



# Upgrading rate of papillary breast lesions diagnosed by core-needle biopsy

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## PURPOSE

We aimed to estimate the upgrading rate of core-needle biopsy (CNB)-diagnosed papillary breast lesions to atypical or malignant papillary lesions on subsequent surgery.

## MATERIALS AND METHODS

We performed a retrospective review of medical records and imaging findings of patients diagnosed by CNB as having papillary lesions from January 1, 2005 to May 31, 2011. Outcomes were determined by pathology findings from surgical excision or by imaging findings at 12 months follow-up.

## RESULTS

Of 130 papillary lesions in 127 patients, the upgrading rates were 0% for benign papillary lesion to malignancy, 19% for benign papillary lesion to atypical papillary lesion, and 31% for atypical lesion to malignancy. Most of the malignancies were ductal carcinoma *in situ*. The presence of malignant lesions was related to specific symptoms (palpable mass or nipple discharge;  $P = 0.020$ ) and to a higher Breast Imaging Reporting and Data System (BIRADS) category ( $P = 0.017$ ).

## CONCLUSION

CNB is accurate in the diagnosis of benign papillary lesions. If no atypical cells are present, no malignancy is found. The presence of atypia on CNB strongly indicates a need for surgical excision.

The histopathological characteristics of papillary breast lesions include a papillary arborescent-growth pattern supported by a fibrovascular stalk with or without an intervening myoepithelial cell layer (1, 2). The term “papillary breast lesion” encompasses a broad spectrum of histopathologies, including single papilloma, papillomatosis, atypical papilloma or papillomatosis, and intraductal papillary carcinoma with or without invasion (1).

A precise diagnosis of papillary lesions obtained from a core-needle biopsy (CNB) under image guidance is sometimes not possible. Because the presence vs. absence of a continuous basally-oriented myoepithelial cell layer is the key feature distinguishing benign from malignant papillary breast lesions (1, 3), it is difficult for a pathologist to distinguish among benign, atypical, and malignant lesions on the basis of limited and fragmented tissue obtained from CNB (1–3).

Reported upgrading rates from benign papillary lesions diagnosed by CNB to malignant papillary lesions diagnosed on subsequent surgical excision range from 0% to 29% (2–15). Some investigators have suggested that benign papillary lesions without atypia diagnosed by CNB, in combination with concordant imaging findings, can be safely followed without further surgery (2–7). However, many recent studies advocate the complete excision of any papillary lesion diagnosed by CNB (1, 8–17).

Atypical papillary lesions, defined as papillomas with atypical features or with coexistent atypical ductal hyperplasia (5), are associated with a significant risk of cancer (1–8, 11, 13–21). There is a consensus that this diagnosis warrants complete surgical excision. A significant number of CNB-diagnosed benign papillary lesions are upgraded to atypical papillary lesions on subsequent surgery (2, 8–10, 12).

The primary objective of the present study was to estimate the upgrading rate of CNB-diagnosed papillary lesions to either atypical or malignant papillary lesions on subsequent surgical excision. A secondary objective was to identify patients with CNB-diagnosed papillary lesions who might not require excisional biopsy.

## Materials and methods

This study was conducted with Institutional Review Board approval. The investigators retrospectively reviewed the medical records of patients who underwent CNB at Ramathibodi Hospital, Mahidol University, Bangkok, Thailand between January 1, 2005 and May 31, 2011. The patients were followed for at least one year after CNB because this follow-up period has been shown to be sufficient for detecting false-negative CNB results (22, 23).

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The characteristics of patients, mammography and ultrasonography (US) findings, CNB data, details of subsequent surgery or clinical and imaging follow-up, and all pathology reports were reviewed and recorded by the principal investigator, who is a radiologist specializing in breast imaging with 11 years of experience. A specialist in breast pathology with 11 years of experience reviewed the histopathological sections in ambiguous cases.

