

# Diagnostic Accuracy of Vacuum-Assisted Stereotactic Core Needle Biopsy for Breast Lesions

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**Objective:** To evaluate the diagnostic accuracy of the vacuum-assisted stereotactic core needle biopsy (CNB) for breast lesions.

**Material and Method:** Sixty-four lesions that had undergone vacuum-assisted stereotactic CNB between January 2003 and December 2005 in Ramathibodi Breast diagnostic center were included in this study. Pathologic results of CNB were reviewed and correlated with pathologic results of subsequent open surgery. For benign lesions without surgery, the authors correlated the result of CNB with stability of the lesion at or more than 2-year interval follow-up. Agreement rate, high-risk under estimate rate, Ductal carcinoma in situ (DCIS) underestimate rate, false negative rate, and sensitivity were assessed.

**Results:** The pathologic results for the CNB were malignancy in 20%, high-risk in 13%, and benign in 67%. The agreement rate was 93.8% (60 of 64). The under estimate rate for atypical ductal hyperplasia (ADH) was 50% (3 of 6). There was no underestimate for DCIS in the present study. Of 43 benign lesions, malignancy was found at subsequent open surgery in one lesion and false negative rate was 6%. Calculated sensitivity was 96%.

**Conclusion:** Vacuum-assisted CNB is an accurate method for evaluating breast lesions. This procedure is an alternative to surgical excision for lesion assessments.

**Keywords:** Stereotactic core needle biopsy, Breast lesions, Breast cancer, Underestimation rate, Diagnostic accuracy

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The increasing use of mammography has led to the detection of a large number of lesions that require further histopathologic work up. However, surgical biopsy of all suspicious or undetermined lesions would lead to physical and psychological stress for the patient, operative and perioperative risk and high cost. Furthermore, postoperative scarring, particularly after multiple surgeries or complications, may lead to impaired diagnostic assessment of future mammogram<sup>(1,2)</sup>.

Percutaneous imaging guided breast biopsy is an alternative to surgical biopsy for the histological assessment of mammographic abnormalities, which is less invasive compared to surgical biopsy. Complications of the procedures are unusual. Frequency of hematoma and infection are less than

one in 1,000. Furthermore, because 70-80% of non-palpable lesions referred for biopsy are benign, percutaneous imaging guided biopsy can also decrease the number of surgical procedures<sup>(3-5)</sup>.

Percutaneous imaging guided biopsy is most often performed under stereotactic or sonographic guidance. Even though, sonographic guided biopsy may be preferable in aspects of patient comfort, radiation exposure, procedure time and cost but the procedure is not preferable for calcification or small solid mass that are more apparent on mammography<sup>(4)</sup>.

Stereotactic core needle biopsy can be used for specific types of mammographic lesions particularly the lesions that are sonographically unapparent<sup>(4)</sup>.

Unlike excisional biopsy, the aim of core needle biopsy is to sampling rather than completely remove the mammographic abnormality<sup>(6)</sup>. The accuracy of core needle biopsy depends on the characteristic of the lesion, experience of the radiologist, the radiographer, and quality of the machine<sup>(3)</sup>.

Development of vacuum-assisted breast biopsy allows contiguous tissue retrieving with a

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significantly larger volume of tissue. Such a larger volume of tissue may help to prevent potential errors (like tissue displacement during needle biopsy, for example) and reduce sampling error<sup>(1)</sup>. Moreover, while compared with the 14-gauge automated needle, the vacuum-assisted devices obtain larger tissue specimen<sup>(4)</sup>.

In 2003, Rotter et al reported no false negative occurred among the 752 follow-up cases which underwent stereotactic vacuum-assisted core needle biopsy<sup>(1)</sup>. Leifland et al reported sensitivity and specificity of stereotactic core needle biopsy were 90% and 98.8%, respectively<sup>(7)</sup>.

Vacuum-assisted stereotactic core needle biopsy has become a preferable method for histological assessment of mammographic abnormalities.

