Original Article

Sensitivity and Specificity of Breast Mass Core Needle Biopsy for Discrimination Surgical Group from Non-Surgical Group in Thammasat University Hospital

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Abstract

Introduction: To determine sensitivity and specificity of breast core needle biopsy (CNB) at Thammasat

University Hospital (TUH).

Method: Descriptive retrospective study of 161 breast CNBs with corresponding open surgical biopsy

specimens from Pathology Unit at TUH from January 2011 to December 2015. All cases were reviewed by breast pathologist to establish diagnose. The diagnoses were categorized into pathology category classification (B1-5) according to the UK National Health Service Breast

Screening Program (NHSBSP).

Results: 161 female patients were included in this study. The sensitivity and specificity of breast CNB

in discrimination surgical group from non-surgical group were 94% and 81.5%, respectively.

Discussion and The accuracy of breast CNB of TUH in discrimination surgical group from non-surgical group is

Conclusion: good.

Key words: Breast mass, Breast core needle biopsy, Pathology, Surgical group, Non-Surgical group

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Introduction

Breast cancer is the important health problem in Thailand. According to hospital-based cancer registry data 2015 by National Cancer Institute Department of Medical Services, Ministry of public health, Thailand, breast cancer was the first rank among the initially diagnosed cancer in female (24.66%).¹

Nowadays breast mass patients in Thammasat university hospital (TUH) were increased. From the cancer survey during 1st January 2008 to 31st August 2010 revealed that breast cancer is the most common cancer for female patients in Thammasat University Hospital.

The combined diagnosis from core needle biopsy (CNB)diagnosis, clinical data, and radiologic finding are the standard method². The histological type of tumor, tumor grade, and hormonal receptor status will affect the further management, prognosis evaluation, and lymph node status in each patient.³ In case of negative results for malignancy, the patient may omit and unnecessary surgery^{2, 4}.

Therefore, the evaluation of sensitivity and specificity of breast core needle biopsy compare to open surgical biopsy and factors that associated with discordance are important for further improvement of core needle biopsy service in Thammasat university hospital.

Method

This descriptive retrospective study was approved by Ethics committee of Faculty of Medicine, Thammasat University Hospital.

One hundred and sixty-one cases of breast CNBs with corresponding open surgical biopsy specimens from Pathology Unit at TUH from January 2011 to December 2015 were collected. All cases were reviewed by a breast pathologist. The diagnoses were categorized according to UK National Health Service Breast Screening Program (NHSBSP) as B1-B5.

The lesions were divided according to further management into the lesion of uncertain or more risk for malignancy (B3-B5) that need additional surgery as "Surgical group". The lesions with low risk for malignancy (B1-B2) were classified as "Non-surgical group". Pathologic diagnosis, patient's age, radiologic diagnosis in BIRAD system, lesion size, and CNB length were collected.

The data were analyzed via STATA, the data analysis and statistical software Version 121 se. Demographic data were presented as percentage, mean, and median value.

Pathology category classification (B1-5) according to the UK National Health Service Breast Screening Program (NHSBSP)⁵ is included

B1 (Normal tissue): Normal breast duct and lobule, mature adipose tissue, stroma, and microcalcifications associated with atrophic or normal terminal duct lobular units (TDLUs)

B2 (Benign lesions): Fibroadenoma, fat necrosis, duct ectasia, usual ductal hyperplasia (UDH), sclerosing adenosis, abscess and hamartoma

B3 (Uncertain malignant potential): Atypical ductal hyperplasia (ADH), lobular neoplasm, phyllodes tumor, papillary lesion, flat epithelial atypia, radial scar and complex sclerosing lesion

B4 (Suspicious): A definite malignant diagnosis ductal carcinoma in situ (DCIS) or invasive carcinoma is not possible because of crush artifact, poor fixation or a small questionable focus of non-diagnostic cells

B5 (Malignant): An unequivocal malignant diagnosis (includes DCIS and invasive carcinoma)

Results

One hundred and sixty-one female patients were divided into surgical group (N = 134) and non-surgical group (N = 27). The average ages of surgical and non-surgical group were 54.4 and 47.4 years, respectively. The median BIRADs of surgical and non-surgical group were 4, both. The median lesion

sizes of surgical and non-surgical group were 2.5 and 1.5 cm, respectively. The CNB lengths of surgical and

non-surgical group were 4.05 and 2.9 cm, respectively. (Table 1)

