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Is sentinel lymph node biopsy necessary for the patients diagnosed with breast ductal carcinoma in situ using core needle biopsy or vacuum-assisted biopsy as the initial diagnostic method?

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Abstract ***Objective:*** Axillary lymph node status is one of the most important prognostic indicator of survival for breast cancer, especially in ductal carcinoma *in situ* (DCIS). The purpose of this study was to investigate whether sentinel lymph node biopsy (SLNB) should be performed in patients with an initial diagnosis of DCIS. ***Methods:*** A retrospective study was performed of 124 patients with an initial diagnosis of DCIS between March 2000 and June 2014. The patients were treated with either SLNB or axillary node dissection during the surgery, and we compared the clinicopathologic characteristics, image features, and immunohistochemical results. ***Results:*** Eighty-two patients (66.1%) had pure DCIS and 25 (20.2%) had DCIS with microinvasion (DCISM), 17 (13.7%) updated to invasive breast cancer (IBC). 115 patients (92.7%) underwent SLNB, among them, 70 patients (56.5%) underwent axillary node dissection. 3 of 115 patients (2.6%) had a positive sentinel lymph node, only 1 (1.4%) of 70 patients had axillary lymph node metastasis, in 84 patients (66.7%) who were diagnosed DCIS by core needle biopsy (CNB) and vacuum-assisted biopsy (VAB). 26 patients (31.0%) were upstaged into IBC or DCISM in the final histological diagnosis. The statistically significant factors predictive of underestimation were large tumor size, microcalcifications, comedo necrosis, positive Her-2 status, negative estrogen receptor status. ***Conclusion:*** The metastasis of sentinel lymph nodes in pure DCIS is very low, but the underestimation of invasive carcinoma in patients with an initial diagnosis of DCIS is an usual incident, especially in the cases when DCIS is diagnosed by CNB or VAB. Our findings suggest patients presenting with a preoperative diagnosis of DCIS associated with large tumor sizes, microcalcifications, comedo necrosis, positive Her-2 status, negative ER status are more likely to be DCISM and IBC in final diagnosis. SLNB should be performed in this part of patients.

Key words ductal carcinoma *in situ* (DCIS); breast cancer; sentinel lymph node biopsy (SLNB); core needle biopsy (CNB); vacuum-assisted biopsy (VAB)

Ductal carcinoma *in situ* (DCIS) of the breast is a preinvasive or noninvasive malignant lesion without breaking out of the duct. Recent years, the widely use of mammography for screening has increased the number of DCIS [1]. Because both sentinel lymph node (SLN) metastasis and axillary lymph node (ALN) metastasis is rare in DCIS [2–4], the management of the lymph node has greatly changed in recent years. Guidelines suggest that it is not necessary to pure DCIS perform SLN in. The resection area has narrowed from whole breast irradiation with axillary lymph node dissection (ALND) to lumpectomy (breast-conserving therapy).

Performance of SLN mapping and resection in the surgical staging of the clinically negative axilla is recommended for assessment of the pathologic status of the ALNs in patients with early invasive breast cancer (IBC), surgeons had a long debate as to whether sentinel node biopsy should to be done in DCIS for routine use. The rates of positive sentinel node biopsy in patients with DCIS is between 1.4% and 10% [5–8], lots of studies proved that sentinel node biopsy in pure DCIS is unwarranted [9–10]. However, about 15% of patients who were initially diagnosed with DCIS using core needle biopsy or vacuum-assisted biopsy have IBC identified in the excision or mastectomy specimens [11]. Furthermore, some studies reported that DCIS with microinvasion (DCISM) was associated with a high incidence of lymph node metastasis [12–13].

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The aim of this study is to examine the pathologic and clinical characteristics of patients with diagnosis of DCIS to evaluate whether sentinel node biopsy is required, especially using core needle biopsy or vacuum-assisted biopsy as the initial diagnostic method.