Mammography was performed in craniocaudal and mediolateral oblique views using a digital mammography machine (Selenia, Danbury, Connecticut, USA). Additional US examination was performed for all lesions using two US machines (HDI 5000 Philips Ultrasound, Bothell, Washington, USA and [after January 2008] iU22 Phillips Ultrasound). The lesions were characterized retrospectively using the relevant Breast Imaging Reporting and Data System (BIRADS) criteria of the American College of Radiology, based on the combination of mammographic and US results (23).

Lesions located  $\leq 3$  cm from the nipple were classified as "central", and those located  $>3$  cm from the nipple were classified as "peripheral". The presence of ductal dilatation was evaluated from the US images.

The guidance modality was chosen based on the type of lesion observed. US-guided biopsy was performed with a 12–5 MHz linear array transducer and a 13-gauge coaxial introducer needle or a 14-gauge cutting needle (MDTech, Gainesville, Florida, USA) with a long-throw (22 mm). All needle biopsies were performed using an automated biopsy gun (Magnum, Bard Peripheral Technologies, Covington, Georgia, USA) with a freehand technique. Six core specimens were usually retrieved by this procedure.

Stereotactic-guided biopsy was performed with a dedicated CNB unit using an 11-gauge directional vacuum-assisted CNB instrument (Mammotome, Biopsys/Ethicon Endo-Surgery, Cincinnati, Ohio, USA) on a prone breast biopsy table (LORAD MultiCare Platinum, Danbury, Connecticut, USA). Twelve core specimens were routinely retrieved by this procedure. All biopsies were performed by

three breast-imaging radiologists with at least 10 years of experience each.

Papillary lesions and their various subtypes were reported by experienced pathologists on an official pathology report form. The final pathology for the purposes of this study was the most worrisome pathology observed from biopsy or surgical specimens. An upgraded lesion was defined as one that was classified as benign or atypical on initial CNB but was classified as atypical or malignant, respectively, after surgical excision (2). The upgrading rate of a lesion was defined as the number of upgraded lesions divided by the total number of lesions.

Continuous variables and counts were summarized as the mean, median, and range, while categorical variables were summarized as counts and percentage. Variables were tested for association with the presence of malignancy, or with the presence of pure papillary lesions, using logistic regression analysis. All statistical analyses were performed using Stata v.9 statistical software (Stata Corp., Abilene, Texas, USA). The criterion for statistical significance was a two-sided *P* value of 0.05 or less.

## Results

During the study period, 2569 patients underwent image-guided CNB of breast lesions. There were 179 cases (6.7% of the total) of CNB-diagnosed papillary lesions. Of these 179 cases, 24 were excluded because of the presence of malignant papillary lesions, and 25 were excluded because of lost medical records (15), absence of imaging data (6), or follow-up intervals of less than one year (4).

The final study sample consisted of 130 lesions (in 127 patients) diagnosed as nonmalignant papillary lesions by image-guided CNB. The mean age of the patients in the study group was  $50 \pm 9.4$  years. Forty-eight patients (37%) were in menopause. A past history of breast cancer was reported in 10 patients (8%). Seventy-eight patients (60%) had no breast symptoms or signs. All lesions were detectable by imaging studies. A palpable mass as the presenting symptom was reported in 44 patients (34%). Eight patients (6%) had a nipple discharge. US was performed

on all patients. Mammography was performed in 123 patients for 126 lesions (97%). Four young patients underwent US examination only.

Fatty breast density were observed in three patients (2%), scattered fibroglandular density in 19 patients (15%), heterogeneous density in 89 patients (71%), and extremely dense breasts in 15 patients (12%). Thus, most of the patients had a dense breast type. For this reason, 41 lesions (33%) were not visible on mammography. Of the lesions that were visible on mammography, 67 (53%) manifested as a mass. Of these, 52 (41%) were noncalcified masses with a circumscribed, obscured or indistinct border, 12 (10%) were calcified masses, and three (2%) were spiculated masses that aroused concern as possible malignant tumors. Eight lesions (6%) were pure calcifications, two (2%) were architectural distortions, and eight (6%) displayed asymmetric density.

