10 G access, or an excisional biopsy], MMG density, shape of the calcifications, distribution of the calcifications, US imaging (hypoechoic mass, hypoechoic lesion, cystic lesion, or ductal ectasia), MRI imaging [mass enhancement or non-mass enhancement], and enhanced lesion (small or large) were analyzed as to whether they correlated with the presence of invasive carcinoma after the definitive resection.

All imaging data were reviewed by a single breast surgeon. The data were sorted by category according to the Breast Imaging Reporting and Data System (BI-RADS; American College of Radiology, Reston, VA USA) assessment category. BI-RADS MRI lexicon classifies lesions with contrast enhancement which is defined "enhanced lesion" in this study into focus, mass enhancement and non-mass enhancement. In this study, lesions that are less than 5 mm in size and suggest malignancy are included in mass

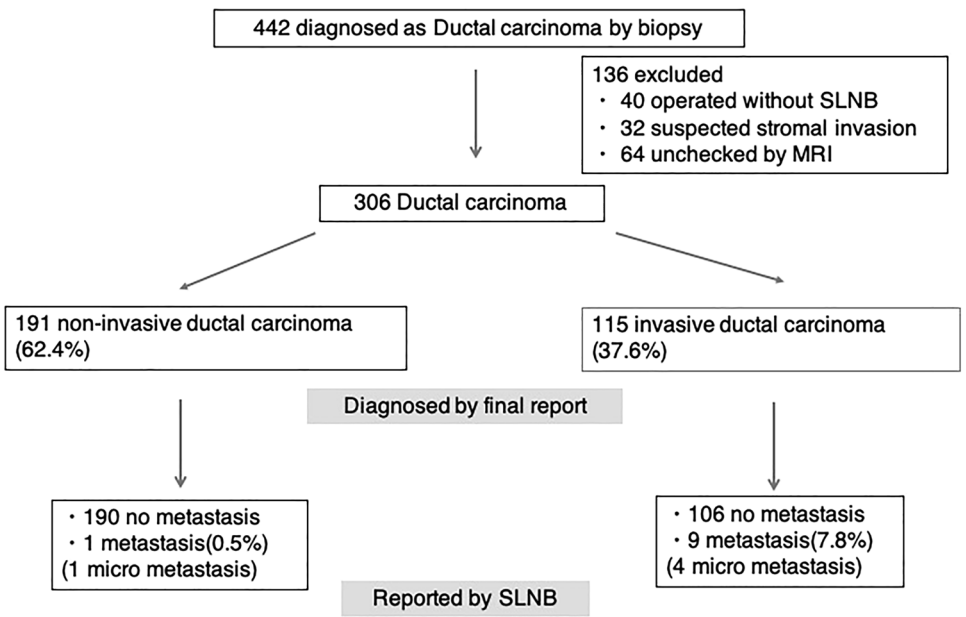

Fig. 1 496 ductal carcinoma were preopelatively diagnosed by core needle biopsy or excisional biopsy, 306 ductal carcinoma were classified as invasive or non-invasive by final report, metastasis or no metastasis bySLNBFig.1 496 ductal carcinoma

enhancement. We classified enhanced lesions into two categories of mass or non-mass enhancement and measured the maximum lesion size of each enhancement type on the sagittal view of the contrast-enhanced T1-weighted MRI. The receiver operating characteristic (ROC) curve of the maximum lesion size for postoperative invasive disease risk was described according to the enhancement type. We defined the cut-off value at the point, where the sum of sensitivity and specificity was maximum and the enhanced lesions above the cut-off value as "large" and which below the cut-off value as "small".

We performed each biopsy with the aid of US guidance using a VACNB device [BARD Vacora; C.R. Bard/Becton, Dickinson, East Rutherford, NJ USA]. CNB devices [BARD Monopty; C.R. Bard/Becton, Dickinson] were sometimes used for patients with a high bleeding risk. If the target lesions were calcifications detected only by MMG imaging, we performed the biopsy with the aid of stereotactic MMG guidance using a VACNB device [Mammotome; Leica Biosystems, Wetzlar, Germany]. We also performed an excisional biopsy if the target lesions collected by needle biopsy were not correctly diagnosed as benign or malignancy (e.g., in the case of atypical ductal hyperplasia).