Materials and methods

A retrospective study was performed of 124 patients with an initial diagnosis of DCIS or DCISM at Wuhan Central Hospital, who were reviewed from March 2000 to June 2014. The patients were diagnosed with DCIS preoperatively, 84 by guided CNB or VAB and 38 by excision, 2 patients were diagnosed by fine needle aspiration (FNA). Every patient underwent breast mammography, ultrasonography before surgery. All patients underwent breast surgery such as mastectomy with sentinel lymph node biopsy (SLNB) and with or without ALND, lumpectomy with or without SLNB. Fifteen to thirty minutes after injecting methylene blue around mammary areola, SLNs were removed for biopsy.

All surgical specimens and lymph nodes were reviewed under microscope, using H&E stain and immunohistochemical stain. SLNs were classified as positive or negative. Microinvasive disease was defined as tumor invading ≤ 1 mm, according to AJCC staging manual for breast cancer.

Table 1 Patient characteristics

Characteristics	*n*	%
Age (years)		
Mean	47.5 ± 12.8	
Range	25–79	
Tumor size (mm)		
Mean	23.9 ± 10.1	
Range	10–60	
Nuclear grade		
Low grade	43	34.7
Intermediate grade	44	35.5
High grade	37	29.8
Palpable mass	75	60.5
Comedo necrosis	56	45.2
Microcalcifications	50	40.3
Initial diagnose methods		
CNB or VAB	84	67.7
Excision	38	30.6
FNA	2	1.6
Operation methods		
Mastectomy with SLNB and ALND	70	56.5
Mastectomy with SLNB	25	20.2
Lumpectomy with SLNB	20	16.1
Lumpectomy without SLNB	9	7.3
Menopausal state		
Premenopausal	49	39.5
Postmenopausal	75	60.5

The clinicopathological characteristics such as age, tumor size, nuclear grade, initial diagnostic method, operation method, palpable mass, menopausal state and microcalcification on mammogram. Underestimated prognostic factors included age, tumor size, nuclear grade, comedo necrosis, palpable mass, menopausal state, estrogen receptor (ER), progesterone receptor (PR), initial diagnostic method, operation method, Her-2, and Ki67.

Patients were divided into two groups. The underestimated group contained patients who were upgraded to DCISM or IBC in final diagnosis. The consistent group contained patients whose final diagnosis was the same as initial diagnosis.

After surgery, adjuvant endocrine therapy was carried out for all DCIS, DCISM patients and patients with IBC who had positive ER or PR status, in addition, IBC patients were treated with adjuvant chemotherapy. Radiotherapy was followed when patients were treated with lumpectomy.

The patients were followed up at six-month intervals during the first two years following adjuvant treatment, and then annually. During each time, physical examinations were carried out and we performed blood routine, blood biochemical tests, and breast tumor markers, annual mammography and breast ultrasonography, annual abdominal CT and additional examinations including bone ECT, according to guidelines. All of the patients were monitored for metastasis and relapse. Overall survival (OS) was described as the period from the time of the patient's diagnosis until death. Disease free survival (DFS) was defined as the period from the time of patient's diagnosis until determining a local relapse or metastasis.

The statistical package for SPSS version 19.0 was used for statistical analyses. The chi-square test and *t*-test were used for analyses. A *P* value less than 0.05 was considered significant.

Results

Clinicopathologic characteristics of the patients

Table 1 showed the characteristics of the patients. The average age of the 124 patients was (47.5 ± 12.8) years (range, 25–79 years). Forty-nine (39.5%) were premenopausal, 75 (60.5%) were postmenopausal, and all patients were female, 20 (16.1%) underwent lumpectomy with SLNB and 9 (7.3%) had lumpectomy without SLNB, 25 (20.2%) had mastectomy with SLNB, 70 (56.5%) underwent mastectomy with ALND. The average tumor size was (23.9 ± 10.1) mm (10–60 mm), and of 43 (34.7%) patients had low grade tumor, of 44 (35.5%) patients had intermediate grade tumor, of 37 (29.8%) patients had high grade tumor, 56 (45.2%) of the patients had comedo-