In the present study, the authors undertook a review of the data from Ramathibodi Hospital to evaluate the diagnostic accuracy of the breast lesions, which underwent vacuum-assisted stereotactic core needle biopsy.

#### **Material and Method**

The present study was approved by the ethics committee of the Faculty of Medicine, Ramathibodi Hospital, Mahidol University.

During the 3-year interval between January 2003 and December 2005, 80 women underwent vacuum-assisted stereotactic core needle biopsy at the Breast Diagnostic Center, Department of Radiology, the Faculty of Medicine, Ramathibodi Hospital.

Eleven patients did not undergo open surgery and had no complete 2-year interval follow-up to ensure the benignity of the lesions. Furthermore, five patients had no medical record about detail of the lesion that underwent core needle biopsy. These patients were excluded.

Of the remaining 64 patients, 25 patients (39%) underwent open surgery and had the same pathological report and 37 patients (58%) had completed at least 2-year interval follow-up for their benign lesions. Two patients (3%) with malignant lesions from core needle biopsy did not undergo open surgery in Ramathibodi Hospital. They were categorized as "malignant" in the final result. Each of the patients had only one lesion that underwent vacuum-assisted stereotactic core needle biopsy.

Data were retrospectively collected from medical records, mammographic and ultrasonographic images, and reports as well as pathological reports.

#### ***Performance of vacuum-assisted stereotactic core needle biopsy***

Mammography was performed in cranio-caudal view (CC view) and mediolateral oblique view (MLO view) by using two mammography machines (Lorads M-IV; Danbury, CT, USA and Senographe DMR; GE, Milwaukee, WI, USA). Since November 2004, mammography was obtained from digital mammographic unit (Lorads selenia; Danbury, CT, USA). An additional ultrasonography (US) (HDI 5000; Philips ultrasound, Bothell, WA, USA) of the breasts was performed in almost all patients immediately after mammography, except for cases with almost entirely fatty breasts.

The Breast Imaging Reporting and Data System (BI-RADS) assessment categories was based on the combined results of both mammography and US, which were classified into 6 categories according to the American College of Radiology (ACR) BI-RADS 4<sup>th</sup> edition.

Biopsy was performed to establish the histopathological diagnosis for mass, calcifications, or lesion visible at mammography, when they were suspicious for malignancy.

Before February 2005, vacuum-assisted stereotactic core needle biopsy was performed with an add-on stereotactic device with digital imaging (Lorad stereoLoc II, Danbury, CT, USA). Beyond this period, stereotactic core needle biopsy was performed by 11-gauge directional vacuum assisted core needle biopsy (VAB) instrument (Mammotome; Biopsy Ethicon Endo-Surgery, Cincinnati, OH, USA) with prone breast biopsy table (LORAD MultiCare Platinum, Danbury, CT, USA). Twelve core samples were routinely obtained for the cluster of microcalcifications. If the post biopsy film revealed inadequate removal of suspicious microcalcifications, the extended stereotactic core needle biopsy was attempted until the specimens were adequately retrieved. Completely removing all the suspicious microcalcifications was not the aim of the procedure but to obtain an adequate specimen for pathologic diagnosis. Procedure was performed for all lesions evident as calcifications by three radiologists with expertise in stereotactic core needle biopsy.

No complication after the procedure was found in the presented patients.

The details of intervention procedures following mammography performed at Ramathibodi Hospital will be retrospectively reviewed.

Mastectomy was performed by five attending surgeons, while excisional biopsy was also performed

by these surgeons or in-training residents of the surgical department under supervision of the attending surgeons.

Pathological specimen was interpreted by 12 pathologists. One of them had expertise in breast pathology. They interpreted the specimen with knowledge of the clinical information and previous pathological result of the patient.

Pathology was classified by the most worrisome pathological finding from any kind of biopsy or surgery. For example, if the pathology from VAB was atypical ductal hyperplasia (ADH) but the pathology from subsequent surgical biopsy was ductal carcinoma in situ (DCIS), the pathology of this case was DCIS. If the specimen contained both ADH and fibrocystic change, the pathology was ADH.