On US study, most of the 130 lesions ( $n=102$ ; 79%) were solid masses and 23 (18%) were complex or complicated cysts. Five lesions (4%) were not visible on US. The location of the lesion was central in 76 cases (58%), and peripheral in 54 cases (42%). Associated ductal dilatation demonstrable on US images was observed for 34 lesions (26%). The mean diameter of lesions measured on US was  $1.3 \pm 0.8$  cm (median, 1.0 cm; range, 0.4–5.3 cm).

Most of the mammographic and US studies were classified as BIRADS 4; i.e., 4A: 68 lesions (52%), 4B: 38 lesions (29%), 4C: 13 lesions (10%). Four lesions (3%) were classified as BIRADS 5; of these, three were spiculated masses and one was a mass with internal calcifications. Seven lesions (5%) were classified as BIRADS 3, but the patient or the attending surgeon requested CNB-histological diagnosis.

US was used to guide CNB for most of the lesions ( $n=122$ ; 94%). Stereotactic guidance was used for the other eight lesions. The CNB and pathological findings are summarized in Table 1. Subsequent excisional biopsy was performed for 84 lesions (65%). Of these, 31 lesions (37%) were diagnosed as papillary lesions with atypia, and malignancy was found in 12 lesions (14%) in 12 patients.

The malignant lesions were predominantly ductal carcinoma *in situ* (DCIS), which was detected in 10 of 12 patients (83%). Invasive cancer was diagnosed in only two patients (17%), i.e., invasive ductal carcinoma (IDC) grade II (size 2.5 cm) and IDC grade I (size 0.5 cm). Axillary lymph node metastasis was not identified in any of the 12 patients.

Follow-up information is also presented in Table 1. The majority of the patients (35 of 46; 76%) had a follow-up period of 24 months or more. Seven patients with CNB-diagnosed papillary lesions with atypia underwent only radiological follow-up because they refused surgery. No malignancy or progression of the lesion requiring subsequent biopsy was found in this group. No subsequent malignancy was detected in any patient who did not initially undergo surgery.

The overall upgrading rates of CNB-diagnosed benign and atypical papillary lesions were 19% and 31%, respectively (Table 2). There was no upgrade to malignancy in the group with benign (pure) papillary lesions. In the subset of patients in whom all lesions were surgically excised, the upgrading rates for benign and atypical papillary lesions were 33% and 38%, respectively (Table 3).

A multiple logistic regression analysis revealed that the presence of malignant lesions was significantly related to only two factors: presenting symptoms (palpable mass or nipple discharge,  $P = 0.020$ ) and higher BIRADS category ( $P = 0.017$ ) (data not shown). No clear association was found between malignant lesions and age, menopausal status, personal history of breast cancer, breast density, mammographic and US findings, location of lesion, size of lesion, associated ductal dilatation, guidance modality for CNB, or number of core specimens ( $P > 0.05$  for all).

A similar logistic regression analysis did not reveal significant relationships between a final diagnosis of pure papillary lesions (i.e., initial CNB-diagnosed papillary lesions without atypia that were not upgraded to atypical lesions or malignant lesions, as was the case for 74 of 130 lesions) and any other factors mentioned previously ( $P > 0.05$  for all). Thus, no information was available for identifying patients who were likely to