Table 2 Comparison between initial and final pathologic diagnosis

Initial diagnosis	*n*	Final diagnosis	No.	%	Initial diagnostic methods					
					CNB or VAB		Excision		FNA	
					n	%	*n*	%	*n*	%
DCIS	114	DCIS	82	71.9	52	63.4	30	36.6	0	0.0
		DCISM	16	14.0	10	62.5	4	25.0	2	12.5
		IBC	16	14.0	15	93.8	1	6.3	0	0.0
DCISM	10	DCIS	0	0.0	0	0.0	0	0.0	0	0.0
		DCISM	9	90.0	6	66.7	3	33.3	0	0.0
		IBC	1	10.0	1	100.0	0	0.0	0	0.0

type necrosis. Seventy-five (60.5%) patients had palpable masses on physical examination and 50 (40.3%) patients had microcalcification on mammogram. Of 16 patients had DCISM and of 17 patients had IBC with an initial diagnosis of DCIS. All the surgical margins were tumor free. Of 84 (67.7%) patients underwent core needle biopsy (CNB) or vacuumassisted biopsy (VAB) and 38 (30.6%) patients underwent excision biopsy as the initial diagnostic biopsy method.

Comparison between initial and final pathologic diagnosis

Ninty-one (73.4%) patients had the same diagnosis between initial diagnosis and final diagnosis. Sixteen (19.0%) of 84 patients with a CNB or VAB diagnosis of DCIS had IBC, and 10 (11.9%) of 84 patients had DCISM in final pathologic diagnosis. Thirty-three (26.6%) of 124 patients were underestimated on initial diagnosis, among them 16 patients upgraded to DCISM, and 17 patients upgraded to IBC. Twenty-six of 84 patients who had DCISM in the CNB or VAB method, the rate of underestimation was relatively high at 31.0% (Table 2).

Comparison between consistent group and underestimated group in initial diagnosis of DCIS

In Table 3, we compared the consistent group and underestimated group in initial diagnosis, the underestimated group had larger tumor size ($P < 0.001$), more negative ER status ($P = 0.003$), more comedo-type necrosis under microscope, more microcalcifications on mammogram, most important, a higher rate of underestimation by using CNB or VAB as the initial diagnostic method ($P = 0.007$). Furthermore, the underestimated group had more negative Her-2 status. No significant differences were found out in mean value of age, nuclear grade, menopausal state, palpable mass on physical examination, Ki-67 expression, operation method.

SLNs and ALNs in patients with an initial diagnosis of DCIS

We evaluated the results of positive SLN and positive ALN in all patients. The 115 patients were treated by SLNB as initial diagnosis procedure, among them 3 patients had positive SLN, 70 patients were treated by mastectomy and ALND, only one patient had positive ALN. Among 3 positive SLN patients, one of them had positive ALN.

Positive lymph nodes in patients

The patients who had positive SLN or ALN belonged to underestimated group. In Table 4, the patient who had positive ALN had positive SLN at the same time, and she was diagnosed with IBC finally. Other 2 patients with positive SLN were diagnosed with DCISM at last.

Follow-up working of the patients

The median follow-up time was 41 months (3–164 months). Only 2 (2.3%) of 87 patients had local relapse detected by ultrasonography, one was treated with lumpectomy without SLNB, the other one had lumpectomy with SLNB, both of them were diagnosed with pure DCIS. No metastasis and relapse was found in the other patients in this group of patients. No patient dead during follow-up time. The loss ratio of follow-up was 29.8% (37/124).

