Original Article

Significant Factors Predicting Malignant Upgrading in Benign Papillary Lesions of the Breast

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Background: Clinical management of benign papilloma of breast diagnosed on core needle biopsy (CNB) remains controversy. Factors associated with malignant upgrading in CNB are inconclusive.

Objective: To identify factors associated with malignant upgrading in CNB of benign papillary lesion of the breast.

Materials and Methods: A retrospective review study of 423 papillary lesions in 404 patients diagnosed on imaged-guided CNB was included. Total 351 lesions were benign papilloma and 220 lesions were surgically removed. An upgrade rate was noted when surgical specimen found ductal carcinoma in situ (DCIS), invasive ductal carcinoma (IDC) or other malignancy. Clinical, radiographic and pathological variables were analyzed in order to find factors associated with malignant upgrading.

Results: Of the 220 benign papillary lesions on CNB, excision specimens revealed 163 benign papilloma, 6 atypical papilloma, 5 DCIS, and 1 IDC. Malignant upgrade rate was 3.42%. Age >50, thin/arborizing fibrovascular core and intralesional atypia are factors associated with malignancy on excision specimens.

Conclusion: Papillary lesion of the breast could be managed by clinical follow-up without excision. However, factors associated with malignant upgrading in CNB of benign papillary lesion of the breast are patients aged >50, thin/arborizing/mix fibrovascular core and intralesional atypia.

Keywords: Breast, Core needle biopsy, Malignant upgrading, Papillary lesion

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Up to 10% of benign breast tumor and 1 to 4% of all breast neoplasm are papillary lesions of the breast[1,2]. Presenting symptoms of papillary lesion of the breast vary from palpable mass, abnormal nipple discharge or abnormal screening mammogram/ultrasound. Due to heterogeneity of the disease, diagnosis of malignant papillary lesion from core needle biopsy (CNB) is not easy. Previous studies reported rates of upgrading from benign in core needle biopsy to malignant papillary lesion in surgical specimens ranged from 3.4 to 38%[3-11]. Therefore, excisions of all papillary lesion of breast diagnosed by CNB may lead to unnecessary surgery. Observation or serial follow-up with reliable imaging may be safe. Factors related to upgrading to malignancy in previous publications include age[3,4,10], size[8,10], palpable mass[9], nipple discharge[3], BI-RADS[10], non-board fibrovascular core[7], atypia[3,5,6], microcalcification[4], distant to nipple[10], positive CK5/6[7]. However, to date, there is still controversy regarding reliable factors that breast surgeon can use to select which papillary lesions should be removed. The present study aims to reveal prevalence of malignant upgrading in a large sample size study and to identify significant factors associated with upgrading to malignancy of benign papillary lesions diagnosed by CNB.

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Materials and Methods

A retrospective study at a tertiary medical school was conducted. Pathological database of all core needle biopsy during June 2007 to October 2012 was searched. Total 12,240 breast CNBs were identified, there were 423 papillary lesions in 404 patients diagnosed by searching keywords “papilloma”, “papillary” and “papillomatosis”. Seventy-two lesions showed malignant features on CNB and were excluded from the study. Three hundred and fifty-one lesions demonstrated no malignant features. The study was ethically approved by Institutional Review Board (SIRB) under International Ethical Guidelines for Biomedical Research Involving Human Subjects.

Final diagnosis of surgical removal specimens is defined by pathological microscopic examination and is divided into three groups: 1) benign, 2) atypia (include atypical ductal hyperplasia (ADH) or atypical lobular

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hyperplasia (ALH)) and 3) malignant (include ductal carcinoma in situ (DCIS), lobular carcinoma in situ (LCIS), papillary carcinoma, invasive ductal carcinoma (IDC). Clinical data were collected. Mammograms and ultrasound pictures were reviewed. Mammogram and ultrasound finding were graded according to Breast Imaging Reporting and Data System (BI-RADS). All CNB and excision specimens were reviewed by breast pathologist for pathological characters according to standard pathology definition guideline[2]. Missing specimens were re-cut from paraffin block and stained with Haematoxylin Eosin (H&E). Inconclusive slides were stained with special immunohistochemistry staining as pathologist requested, such as CK5/6 and p63.