Table 1 Demographic data of patient with breast mass

Variable	Surgical group	Non-Surgical group
Patients (N = 161)	N = 134	N = 27
Female (%)	134 (100%)	27 (100%)
Age (median)	30 - 85 (52) years	28 - 74 (47) years
BIRADs (median)	3 - 5 (4)	3 - 5 (4)
Lesion size (median)	0.3 - 15 (2.5) cm	0.2 - 4 (1.5) cm
CNB length (median)	0.4 - 7.4 (4.05) cm	0.3 - 4.6 (2.9) cm

Sensitivity and specificity of breast core needle biopsy in discrimination surgical group from non-surgical group were 94% and 81.5%, respectively. The area under ROC curve was 0.88. Positive and

negative predictive values were 96.2% and 73.3%, respectively. There were thirteen discordant cases. Five cases were false positive case and eight cases were false negative case. (Table 2)

Table 2 Comparing results between core needle biopsy diagnosis to open surgical biopsy

Open surgical biopsy	CNB		Total
	Surgical group	Non-surgical group	
Surgical group	126	8	134
Non-surgical group	5	22	27
Total	131	30	161

Factors that associated with discordance were sampling error (2 out of 13 cases), papillary lesions (one out of 13 cases), small size of atypical

or malignancy component; e.g. atypical ductal hyperplasia (ADH) (one out of 13 cases), and fibroepithelial lesions (9 out of 13 cases). (Table 3)

 Table 3
 Pathologic diagnoses of discordant cases

Case No.	Age	BIRADs	CNB Diagnosis	Open biopsy diagnosis
1	61	4	UDH with sclerotic stroma	Invasive ductal carcinoma
2	80	5	Chronic inflammation with dilated mammary duct	Encapsulated papillary carcinoma
3	51	4	ADH with fibroepithelial lesion,	Complex fibroadenoma with
			favor fibroadenoma	sclrosing adenosis with UDH
4	65	4	Fibrofatty tissue	Sclerosing adenosis with
				intraductal papilloma with UDH
5	63	4	Fibroepithelial lesion, favor fibroadenoma	Benign phyllodes
6	47	4	Fibroepithelial lesion, favor fibroadenoma	Benign phyllodes
7	52	4	Fibroepithelial lesion, favor fibroadenoma	Benign phyllodes
8	35	4	Fibroepithelial lesion, favor fibroadenoma	Benign phyllodes
9	49	4	Fibroepithelial lesion, favor fibroadenoma	Benign phyllodes
10	50	4	Fibroepithelial lesion, favor phyllodes tumor	Fibroadenoma
11	43	4	Fibroepithelial lesion, favor phyllodes tumor	Fibroadenoma
12	39	3	Fibroepithelial lesion, favor phyllodes tumor	Fibroadenoma
13	39	4	Fibroepithelial lesion, favor phyllodes tumor	Fibroadenoma

Discussion and Conclusion

The previous studies of sensitivity and specificity of core needle biopsy were 94.4 - 97.4% and 88.3 - 100%, respectively^{6 - 14}. Luechakiettisak P et al studied at Surat Thani hospital, Thailand. The sensitivity and specificity of his study were 92% and 100%, respectively.

For our study, the sensitivity and specificity of breast core needle biopsy in discrimination surgical group from non-surgical group were 94 % and 81.5 %, respectively. The sensitivity and specificity of our study are quite lower than previous studies that categorized the diagnoses to malignant and benign group. The additional subclassification of diagnoses for management purpose into surgical (B3 - B5) and non-surgical group (B1 - B2) according to UK National Health Service Breast Screening Program (NHSBSP) in our study might increase the discordant cases.

Area under ROC curve of this study was 0.88 (0.8 - 0.9 = "good"). It indicated that the accuracy of

breast CNB of TUH in discrimination surgical group from non-surgical group is good. Factors that associated to discordance in our study were

1. Sampling error

The case number 1"invasive ductal carcinoma" was previously called "UDH with sclerotic stroma" in CNB. The imaging review showed technical difficulties from poor lesion visualization and dense fibrotic tissue (Figure 1). Case number 4 "sclerosing adenosis with intraductal papilloma and usual duct hyperplasia" was called fibrofatty tissue by CNB. The review showed poor lesion visualization. Youk JH *et al* identified that the radiologists should beware the possibility of false negative case. They should prepare for re-biopsy or advise the patient to receive open surgical biopsy in case of pathologic-histologic discordance. Factors that associated to discordance in this study were lesion visualization, needle visualization, and deep lesions 15.