Discussion

DCIS of the breast is a preinvasive or noninvasive malignant lesion within the mammary ductal-lobular system. According to the definition, DCIS is not a systemic disease, axillary nodal involvement and the SLN metastasis in patients with pure DCIS of the breast is rare. However, several studies revealed lymph nodes in patients with DCIS reported ALN metastasis, especially who were diagnosed pure DCIS on initial biopsy, but upgraded to DCISM or IBC finally [9, 12], these patients require ALN staging for prognosis and guiding adjuvant therapy. Sometimes, positive SLNs do not mean positive ALNs, the findings of SLNB may lead to overtreatment, such as mastectomy plus ALN staging, which may reduce patient's quality of life. So that, surgeons had a long debate as to whether sentinel node biopsy should to be done in DCIS for routine use.

SLNB is an accurate and efficient method for predicting whether ALNs have metastasis. When SLNB has been

Table 3 Comparison between consistent and underestimated groups in initial diagnosis of DCIS

Factors	Consistent group		Underestimated group		*P*-value
	n	%	*n*	%	
Total	91		33		
Mean age (years)	48.2 ± 13.0		45.6 ± 12.5		0.30
Mean tumor size (mm)	21.8 ± 8.9		29.5 ± 11.0		< 0.001
Nuclear grade					0.609
Low+ Intermediate	65	71.4	22	66.7	
High	26	28.6	11	33.3	
Menopausal state					0.690
Premenopausal	35	38.5	14	42.4	
Postmenopausal	56	61.5	19	57.6	
ER					0.003
Positive	60	65.9	12	36.4	
Negative	31	34.1	21	63.6	
PR				42.4	0.230
Positive	50	54.9	14		
Negative	41	45.1	19	57.6	
Comedo necrosis	56	12	35	21	0.013
Microcalcifications	61	13	30	20	0.006
Palpable mass	34	15	57	18	0.415
Initial diagnose method					0.007
CNB or VAB	58	63.7	26	78.8	
Excision	33	36.3	5	15.2	
FNA	0	0.0	2	6.1	
Operation method					0.074
Mastectomy	66	72.5	29	87.9	
Lumpectomy	25	27.5	4	12.1	
Ki-67 (%)					0.556
≥ 14	28	30.8	12	36.4	
< 14	63	69.2	21	63.6	
Her-2					0.026
Positive	18	19.8	13	39.4	
Negative	73	80.2	20	60.6	

Table 4 SLNs and ALNs in patients with an initial diagnosis of DCIS

Operation methods	*n*	%	Positive SLN		Positive ALN	
			n	%	*n*	%
Mastectomy with SLNB and ALND	70	56.5	3	2.6	1	1.4
Mastectomy with SLNB	25	20.2	0		0	
Lumpectomy with SLNB	20	16.1	0		0	
Lumpectomy without SLNB	9	7.3	0		0	

carried out by an experienced surgeon, the reliability is high. Several papers reported that the rates of positive SLNB results of DCIS between 1.4% and 10% [5–8], and in these patients, the risk of ALNs metastasis was less than 1%. However, the risk of SLN metastasis was higher for patients with a final diagnosis of DCISM and IBC compared with pure DCIS [12–14]. Because the final pathological result of DCISM and invasive cancer is an important predictor of positive SLNs, so we evaluated the clinicopathologic predictors of DCISM and IBC in patients with a preoperative diagnosis of DCIS.

Comparison between consistent group and underestimated group in initial diagnosis of DCIS had been performed, using CNB or VAB, though this study, we investigated several predict factors of DCISM and IBC, we studied the differences of IHC, clinicopathological characteristics and imaging features. We found that there were significant different in tumor size, ER status, comedo necrosis, microcalcifications, initial diagnose method, Her-2 status. And there was no difference between age, menopausal state, palpable mass, Ki-67. We found that larger DCIS size was more likely to be associated with mi-

croinvasive cancer or invasive cancer. And several papers also proved this conclusion, when tumor size was larger than 2 cm, more microinvasive cancer or invasive cancer may occur [14–17]. Mammography play an important role in early detection of breast cancer, and it is highly sensitive for detecting calcifications, especially in DCIS. We carefully examined all calcifications and compared calcifications in DCIS, DCISM and IBC. In this study, if microcalcification exist on mammogram, it was more likely to be DCISM and IBC. Age, menopausal state, played unimportant roles in predicting DCISM or IBC.