Statistical analysis

Numerical data, age, size by ultrasound, distance from nipple were compared with ANOVA test, mean, median, SD. Other categorical data such as BI-RADS, ultrasound and mammogram characters, pathologic fibrovascular core, calcification, metaplasia, adenosis, and sclerosis were compared with Fisher's exact test. Logistic regression multivariate analysis was performed using SPSS 17. A *p*-value <0.05 was considered statistically significant.

Results

A total 423-papillary lesions of the breast in 404 patients were recruited from 12,240 CNB. Therefore, prevalence of papillary lesion in this study was 3.45% (423/12,240 lesions). Total 351 lesions were non-malignant papillary lesions on breast CNB. Of 351 lesions, 220 were surgical removed (62.67%). Additionally, 45/220 lesions on core needle specimen were excluded due to no available clinical data (13/45), and pathologic review by breast pathologist found non-benign papillary lesion (32/45). Therefore, total 175 papillary benign lesions on CNB were finally analyzed in this study. The final pathological report of all 175 benign lesions on CNB were reviewed; and that 163 (93.1%), 6 (3.4%), 5 (2.8%) and 1 (0.57%) were proven benign, atypical ductal hyperplasia/atypical papillary lesion, DCIS and IDC, respectively (Figure 1). Therefore, in this study upgrade rates to malignant lesions (DCIS and IDC) were 3.42%.

Regarding clinical data, mean age of patients in the present study was 50.99 years old (range from 27 to 82). Mean BMI was 23.37 (range from 14.67 to 24.92). No statistically difference in menopausal status, history of hysterectomy or oophorectomy, history of hormonal use or familial history of cancer. A majority of cases presented with palpable mass (86%), average size 9.52 mm (range 3.5 to 45 mm) with mean distance from nipple 3.52 cm (0.9 to 9.35 cm).

On radiological review, mammogram and ultrasound revealed with BI-RADS 4A (42.2%) and 4B (43.4%). Most CNB were obtained by ultrasound guided (96%). Stereotactic-guided CNB was performed in abnormal calcification without palpable lesion (4%). Mammograms presented with mass in 23.8%, calcification 17.1% and negative mammogram 59.1%. Calcification usually presented as a small cluster of

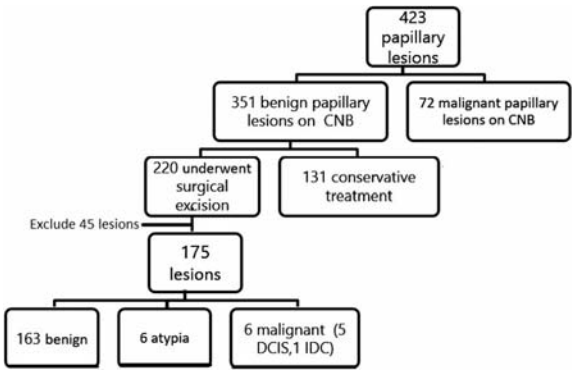

Figure 1. Diagram showed selection of 423 papillary lesions of the breast included in this study and finally 6 lesions were confirmed malignancy.

coarse/heterogonous lesion without architectural distortion. Ultrasound is good and reliable tool for intraductal papilloma detection, which usually revealed oval hypoechoic mass with indistinct margin and abrupt boundary. Duct dilatation related to abnormal nipple discharge, but was only found in 21% of cases. Core needle specimens of intraductal papilloma mostly characterized as board and sclerotic more than thin/arborizing or mix fibrovascular stalk. Coexisted findings were adenosis (63%), apocrine metaplasia (45%), squamous metaplasia (1%), usual ductal hyperplasia (mild 35%, moderate 35%, florid 19%) and sclerosing adenosis (10.2%), radial scar (5.9%) and calcification (14.6%).