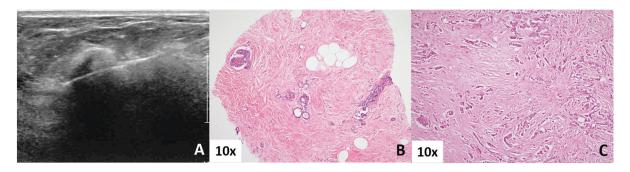


Figure 1False negative case from sampling error. A, Ultrasonagraphy during CNB biopsy. B, CNB; Usual ductal hyperplasia with sclerotic stroma. C, Open biopsy; Invasive ductal carcinoma with sclerotic stroma and desmoplastic reaction

2. Papillary lesion

The case number 2 "encapsulated papillary carcinoma" was initially diagnosed as "chronic inflammation with dilated mammary duct" by CNB. Review histology of CNB showed obtained tissues from fibrous

capsule and cystic component of encapsulated papillary carcinoma without atypical cells, thus the significant component of the papillary lesion is not received for CNB diagnosis (Figure 2).

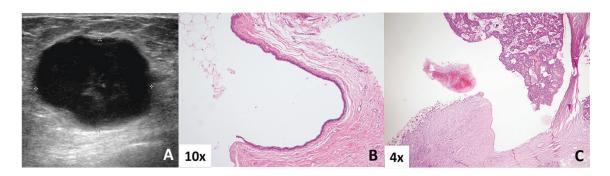


Figure 2 False negative case from papillary lesion, A. Ultrasonography showed solid cystic mass. B, CNB; Chronic inflammation with dilated mammary duct. C, Open biopsy; Encapsulated papillary carcinoma

Bilous M identified that the sample obtained by CNB might not have included the most significant area for diagnosis due to the heterogeneity of the lesion. These included intraduct papilloma, intraduct papilloma with atypia, intracystic (encapsulated) papillary carcinoma, solid papillary carcinoma and invasive papillary carcinoma. Papillary lesion was one of the lesions that are known to have a high incidence of 'upgrading' after excision ('underestimation' by CNB)⁵.

3. Small size of atypical or malignancy component; e.g. atypical ductal hyperplasia (ADH)

The case number 3 CNB showed foci of less than 2 millimeters of low grade atypical duct proliferation thus the initial diagnosed was ADH with fibroepithelial lesion. Since the clinical of breast mass was suspected with suspicious for atypical epithelial proliferation then excisional biopsy was performed. The following biopsy diagnosed was complex fibroadenoma with sclerosing adenosis and UDH (Figure 3).

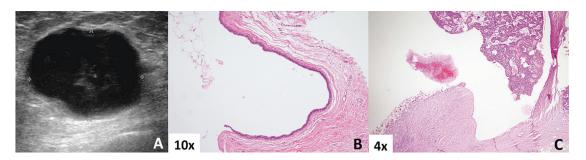


Figure 3 False positive case. A, Ultrasonography revealed irregular hypoechoic nodule. B, CNB; Atypical ductal hyperplasia. C, Open biopsy; Usual ductal hyperplasia without atypical ductal hyperplasia despite further step sections.

Chiramongkol N *et al* identified that 19.8% of patients that were diagnosed ADH on CNB then underwent surgical excision at their institute was subsequently upgraded to malignancy after surgical excision. Amongst the malignant cases, the histological results revealed that 13 (15.1%) patients had DCIS and 4 (4.7%) patients had invasive carcinoma. Presentation with palpable breast mass was the independent factor that associated with upgrading to malignancy on subsequent surgical excision. In the patients who presented with palpable breast mass and were diagnosed as ADH on CNB, subsequent excision should be performed to exclude upgrading to malignancy¹⁶.