**Table 1.** Core-needle biopsy, excisional biopsy, pathology, and follow-up results

	Summary (n=130, unless stated otherwise)
<b>Modality of CNB</b>	
US-guided	122 (94%)
Stereotactic	8 (6%)
<b>Number of cores</b>	
Mean±SD	5.8±2.6
Median (range)	6 (2–16)
Frequency (proportion) of six or more cores	65/130 (50%)
<b>Papillary lesions on CNB</b>	
No atypia	91 (70%)
With atypia	39 (30%)
<b>Excisional biopsy results</b>	
Benign papillary lesion without atypia	41/84 (49%)
Papillary lesion with atypia	31/84 (37%)
Malignancy (DCIS and IDC)	12/84 (14%)
<b>Follow-up time for patients without excision (months, n=46)</b>	
Mean±SD	42.1±18.7
Median (range)	47 (12–70)
<b>Follow-up BIRADS category for patients without excision (n=46)</b>	
1	4 (9%)
2	37 (80%)
3	5 (11%)
<b>Final diagnosis for follow-up &gt;12 months (n=130)</b>	
Benign papillary lesion	80 (62%)
Papillary lesion with atypia	38 (29%)
Malignancy (DCIS and IDC)	12 (9%)
<b>Final diagnosis for follow-up &gt;24 months (n=119)</b>	
Benign papillary lesion	70 (59%)
Papillary lesion with atypia	37 (31%)
Malignancy (DCIS and IDC)	12 (10%)
<b>Type of malignancy (n=12)</b>	
DCIS	10 (83%)
IDC	2 (17%)

BIRADS, Breast Imaging Reporting and Data System; CNB, core-needle biopsy; DCIS, ductal carcinoma *in situ*; IDC, invasive ductal carcinoma; SD, standard deviation; US, ultrasonography.

**Table 2.** Final status of patients at the last follow-up

	Pathology from CNB (n=130)	
	No atypia (n=91)	With atypia (n=39)
Final diagnosis (n=130)		
Benign papillary lesion	74 (81%)	0
Papillary lesion with atypia	17 (19%)	27 (69%)
Malignancy	0	12 (31%)

CNB, core-needle biopsy.

**Table 3.** Pathology from core-needle biopsy and subsequent pathology from surgical excision

Pathology from surgical excision (n=84)	Pathology from CNB (n=84)	
	No atypia (n=52)	With atypia (n=32)
Benign papillary lesion	35 (67%)	0
Papillary lesion with atypia	17 (33%)	20 (62%)
Malignancy	0	12 (38%)

CNB, core-needle biopsy.

**Table 4.** Papillary lesions of the breast diagnosed by core-needle biopsy: summary of published studies

Study	Year	Biopsy technique	Total number of cases	Total number of upgrade to malignancy at surgery	
				Benign	Atypia
Liberman et al. (24)	1999	14G CNB 11G, 14G VAB	26	0/7 (0%)	3/10 (30%)
Rosen et al. (2)	2002	14G CNB 11G, 14G VAB	46	0/27 (0%)	3/8 (38%)
Agoff and Lawton (4)	2004	14G CNB 9G, 11G VAB	41	0/16 (0%)	12/25 (48%)
Gendler et al. (8)	2004	11G, 14G CNB 11G VAB	87	10/77 (13%)	5/10 (50%)
Ivan et al. (3)	2004	16G, 18G, 20G CNB 11G, 14G VAB	50	0/30 (0%)	5/8 (63%)
Renshaw et al. (5)	2004	11G, 14G CNB	38	0/18 (0%)	14/20 (70%)
Liberman et al. (9)	2006	14G CNB 11G VAB	35	5/35 (14%)	NS
Mercado et al. (10)	2006	14G CNB 11G VAB	48	2/48 (5%)	NS
Sydnor et al. (6)	2006	14G CNB 11G, 14G VAB	63	4/48 (8%)	10/15 (67%)
Sohn et al. (7)	2007	14G CNB 11G, 14G VAB	215	2/174 (1%)	5/26 (19%)
Kil et al. (19)	2008	14G CNB 11G VAB	76	6/68 (9%)	3/8 (38%)
Shin et al. (11)	2008	14G CNB 8G, 11G VAB	124	12/100 (12%)	1/17 (6%)
Skandarajah et al. (12)	2008	14G CNB	80	15/80 (19%)	NS
Tseng et al. (13)	2008	14G CNB	35	7/24 (29%)	5/7 (71%)
Jaffer et al. (14)	2009	16G, 18G, 20G CNB 14G VAB	104	9/104 (9%)	NS
Chang et al. (15)	2010	14G CNB	100	4/100 (4%)	NS
Youk et al. (18)	2010	14G CNB	30	NS	7/30 (23%)
Youk et al. (20)	2011	14G CNB	160	8/160 (5%)	NS
Present Study	2013	14G CNB 11G VAB	130	0/91 (0%)	12/39 (31%)