Among 175 lesions included in the present study, 6 lesions were found upgraded from benign on CNB to malignant (DCIS and IDC) in surgical specimens. Univariated analysis to identify factor associated with malignant upgrade was shown in Table 1 to 3. Focusing on clinical data, only age >50 was associated with upgrading with $p = 0.046$ (Table 1). Regarding to radiological factor, no single radiographic characters significantly associated with upgrading from benign to malignant papillary lesion (Table 2). On analysis of pathological factor, thin/arborizing or mix fibrovascular stalk on CNB pathological exam ($p = 0.005$) and coexisting intralesional atypia ($p<0.001$) were found significantly related with upgrading from benign on CNB to malignant on surgical removal specimen (Table 3).

On multivariated analysis, three factors were found significantly associated with malignant upgrading. These included age >50 (RR = 4.64), thin/arborizing or mix fibrovascular stalk in CNB specimen (RR = 4.43) and coexisting intralesional atypia in CNB specimen (RR = 20.57). Mean follow-up time after excision in 175 lesions was 40 months (range from 8 to 72). On follow-up clinic, most lesions were BI-RADS 2 or 3 (96%). There were three BI-RADS 4 lesions in the excision group. Two of these were proven benign but one was IDC.

Of those 131 patients in non-surgical removal group,

Table 1. Univariated analysis of clinical factors associated with malignant upgrading for benign papillary lesions detected in CNB (total 175 lesions; 163 benign, 6 atypia and 6 malignancy)

Factors	Benign (%)	Atypia (%)	Malignant (%)	p-value
Age (mean, years)	50.52	59.83	55	0.046
BMI (mean, kg/m^2)	23.3	25.32	23.82	0.436
Menstrual status				0.653
Premenopausal	61 (49.6)	0	3 (50)	
Postmenopausal	62 (50.4)	0	3 (50)	
Hysterectomy	26 (16)	1 (16.7)	0	0.567
Oophorectomy	18 (11)	0	0	0.478
Hormonal use	19 (11.7)	0	1 (16.7)	0.623
Oral contraceptives use	46 (28.2)	2 (33.3)	1 (16.7)	0.79
Familial history of cancer	33 (20.2)	2 (33.3)	1 (16.7)	0.717

mean follow-up time was 42.4 months. One patient in this group subsequently presented with malignant invasive lobular carcinoma in the axillary lymph node without any breast lesion (1/131; 0.76%).

Discussion

In surgical practice, a controversy is addressed in managing breast papillary lesions on CNB. This is probably due to wide spectrum of disease and intralesional heterogeneity[2,13]. Previously, excision of papillary lesions of breast on CNB was recommended. However, later this practice was challenged and serial follow-ups with imaging was advised by many publications.

In previous publications, upgrade rates of malignancy after surgical removal varied from 3.4 to 38%[3-12]. In the present study, rates of upgrading to malignancy is 3.42%, which is comparable to previous studies[1,2]. Rizzo M et al, reported upgrade rates of 28.6% (which was high) in 276 excisions; however, most women in the study were African American[12]. Youk JH et al demonstrated upgrade rates of 5% in Asian populations[10]. Therefore, ethnicity could be another factor responsible for upgrading to malignancy in papillary lesion of the breast.

Although there were many previous reports demonstrated factors relating to upgrading to malignancy (Table 4), the present study is different. The present study is advantageous in terms of the number of patients recruited in the present study and that all factors in terms of clinical, radiographic and pathological factors were included. Among many factors, previous publications included advanced age in association with upgrading to malignancy[3,10,12,14,15]. It is known that the rate of breast malignancy increases with age. Findings from our study also support that age >50 is one of the significant factors related to upgrading to malignancy with the risk ratio of 4.64.

Methods of CNB specimen obtained, BI-RADS, size >1.5 cm, multiple lesions, microcalcification, distance from nipple >3 cm were previously linked to malignancy upgrading[4,8,10,15]. However, some studies were contradicting and found with no association[5,12]. Results from our study could not find any statistic association between any radiographic character and malignant upgrading to malignancy in papillary lesions diagnosed on CNB.