Statistical methods

We used univariate logistic regression analysis to screen for potential predictors of invasive disease on the final pathology. Next, we used multivariate logistic regression analysis for the significant factors from the univariate analyses. Finally, using the significant characteristics from the multivariate analysis, the incidence of invasive disease was compared. Only preoperative factors were used for these analyses. Statistically significant differences were defined as having P values < 0.05, and the confidence intervals (CIs) were set at 95%. All statistical analyses were conducted using IBM SPSS Statistics software (version 23.0; IBM Corp., Armonk, NY USA).

Results

The median age of the patients was 55.5 years (range, 24–83). A palpable mass was observed in 108 patients (35.3%). As for the biopsy method, 195 patients (63.7%) underwent needle biopsy under ultrasonography guidance, mainly collecting tissue using a VACNB device. A total of 98 patients (32%) were diagnosed by ST-MMT, and an excisional biopsy was performed in 12 patients (3.9%) who were not diagnosed by needle biopsy. Regarding the hormone receptor status of the biopsy specimens, 247 patients (80.7%) were estrogen-receptor (ER) positive and 226 (73.9%) were progesterone-receptor (PgR) positive. In MMG density, 176 patients (57.6%) were of the most common heterogeneously dense cases. Microcalcification on MMG imaging was confirmed in 151 patients (50.6%). When we classified cases by US imaging, 125 patients (40.8%) had hypoechoic masses, 146 patients (47.7%) had hypoechoic lesions, and 13 patients (4.2%) had other findings. Nothing significant was observed on US imaging in 22 patients (7.3%). On MRI imaging, 79 patients (25.8%) showed mass enhancement and 211 patients (69%) showed mostly non-mass enhancement. Of the total, 16 patients (5.2%) showed no findings on MRI (Table 1).

Overall, 306 patients who were diagnosed with ductal carcinoma without stromal invasion and who underwent breast surgery with concomitant SLN surgery at Keio University Hospital met the study criteria. Of these, 115 patients (38%) were upstaged to invasive disease (115 patients were assigned to the invasive group) and 191 patients (62%) were diagnosed with pure DCIS (191 were assigned to the non-invasive group) on final pathology. Of the invasive group, 94 patients (84.7%) were diagnosed with invasive cancer with a pathological tumor size (pT) < 1.0 cm. As the result of SLN surgery, nine (7.8%) had SLN metastases of the invasive group; on the other hand, only one (0.5%) had SLN micrometastases of the non-invasive group. The SLN positive rate was significantly higher in the invasive group than in the non-invasive group ($P = 0.001$). Of the nine patients in the invasive group, four had SLN micrometastases (Fig. 1).

Univariate analysis of the invasive disease predictors showed that the frequency of the invasive group was significantly higher in the patients with a palpable mass ($P = 0.003$). By biopsy method, the proportion of patients who were diagnosed by ST-MMT was larger in the DCIS group, and this group had more patients who underwent excisional biopsy because of a preoperative diagnosis such as "suspected DCIS" ($P = 0.014$). In the US findings, the number of patients with hypoechoic masses was significantly higher in the invasive group ($P < 0.001$). On the other hand, the patients with a hypoechoic lesion, which cannot be identified as a mass, were relatively more frequent in the DCIS group. In the MRI findings, the ratio of mass enhancement to non-mass enhancement was the same in the invasive group as in the DCIS group. In the invasive group, the number of patients with no findings on MRI was 1 (0.9%), whereas in the DCIS group, 15 patients (7.9%) had an enhanced lesion ($P = 0.028$). The cut-off value for MRI large enhanced lesions indicated by ROC curve was 1.1 cm for mass and 3.1 cm for non-mass enhancement. The incidence of MRI large enhanced lesion was significantly more in the invasive group than in the DCIS group. ($P = 0.003$; (Table 2).

Multivariate analysis of the predictive factors of invasive disease revealed a significant difference ($P < 0.001$) in hypoechoic mass on US (2.86; 95% CI: 1.71–4.78) and in large enhanced lesion on MRI (2.33; 95% CI: 1.39–3.91; $P = 0.001$; Table 3).