CNB, core-needle biopsy; NS, not stated; VAB, vacuum-assisted biopsy.

have only pure papillary lesions and no clear need for a surgical biopsy.

A radiological imaging example of a benign papilloma diagnosed on both

CNB and surgical biopsy is shown in Fig. 1. A case of atypical papilloma diagnosed on CNB that was upgraded to IDC on subsequent surgery is shown in Fig. 2.

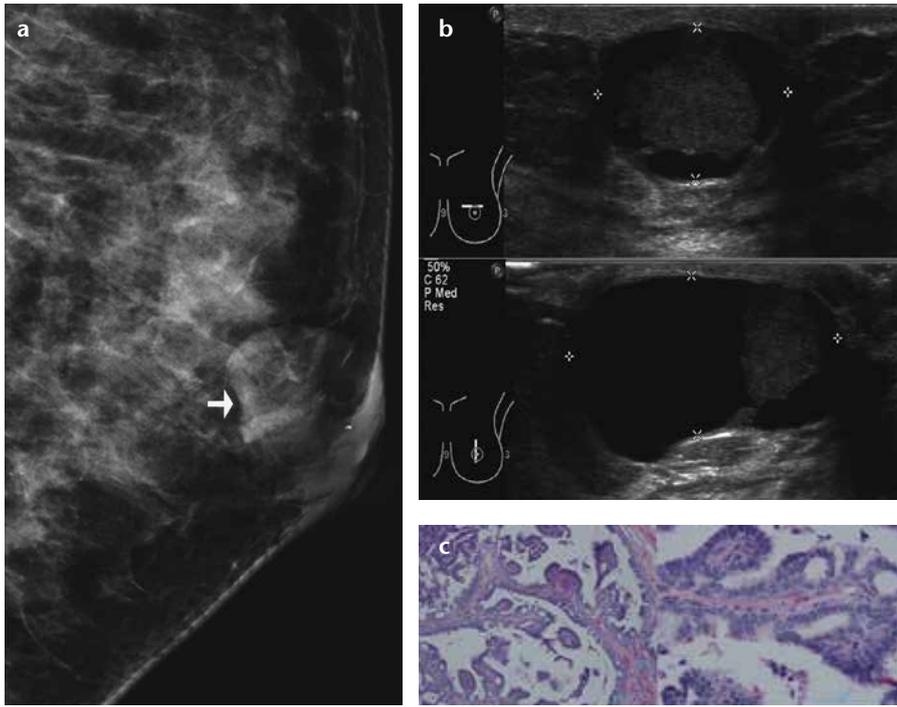
## Discussion

The management of papillary lesions of the breast remains a challenge, particularly when the lesions are initially diagnosed by CNB. Should such lesions be followed by imaging studies and clinical examination or be subjected to surgical excision? The primary concern is the possibility of sampling error by CNB that leads to missed cancers (1). Papillary lesions, particularly those with atypia, may be precursors of papillary cancers or other invasive breast cancers (1, 11). Some investigators have reported finding the majority of atypical or malignant cells adjacent to but not at the biopsy bed of the papillary lesion (12, 14). Therefore, even complete removal of a lesion may not eliminate the threat of malignancy. Such lesions should be excised completely with a small rim of uninvolved breast tissue (1).