Pathological factors seemed to be related to upgrading to malignancy in papillary lesion diagnosed on CNB. The upgrade rate was highest in intraductal papilloma with ADH (22.2%)[5]. Ahmadiyeh N et al found high rates of upgrading to malignancy carcinoma (22.5%) in atypical papilloma group, whereas the rate was 3% in papillary lesion without atypia[15]. Atypia therefore showed strong factors related to malignant upgrading[3,6]. Results from the present study are comparable to many previous studies; intralesional atypia is the strongest factor related to malignant upgrading with the risk ratio of 20.57.

Distinguishing atypical epithelial proliferation in CNB can be difficult in some cases. Immunohistochemical staining is helpful in distinguishing benign epithelial proliferation from atypical or malignant lesions[7]. In addition, thin/arborizing or mix fibrovascular core showed statistically significant association with malignancy in the present study (risk ratio 4.43), whereas no other coexisting findings, calcification, duct dilatation showed any significance.

In non-excision group only one lesion in 131 lesions (0.07%) developed invasive carcinoma after 42 months of following-up. The lesion, however, demonstrated no papillary features and that no pathological lesions in the breast. The authors suspected that this malignant lesion may not relate to previous benign papillary lesion. Therefore, this may support safely follow-up with imaging in patients who are less than 50 years old and CNB showed benign papillary lesion without atypia.

Conclusion

The present study demonstrated 3.42% of upgrading to malignancy in patients who have papillary lesions of breast in CNB. Among all factors age >50, thin/arborizing fibrovascular core and intralesional atypia are three significant factors associated with malignancy on excision specimen. Therefore, the authors recommend considering surgical removal of papillary lesion on CNB in patient who are more than 50 years and atypia and thin/arborizing fibrovascular core found in CNB. Otherwise,

Table 2. Univariated analysis of radiographic factors associated with malignant upgrading for benign papillary lesions detected in CNB (Total 175 lesions; 163 benign, 6 atypia and 6 malignancy)

Factors	Benign (%)	Atypia (%)	Malignant (%)	*p*-value
1) General				
Multiple lesion	78 (47.9)	4 (66.7)	2 (33.3)	0.508
BI-RADS				0.786
3	6 (3.8)	0	0	
4a	70 (44.3)	1 (16.7)	3 (50)	
4b	68 (43)	5 (83.3)	3 (50)	
4c	10 (6.3)	0	0	
5	4 (2.5)	0	0	
Concordant	131 (80.9)	6 (100)	5 (83.3)	0.491
Discordant	31 (19.1)	0	1 (16.7)	
Methods obtaining specimen				0.183
Stereotactic guided	5 (3.1)	0	1 (16.7)	
Ultrasound guided	156 (96)	6 (100)	5 (83.3)	
2) Mammogram findings				
Mass	34 (23.8)	3 (60)	1 (20)	0.177
Calcification	26 (17.1)	0	2 (40)	0.242
Morphology				0.534
Absence	3 (12)	0	0	
Coarse/heterogeneous	10 (40)	0	0	
Amorphous	9 (36)	0	2 (100)	
Linear branching	2 (8)	0	0	
Pleomorphic	1 (4)	0	0	
Distribution				0.613
Cluster	16 (64)	0	1 (50)	
Non-cluster	9 (36)	0	1 (50)	
Range				0.208
<10 mm	9 (36)	0	2 (100)	
>10 mm	1 (4)	0	0	
Architectural distortion	15 (10.5)	0	0	0.559
Occult	48 (33.3)	1 (30)		
3) Ultrasound findings				
Size (mm^2)	9.45 (3.5 to 45.6)	11 (6 to 20.9)	10 (6.8 to 14)	0.803
Distance to nipple (cm)	3.4 (0.9 to 9.35)	4.05 (2 to 6.61)	3.94 (1.8 to 7.11)	0.648
Shape				0.561
Round	27 (17.8)	0	1 (16.7)	
Oval	89 (58.6)	3 (50)	3 (50)	
Irregular	36 (23.7)	3 (50)	2 (33.3)	
Margin				0.121
Circumscribed	30 (19.7)	3 (50)	2 (33.3)	
Indistinct	98 (64.5)	3 (50)	2 (33.3)	
Microlobulated	21 (13.8)	0	1 (16.7)	
Angular	3 (2)	0	1 (16.7)	
Boundary				0.132
Abrupt	148 (97.4)	6 (100)	5 (83.3)	
Echogenic halo	4 (2.6)	0	1 (16.7)	
Echogenicity				0.586
Hypoechoic	124 (81.6)	4 (66.7)	6 (100)	
Isoechoic	4 (2.6)	0	0	
Hyperechoic	0	0	0	
Mix	24 (15.8)	2 (33.3)	0	
Acoustic shadow				0.514
Absence	116 (76.3)	3 (50)	4 (80)	
Shadow	5 (3.3)	0	0	
Enhance	31 (20.4)	3 (50)	1 (20)	
Duct dilate	32 (21.1)	0	0	0.515