4. Fibroepithelial lesion

The cases numbers 5 to 13 were fibroepithelial lesions. Five from nine cases were initially diagnosed as "favor fibroadenoma" then the open biopsy were benign phyllodes tumor. These lesions showed intracanalicular epithelial proliferation of "leaf-like" pattern, cellular stroma and stromal overgrowth which did not obtained in CNB specimens, due to tumor heterogeneity of benign phyllodes tumor. Four from nine cases show increase stoma proliferation and diagnosed as "favor phyllodes tumor". The open biopsies were "fibroadenoma" with cellular stroma. Wiratkapun C et al, Dillon MF et al, and Morgan JM et al stated that it was difficult to discriminate histologically between phyllodes tumors and

fibroadenomas particularly in CNB specimens due to tumor heterogeneity in nature^{17 - 19}. Moreover CNB used a sampling technique; it was even more difficult for pathologists to make a clear-cut diagnosis¹⁹.

Retrospective study design was a limitation of our study. Some glass slides and paraffin blocks were sent to other hospital for further treatment or loss. The data of our study might not represent the actual characters of the patients in Thammasat University Hospital.

The sensitivity and specificity of breast core needle biopsy of Thammasat University Hospital in discrimination surgical group from non-surgical group were 94% and 81.5%, respectively. The accuracy of breast CNB of TUH in discrimination surgical group from non-surgical group is good. Factors that associated with discordance were sampling error, papillary lesions, small size of atypical or malignancy component; e.g. atypical ductal hyperplasia (ADH), and fibroepithelial lesions.

From our study, we suggested adding pathology category classification according to the UK National Health Service Breast Screening Program (NHSBSP) to official pathologic report. This classification might be useful for evaluation of clinical-radiologic-pathologic correlation to establish further proper management. In case of discordant cases, the interdepartmental conference is essential.

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บทคัดย่อ

ความไวและความจำเพาะของผลตรวจทางพยาธิวิทยาของก้อนจากเต้านมด้วยเข็มตัดชิ้นเนื้อเปรียบเทียบกับก้อนจากการผ่าตัด ในการจำแนกกลุ่มที่ต้องรับการผ่าตัดออกจากกลุ่มที่ไม่ต้องรับการผ่าตัดในโรงพยาบาลธรรมศาสตร์เฉลิมพระเกียรติ นรี พฤฒิคามภีร์*, อารยา สามหมอ*, ศศิธร สุจริตธนะการ**, วรรณฤดี โลหิตวิเศษ***, วันวิสาข์ หิมะคุณ*

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บทนำ: วัตถุประสงค์การศึกษาเพื่อหาความไวและความจำเพาะในการวินิจฉัยทางพยาธิวิทยาของชิ้นเนื้อซึ่งได้จาก

การตรวจด้วยเข็มตัดชิ้นเนื้อเทียบกับชิ้นเนื้อที่ได้จากการผ่าตัด

วิธีการศึกษา: การศึกษาแบบย้อนหลัง โดยรวบรวมผู้ป่วยก้อนเต้านมในโรงพยาบาลธรรมศาสตร์เฉลิมพระเกียรติที่ได้รับ

การตรวจวินิจฉัยโดยเข็มตัดชิ้นเนื้อ ตั้งแต่เดือนมกราคม ปี ๒๕๕๔ ถึง เดือนธันวาคม ปี ๒๕๕๘ ตรวจวินิจฉัย ทางพยาธิวิทยาซ้ำโดยพยาธิแพทย์ผู้เชี่ยวชาญด้านพยาธิวิทยาเต้านม จำแนกผลการวินิจฉัยตามระบบ UK

National Health Service Breast Screening Program (NHSBSP)

ผลการศึกษา: ผู้ป่วยหญิงทั้งหมด ๑๖๑ ราย ความไวและความจำเพาะของการตรวจด้วยเข็มตัดชิ้นเนื้อในการจำแนกกลุ่ม

ผู้ป่วยที่ต้องรับการผ่าตัดออกจากกลุ่มผู้ป่วยที่ไม่ต้องรับการผ่าตัดเท่ากับ 94% และ 81.5%

วิจารณ์ และ การตรวจด้วยเข็มตัดชิ้นมีความแม่นยำในการจำแนกผู้ป่วยที่ต้องได้รับการผ่าตัดออกจากผู้ป่วยที่ไม่ต้องรับ

สรุปผลการศึกษา: การผ่าตัดทางพยาธิวิทยาในระดับดี

คำสำคัญ: ก้อนเต้านม, การตรวจด้วยเข็มตัดชิ้นเนื้อ, พยาธิวิทยา, กลุ่มที่ต้องรับการผ่าตัด, กลุ่มที่ไม่ต้องรับการผ่าตัด