#### ***Evaluation of the accuracy of vacuum-assisted stereotactic core needle biopsy***

Accuracy of core needle biopsy was determined by either histopathology or by stability of the lesions on the follow-up mammography at least 24-month interval.

A benign diagnosis on core biopsy followed by subsequently diagnosis of malignant disease was considered a false-negative result. Patients with benign cores and subsequent malignant pathology were reviewed in detail with emphasis on clinical presentation, radiographic findings, indications for further investigations, delay in diagnosis and final pathologic diagnosis.

In a patient whom a small focus of high-risk lesion or cancer was disclosed from the core biopsy but was not found on the following surgical procedure due to the lesion was totally removed; the biopsy result was still considered as a true positive biopsy following review. From this assumption, there is no false positive in the present study.

#### ***Statistical analysis***

Continuous variables were summarized as mean with standard deviation or median with interquartile range as appropriate. The false-negative rate was obtained by dividing the number of false-negative cases by the number of patients diagnosed with cancer. Agreement with kappa, 95% confidence interval (95% CI) and underestimate rate of high-risk lesion and DCIS were calculated. Categorical variables were summarized as counts and percentages. Statistical significance is defined as a p-value of 0.05 or less. All

statistical analyses were performed using Stata v.9 (Stata Corp, College Drive, Tx, USA).

## **Result**

### ***Characteristics of study population***

In 64 women (mean age, 51.2 years; SD 9.9), 10 (16%) had a personal history of breast cancer and no one had a family history of breast cancer.

Fifty-six cases (88%) had dense breasts (Heterogeneously dense or extremely dense breasts) and only eight cases (12%) did not (Almost entirely fat breasts or scattered fibroglandular densities). Details of study population are reported in Table 1.

Two cases (3%) had lesions that were detected by physical examination. Thirty-seven cases (58%) had a lesion on the left breast.

All of the 64 lesions were detected on the mammography, most of which were microcalcifications, 62 lesions (97%), including isolated microcalcifications (75%), mass with microcalcifications (11%), asymmetry or architectural distortion with microcalcifications (14%).

Forty-nine lesions (77%) were detected only by mammography while the remaining 15 lesions (23%) were detected by both mammography and US. Most of the lesions seen on US were masses. Detailed characteristics of the lesion are shown in Table 2.

Thirty-eight cases (59%) underwent core needle biopsy performed with an add-on stereotactic device using 11-gauge directional vacuum assisted core needle biopsy instrument and 26 cases (41%) underwent stereotactic core needle biopsy by 11-gauge directional VAB instrument with dedicated prone breast biopsy table.

Numbers of core biopsies were ranging from eight to 20 cores (mean 14 cores; SD 3.49). Number of the obtained calcified specimens ranged from no

**Table 1.** Characteristic of total study population

Characteristics & findings (n = 64)	Summary n (%)
Age (years): mean (SD)	51.2 (9.93)
Personal history of breast cancer	10 (16)
Family history of breast cancer	0 (0)
Mammographic grade of breast density	
Almost entirely fat	2 (3)
Scattered fibroglandular densities	6 (9)
Heterogeneously dense	49 (77)
Extremely dense	7 (11)

**Table 2.** Lesion characteristics

Characteristics and findings (n = 64 unless stated otherwise)	Summary n (%)
Lesions detected by physical examination	2 (3)
Side of lesion (left)	37 (58)
Location of the lesion	
UOQ and LOQ	34 (53)
UIQ and LIQ	9 (14)
Mid portion	21 (33)
Mammographic lesions	
Isolated microcalcifications	48 (75)
Mass ± microcalcifications	7 (11)
Asymmetry, architectural distortion ± microcalcifications	9 (14)
Size of lesion on Mammogram (57 lesions)	
≤ 5 mm	22 (39)
> 5 mm	35 (61)
Morphology of microcalcifications (62 lesions)	
Pleomorphic	46 (74)
Linear and linear branching or indeterminate	10 (16)
Increased number or newly seen punctate	6 (10)
Distribution of microcalcifications (62 lesions)	
Cluster	51 (82)
Linear, segmental, regional or diffused and scattered	11 (18)
Margin of the mass on mammography (7 lesions)	
Circumscribed	1 (14)
Indistinct or spiculated	6 (85)
Lesions seen on ultrasonography (15 lesions)	
Mass ± calcification	8 (53)
Isolated calcification	3 (20)
Architectural distortion ± calcification	4 (27)
BI-RADS	
3	3 (5)
4A	10 (16)
4B	44 (69)
4C	2 (3)
5	5 (8)