Table 3. Univariated analysis of pathological factors associated with malignant upgrading for benign papillary lesions detected in CNB (total 175 lesions; 163 benign, 6 atypia and 6 malignancy)

Factors	Benign (%)	Atypia (%)	Malignant (%)	*p*-value
Fibrovascular core				0.005
Board and sclerotic	109 (79)	1 (16.7)	4 (66.7)	
Thin and arborizing	13 (9.4)	2 (33.3)	0	
Mix	16 (11.6)	3 (50)	2 (33.3)	
Adenosis	87 (63)	1 (16.7)	3 (50)	0.065
Metaplasia				0.935
Absence	91 (66.4)	4 (66.7)	3 (50)	
Apocrine	45 (32.8)	2 (33.3)	3 (50)	
Squamous	1 (0.7)	0	0	
Usual ductal hyperplasia				0.574
Absence	15 (10.9)	0	0	
Mild	48 (35)	3 (50)	3 (50)	
Moderate	48 (35)	1 (16.7)	3 (50)	
Florid	26 (19)	2 (33.3)	0	
Sclerosis				0.426
Absence/delicate	115 (83.9)	4 (66.7)	4 (66.7)	
Sclerosing adenosis	14 (10.2)	2 (33.3)	2 (33.3)	
Radial scar	8 (5.9)	0	0	
Calcification	20 (14.6)	1 (16.7)	2 (33.3)	0.46
Coexisting intralesional benign				0.219
Absence	128 (92.8)	5 (83.3)	5 (83.3)	
Fibroadenoma	6 (4.3)	1 (16.7)	0	
Others	4 (2.9)	0	1 (16.7)	
Coexisting intralesional atypia				0.001
Absence	137 (100)	5 (83.3)	2 (33.3)	
Atypia	0	1 (16.7)	2 (33.3)	
ADH	0	0	2 (33.3)	
Contralateral lesion				0.893
Absence/benign	106 (96.4)	0	6 (100)	
ADL/ALH	1 (0.9)	0	0	
DCIS	0	0	0	
IDC/papillary CA	3 (2.7)	0	0	

Table 4. Review literatures of upgrade rate and factors reported significant associated with malignant upgrading

Year	Author	No. of CNB	No. of excision	Upgrade rate	Factors associated with malignancy
2007	Ashkenazi et al[3]	43	39	44%	Age, atypia
2008	Sakr et al[4]	130		8%	Age >50, nipple discharge, microcalcification
2008	Rizzo et al[5]	345	142	24.5%	ADH
2009	Bernik et al[6]	122	61	38%	Atypia
2010	Pathmanathan[7]	127			Non-board/sclerotic fibrovascular core and epithelial CK5/6 staining
2010	Chang et al[8]	114	87	17%	Size >1.5 cm
2010	Jung et al[9]	160	50	23%	Palpable lesion, mass
2011	Youk et al[10]	160		5%	Age >50, size >1 cm, distance from nipple >3 cm, BI-RADS
2011	Cyr et al[11]	193	82	12%	None
2012	Rizzo et al[12]	276	276	28.6%	Age

follow-up with imaging is safe.