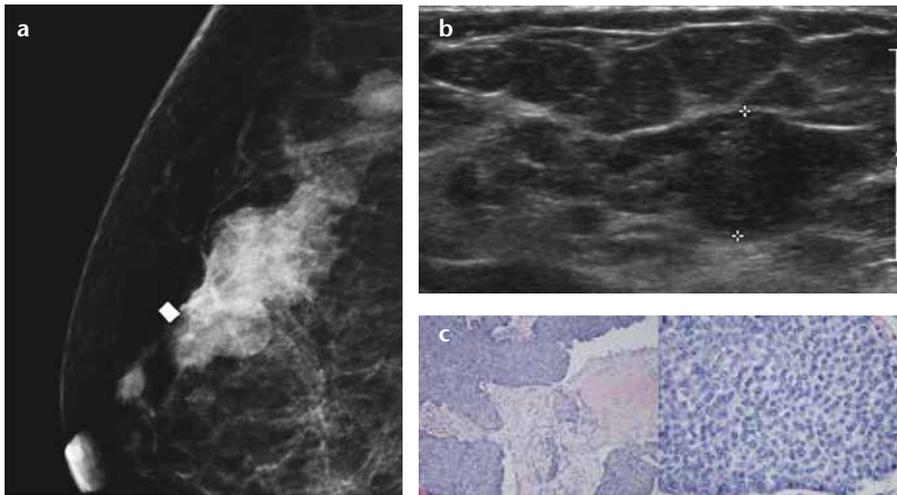
The upgrading rates of the papillary lesions diagnosed by CNB in the present study were 0% for an upgrade of benign papillary lesion to malignancy, 19% for an upgrade of benign papillary lesion to atypical papillary lesion, and 31% for an upgrade of atypical papillary lesion to malignancy. If only the cases involving a subsequent excision were analyzed (84 of 130 lesions; 65%), the upgrading rates were 0%, 33%, and 38%, respectively. These rates were consistent with those reported in other studies (Table 4). Because the upgrading rate of atypical papillary lesion to malignancy is relatively high, complete surgical excision is recommended for all CNB-diagnosed papillary lesions with any type of atypia (1–8, 11, 13–21).

The majority of malignant lesions in the present study were DCIS. Other malignant lesions were early stage invasive ductal cancers. None of the patients had axillary lymph node involvement. Previous studies also found DCIS or papillary carcinoma *in situ* in the majority of patients in upgraded groups (2, 4, 8–10, 12, 18–20, 24). These findings suggest that benign or high-risk papillary lesions tend to carry a favorable prognosis even when malignancy is found.

Many previous studies attempted to identify factors that predict upgrading to malignancy. Chang et al. (15), Kil et



**Figure 1. a–c.** Mass lesion in a 38-year-old female who presented with a palpable mass beneath her left nipple for two months. A mammogram on craniocaudal view (a) shows a 2.5 cm round isodense mass with circumscribed border located just posterior to the left nipple (arrow). US (b) shows a complex cyst with a predominant cystic component. A photomicrograph (c) shows typical findings of intraductal papilloma, including papillary fronds consisting of fibrovascular cores covered by an inner myoepithelial cell layer and an outer epithelial cell layer ( $\times 10$  [left],  $\times 40$  [right]; hematoxylin-eosin).



**Figure 2. a–c.** Mass lesion in a 61-year-old female who presented with a palpable mass in her right breast for two months. A mammogram on mediolateral oblique view (a) shows a lobular mass with a partially ill-defined border and a skin marker above the palpable mass. US (b) reveals a mass with a heterogeneous echo and ductal extension, measuring 3.4 $\times$ 2.4 cm (cursors indicate the tumor border). Core-needle biopsy revealed florid papillomas with foci of atypical cells. Surgical biopsy was performed one month later. A photomicrograph (c) shows invasive papillary carcinoma ( $\times 10$  [left],  $\times 40$  [right]; hematoxylin-eosin). The patient was treated with modified radical mastectomy. None of the 18 lymph nodes examined showed signs of metastasis.

al. (19), and Youk et al. (20) suggested that papillary lesions with a size of 1.5 cm (15, 19) or 1.0 cm (20), or larger should undergo surgical excision.