Furthermore, the breast is controlled by sex hormones, the hormone receptor status is closely related to the prognosis and systemic adjuvant therapy. It was reported that the higher nuclear grade of DCIS, the lower rate of positive ER and PR, which led the worse prognosis, especially in metastasis [7, 14–17]. After surgical treatment, the endocrine therapy should be considered, the therapeutic effectiveness is also depended on positive ER and PR. We studied the ER and PR status of pure DCIS, DCISM and IBC, We found significant difference in ER and PR between DCIS and DCISM, no significant difference between DCIS and IBC. This phenomenon suggests that hormone receptor of tumor may change in different pathological stage, and the patients with DCIS in our study were significantly more likely to have positive ER and PR tumors than patients with DCISM. It seems that the comedo-pattern of necrosis could be seen in all types of DCIS. And comedo necrosis of DCIS is an independent factor for predicting recurrence [18]. Many studies believed that it was no connection between comedo necrosis and invasive behavior [19]. But in this study, women with comedo necrosis had worse outcomes, DICSM and IBC were more likely appeared with this factor. Her-2 status was usually considered more useful in invasive disease but not in DCIS. However, some paper suggested that Her-2 overexpression in DCIS indicate the invasive behavior [20]. In our study, we also proved Her-2 overexpression in DCIS is more likely to be IBC or DCISM.

Several studies found out that preoperative diagnoses of DCIS based on CNB or VAB were very likely to be underestimated [21]. In our study, we got the same result as other studies ($P = 0.007$), about 26.6% (33/124) of DICS had been underestimated, some of them upstaged to DCISM, and some of them upstaged to IBC. This rate is extremely high that it is hard for surgeons to choose whether SLNB should be carried out. The incidence of SLN metastasis among patients with an initial diagnosis of DCIS is substantially higher than among those with a final diagnosis of DCIS. Some authors reported that the risk of SLN metastasis was higher for patients with a final diagnosis of DCISM and IBC compared with pure DCIS [12–14], and the rate of positive SLN ranged from 10% to 30% in patients with DCISM [22]. If we discover any suspected point of upstaging to DCISM or IBC, the SLNB should be performed. Histologic review should be carried out as routine use, if invasive or microinvasive focus is founded in final pathological diagnosis, the probability of positive ALNs is higher than pure DCIS, so do positive MRI or mammography findings. Some papers tried to reveal what kinds of patients were easily to be underestimated. Some surgeons investigated that the patients may be associated with understaging include biopsy device and guidance method, size, grade, mammographic features, and palpability [7, 12–14]. The others found no relationship between underestimation and clinical condition, such as factors mentioned above. But in our study, we found patients diagnosed by CNB or VAB, with large tumor sizes, negative ER status, comedo necrosis, cicrocalcifications, may be more likely to be underestimated. And this is the significant factors predictive of IBC and DCISM in patients with an initial diagnosis of DCIS by CNB or VAB. Patients with these factors should undergo SLNB to prevent missing positive ALNs. Furthermore, if CNB and VAB cut off enough samples by using larger gauge of cuter, or enough amount of samples, the underestimation may be less than we find [23].

This retrospective analysis is limited by the small sample number, short follow-up time and high loss ratio of follow-up. It makes no sense of DFS and OS in this group of patients. Further investigation with larger patient database is necessary to screen the factor, related to underestimation of CNB or VAB.

In conclusion, patients with large tumor sizes, microcalcifications, comedo necrosis, positive Her-2 status, negative ER status are more likely to be DCISM and IBC than other DCIS patients, and SLNB should be performed in patients with DCIS associated with invasive behavior.

Conflicts of interest

The authors indicated no potential conflicts of interest.

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