Table 1 Patients characteristics of 306 ductal carcinoma

		N	Rate (%)
Number of patients		306	
Age			
Median (range)	55.5 (24–83)		
Palpable mass			
Yes		108	35.3
No		198	64.7
Biopsy method			
ST-MMT		98	32
CNB		64	20.9
'VACNB		131	42.8
Excisional biopsy		12	3.9
Unknown		1	0.3
Hormone Receptor			
ER positive		247	80.7
ER negative		55	18
Unknown		4	1.3
PgR positive		226	73.9
PgR negative		76	24.8
Unknown		4	1.3

	N	Rate (%)
Number of patients	306	
MMG		
Density		
Almost entirely fat	19	6.2
Scattered fibroglandular densities	65	21.2
Heterogeneously dense	176	57.6
Extremely dense	46	15
Calc-shape		
Round	28	9.2
Amorphous	47	15.3
Polygonal	56	18.3
Linear	24	7.8
None	151	49.4
Calc -distribution		
Grouped, clustered	75	24.5
Segmental	79	25.8
Linear	1	0.3
Regional、scattered	0	0
None	151	49.4

	N	Rate (%)
Number of patients	306	
US		
Mass	125	40.8
Hypoechoic lesion	146	47.7
Cystic lesion/ductal ectasia	13	4.2
None	22	7.3
MRI		
Mass enhancement	79	25.8
Non mass enhancement	211	69
None	16	5.2
Breast surgery		
Lumpectomy	143	46.7
Mastectomy	163	53.3
pT		
T1mi	27	24.5
T1a	37	31.6
T1b	30	28.6
T1c	14	10.2
T2	7	5.1

Discussion

The role of SLN surgery following a preoperative diagnosis of DCIS is controversial, and there are conflicting published reports on the topic. The risk that an invasive disease with metastatic potential will be underestimated on needle biopsy needs to be balanced against the possibility of potentially unnecessary SLN surgery [3]. We studied patients with a biopsy diagnosis of ductal carcinoma without stromal invasion who are at risk for upstaging to invasive disease using preoperative imaging. By identifying these patients, we posit that patients can forgo concomitant SLN surgery with their definitive breast surgery.

In our study, we found that 38% of patients with a biopsy diagnosis of DCIS had invasive cancer after the final pathology report of the completely excised specimen. In previous studies, a meta-analysis showed that this upstaging occurs in 25.9% of patients with a needle-biopsy diagnosis of DCIS [26]. However, in the present study, after analyzing the primary tumors definitively, 33.6% of the preoperatively diagnosed DCIS were upstaged to invasive disease on final pathology, and this rate was slightly higher than the 25.9% rate that was reported in a previous meta-analysis [27].

All patients underwent SLN surgery in this study. Patients with a final diagnosis of DCIS have a low (0.5%) incidence of lymph node metastasis in our institution. In previous studies, these patients with DCIS have a low (1–2%) incidence of lymph node metastasis on conventional hematoxylin–eosin (H&E) staining and it is likely acceptable to forgo SLN biopsy for these cases diagnosed as DCIS on final pathology [15].

Our multivariate analysis of the predictive factors of invasive disease revealed a significant difference in hypoechoic mass on US (2.86; 95% CI: 1.71–4.78; $P < 0.001$) and in

Table 2 Univariate analysis of predictive factors of invasive disease in patients preoperatively diagnosed with ductal carcinoma ($n=306$)

	Invasive		Non-invasive		*p* value
	N	Rate (%)	*N*	Rate (%)	
Number of patients	115	37.6	191	62.4	
Age					1
≤55	58	50.4	95	49.7	
>55	57	49.6	96	50.3	
Palpable mass					0.003
Yes	53	46.1	55	28.8	
No	62	53.9	136	71.2	
Biopsy method					0.014
ST-MMT	28	24.3	70	36.6	
CNB	28	24.3	36	18.8	
VACNB	57	49.6	74	38.7	
Excisional biopsy	1	0.9	11	5.8	
Unknown	1	0.9	0	0	
Hormone receptor					0.795
ER positive	91	79.1	156	81.7	
ER negative	22	19.1	33	17.3	
Unknown	2	1.8	2	1	
					0.684
PgR positive	82	71.3	144	75.4	
PgR negative	31	27	45	23.6	
Unknown	2	1.7	2	1	
Breast surgery					0.288
Lumpectomy	49	42.6	94	49.2	
Mastectomy	66	57.4	97	50.8	
	Invasive		Non-invasive		*p* value
	N	Rate (%)	*N*	Rate (%)	
Number of patients	115	37.6	191	62.4	
MMG					
Density					0.429
Almost entirely fat	8	7	11	5.8	
Scattered fibroglandular densities	21	18.3	44	23	
Heterogeneously dense	72	62.6	104	54.5	
Extremely dense	24	12.2	32	16.8	
Calc -shape					0.144
Round	13	11.3	15	7.9	
Amorphous	17	14.8	30	15.7	
Pleomorphic	13	11.3	37	22.5	
Linear	10	8.7	14	7.3	
None	62	53.9	89	46.6	
Calc -distribution					0.302
Grouped	22	19.1	53	30.8	
Segmental	31	27	48	25.8	
Linear	0	0	1	0	
Regional、scattered	0	0	0	0	
None	62	53.9	89	43.4	
US					<0.001