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What is already known on this topic?

Controversy regarding management of papillary lesions of the breast diagnosed on core needle biopsy.

What this study adds?

Confirm non-surgical management of papillary lesions of the breast diagnosed on core needle biopsy with low risk of upgrading to malignancy.

Potential conflicts of interest

The authors declare no conflicts of interest.

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ปัจจัยที่มีผลในการทำนายการเป็นมะเร็งในชิ้นเนื้อที่เต้านมที่ได้รับการวินิจฉัยว่าเป็นเนื้องอกชนิดแป็ปปิลลารี่จากการเจาะชิ้นเนื้อ

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ภูมิหลัง: การตัดสินใจทางคลินิกในการรักษาผู้ป่วยที่มีผลการเจาะชิ้นเนื้อที่เต้านมในกรณีที่ผลการเจาะชิ้นเนื้อเป็นแป็ปปิลลารี่ยังเป็นที่ถกเถียงกันอยู่ นอกจากนั้นปัจจัยที่มีผลในการที่จะตรวจพบมะเร็งในชิ้นเนื้อที่ผ่าตัดออกมาในกรณีที่ผลการเจาะชิ้นเนื้อเป็นแป็ปปิลลารี่ยังมีการศึกษาไม่แน่ชัด

วัตถุประสงค์: การศึกษาครั้งนี้มีวัตถุประสงค์เพื่อหาปัจจัยที่มีผลในการทำนายการเป็นมะเร็งในชิ้นเนื้อที่เต้านมที่ได้รับการวินิจฉัยว่าเป็นเนื้องอกชนิดแป็ปปิลลารี่จากการเจาะชิ้นเนื้อ

วัสดุและวิธีการ: ดังนั้น การศึกษาครั้งนี้จึงทำการศึกษาโดยการรวบรวมข้อมูลย้อนหลังในชิ้นเนื้อที่ได้รับการเจาะตรวจจำนวน 423 ชิ้น ในผู้ป่วย 404 คน ในจำนวนนี้ชิ้นเนื้อ 351 ชิ้น ผลการเจาะชิ้นเนื้อเป็นเนื้องอกชนิดแป็ปปิลลารี่ และ มีจำนวน 220 ชิ้นได้รับการผ่าตัดชิ้นเนื้อออกทั้งหมด ในการศึกษานี้จะถือว่ามีการเปลี่ยนระดับการวินิจฉัยเป็นมะเร็งก็ต่อเมื่อเจอมะเร็งเต้านมรวมทั้งชนิดก่อนลุกลาม และ ชนิดลุกลาม

ผลการศึกษา: ผลการศึกษาพบว่า ชิ้นเนื้อที่ได้รับการเจาะแล้วมีการผ่าตัด มีอัตราการเป็นมะเร็งหลังผ่าตัดชิ้นเนื้อร้อยละ 3.42 และปัจจัยที่มีผลต่อการตรวจพบมะเร็ง คือ ผู้ป่วยที่มีอายุมากกว่า 50 ปี และ ชิ้นเนื้อที่ตรวจพบลักษณะ thin/aborizing/mix fibrovascular core และ ตรวจพบภาวะ atypia ในชิ้นเนื้อที่เจาะตรวจ

สรุป: ชิ้นเนื้อที่ได้รับการเจาะออกมาเป็นเนื้องอกชนิดแป็ปปิลลารีแบบไม่ใช่เนื้อร้ายสามารถที่จะติดตามอย่างต่อเนื่องได้โดยไม่จำเป็นต้องรับการผ่าตัด เว้นแต่หากมีปัจจัยเสี่ยงดังกล่าวข้างต้นให้พิจารณาทำการตัดเนื้อออกตรวจเพิ่มเติมต่อไป