However, the size of the lesion was not a significant predictor in the present study. This observation may be partially explained by the fact that US is

integrated with mammography in the screening protocol in our institution, resulting in the incidental discovery of predominantly small, nonpalpable papillary lesions, whether benign or malignant. The median size of papillary lesions in our study was 1.0 cm, which is relatively small in comparison with values from other studies. Tumor size was therefore not a useful variable for distinguishing benign from malignant lesions in the present study.

The location of the papillary lesion is another widely studied risk factor. Some studies reported a tendency for the papillary lesion to be malignant if it was located at the periphery of the breast (19, 20), whereas no such association was found in many other studies, including the present study (3, 6, 8).

Symptomatic lesions, either palpable or associated with nipple discharge, were significantly more likely to be associated with malignancy in the present study. Previous studies did not mention such a finding (19, 20). If such an association exists, surgical excision should be recommended for symptomatic patients with CNB-diagnosed papillary lesions regardless of whether atypia is present.

The presence of dilated ducts with an intraluminal echo is a well-known US finding for papillary lesions. Shin et al. (11) reported that benign papillary lesions tended to be more circumscribed than malignant or high-risk lesions. However, no imaging features are accurate enough to clearly distinguish malignant from benign papillary lesions (4, 6, 8, 9). The same finding was recorded in the present study.

Although no individual mammographic or US characteristic of papillary lesions was able to predict the presence of malignancy, the BIRADS category, which serves as the final assessment or consensus of all imaging characteristics, showed a significant association with malignant papillary lesions in the present study. Similar findings were noted in other studies (18, 20), suggesting that surgical excision should be performed in patients with a high BIRADS category regardless of the initial CNB result. On the other hand, some studies did not find a clear relationship between BIRADS category and upgraded histology (15).

It is sometimes assumed that the use of larger core-needles with a vacuum-assisted technique and a higher number of core specimens results in greater diagnostic accuracy and a consequently lower rate of upgrading; e.g., Shin et al. (11) reported higher accuracy for vacuum-assisted stereotactic guidance biopsy. However, this assumption was not supported by the results of the present study or many previous studies (6, 8, 9, 15). It should be noted that US was used as the guidance modality for CNB in almost all of the lesions (94%) in the present study.

The reliability of the present study was limited by the small sample size, which resulted from the low proportion of papillary lesion (7% of all CNB cases). The low proportion of malignant lesions (12 of 130 patients; 9%) also affected the power of the statistical tests. The results of these tests should therefore be interpreted cautiously and in light of previous findings. For example, it is most likely reasonable to accept the finding that malignant lesions tended to be associated with nipple discharge and with a higher BIRADS category. On the other hand, the absence of a significant relationship between malignant lesions and specific imaging findings may have been due to low statistical power.

In conclusion, CNB was accurate in the diagnosis of benign papillary lesions. If no atypia was present, no malignancy was found. However, a CNB diagnosis of benign papillary lesion could be categorized as high-risk because at least 19% of such cases showed the presence of atypical cells on surgical excision. In particular, it is recommended that patients with symptomatic lesions or a high BIRADS category, or both, should undergo surgical excision. The presence of atypia on CNB strongly indicated the need for surgical excision, primarily in view of the high rate of malignancy (31%). However, all of the lesions diagnosed as malignant were either noninvasive or very early stage cancers. We could not identify patients whose lesion clearly did not require surgical excision. The recommendation that most or all papillary lesions diagnosed by CNB should undergo surgery is still valid.

#### Conflict of interest disclosure

The authors declared no conflicts of interest.

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