Table 2 (continued)

	Invasive		Non-invasive		*p* value
	N	Rate (%)	*N*	Rate (%)	
Hypoechoic mass	64	55.7	61	31.9	
Hypoechoic lesion	44	38.3	102	53.4	
Cystic lesion/ ductal ectasia	2	1.7	11	5.8	
None	5	4.3	17	8.9	
MRI					0.028
Mass enhancement	32	27.8	47	24.6	
Non-mass enhancement	82	71.3	129	67.5	
None	1	0.9	15	7.9	
Enhanced lesion					0.003
Small	44	38.6	100	56.8	
Large	70	61.4	76	43.2	

Table 3 multivariate analysis of predictive factors of invasive disease in patients preoperatively diagnosed with ductal carcinoma ($n=306$)

Independent predictive factors of invasive disease	Odds ratio	95%CI		*p* value
		Lower	Upper	
US: hypoechoic mass	2.86	1.71	4.783	< 0.001
MRI: large enhancement lesion	2.329	1.389	3.905	0.001

large enhanced lesion on MRI (2.33; 95% CI: 1.39–3.91; $P=0.001$). In previous studies, various factors have been reported to be predictive of invasive disease. In reports related to imaging findings, predictive factors for invasive disease have included a mass on MMG imaging and lesions of ≥ 2 cm on MRI imaging [4, 6, 23]. The findings of "US hypoechoic mass" and "MRI large enhanced lesion" (size of mass ≥ 1.1 cm or the spread of the non-mass enhancement ≥ 3.1 cm) were predictors of invasive disease by multivariate analysis in our study. There were 78 patients who satisfied neither of these two conditions, and 62 patients (79.5%) were diagnosed with DCIS in the final pathology.

In previous reports with unique validation methods focusing on combinations of various factors without relying on specific individual factors have at times been published recently [23, 28]. However, to date, few reports of examinations carrying out a detailed classification using US and MRI imaging have been published. Kondo T et al. suggested that the prediction model consisted of six factors of invasive disease could be used to identify patients who most likely would or would not benefit from SLN surgery [29]. These six factors include imaging findings such as US and MRI and detailed pathological findings. It is thought that a more accurate prediction model will be completed by creating such a nomogram based on our data.

In addition to the identified predictive factors of invasive disease, a detailed pathological examination with preoperative biopsy specimens is required to establish the criteria for us to safely omit SLN surgery [4, 8, 22]. However, our study had a retrospective design and did not include some histopathological data (e.g., nuclear grade and comedo necrosis). Recent reports indicate that high-grade DCIS tends to be considered a risk factor for the detection of invasive disease [4, 22]. The LORIS trial revealed that the survival benefit of performing breast surgery for low-grade DCIS was lower than that for intermediate- or high-grade DCIS [30].

Limitations of our study include its retrospective design, which reduced our analyzable sample due to the lack of MRI imaging data in about 19% of the cases. As a result, our sample size became smaller. And all imaging data were reviewed by a single breast surgeon, that must be bias in the lack of the interobserver reliability of the assessment of US and MR imaging. As we focused specifically on image-based diagnosis in this study, adding pathological data could further support the recommendation that forgoing SLN surgery could be the safer approach.

Conclusion

We examined patients diagnosed with ductal carcinoma without stromal invasion by preoperative biopsy and clarified the predictors related to invasive cancer in the final pathological diagnosis based on preoperative US and MRI findings. As the current trend is toward shifting to a reduction in routine concomitant SLN surgery, it is important to identify patients at high risk and make the appropriate treatment selection.

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