UOQ = upper-outer quadrant; LOQ = lower-outer quadrant; UIQ = upper-inner quadrant, LIQ = lower-inner quadrant

calcification found in the specimen to maximum of calcifications in 11 cores (mean calcified core specimen was four cores; SD 2.78). According to technical difficulty, the radiologist recommended further needle localization with excisional biopsy in one case (2%). Details of the core needle biopsy are shown in Table 3.

#### **Open surgery and follow-up data**

Of 64 cases, eight were high-risk lesions, which included ADH (6 cases) and atypical lobular hyperplasia (ALH) (2 cases).

Three cases of ADH diagnosed by core needle biopsy were found to have carcinoma from open

surgery. One had DCIS and two had invasive ductal carcinoma (IDC). (One of them was isolated IDC and another one was DCIS with IDC). One of the ADH cases that IDC was subsequently disclosed had the record of insufficient sampling from the stereotactic core needle biopsy.

For the remaining three ADH cases, one of them had the same pathologic result from open surgery, another one was found to be a benign pathology from the open surgery, and the last one had a stable lesion during complete 2-year follow-up. The authors categorized these three cases as high-risk lesions in the final result.

Two ALH cases were found to be benign lesions from open surgery and still categorized as high-risk lesions in the final result.

Among nine patients of DCIS diagnosed by VAB, eight of them were not upgraded to be IDC and pathology of DCIS was still reported from the open surgery and one of them was found to be a benign lesion (usual ductal hyperplasia) that the authors still considered as DCIS in the final result.

The remaining two cases who were diagnosed IDC had the same pathologic results from the open surgery.

Among forty-three cases that were found to be benign lesions on the core needle biopsy, thirty-six cases of them had completed at least 2 years follow-up and there was no progression of these lesions to high-risk lesion or malignancy. The remaining seven cases underwent further open surgery. Six cases had open surgery because the patient and/or referring physician's unwillingness to accept the result of stereotactic core needle biopsy and all of them were found to have a benign lesion from open surgery. One remaining case of a benign lesion underwent open surgery because of discordant between mammographic findings and pathological result from core needle biopsy. It had invasive carcinoma from open surgery.

Summary of initial biopsy reports and final diagnosis of all 64 cases of the present study population are reported in Table 4.

#### **Agreement, false negative rate, sensitivity and underestimation rate**

In comparison between core needle biopsy and reference standard (open surgery or 2-year interval follow-up), the agreement rate was 93.8% (95% CI 84.8 to 98.3) and kappa was 0.874 (95% CI 0.684 to 1.0), as shown in Table 5. The result was statistically significant with p-value < 0.001.

False negative rate was 4.5% (95% CI 0.1 to 22.8). The underestimated rate of benign lesions was 2.3% (95% CI 0.1 to 12.3), which was one in 43 cases. The underestimated rate of ADH was 50% (95% CI 11.8 to 88.2), which were three in six cases. There is no under estimation for DCIS (Table 6).

Sensitivity of VAB was 95.5% (95% CI 77.2 to 99.9).

#### **Discussion**

The results of the present study show that VAB is an accurate and reliable method for diagnosing a breast lesion. The sensitivity (95.5%, 21/22),

**Table 3.** Details of stereotactic core needle biopsy

Characteristics & findings (n = 64)	Summary
Number of core biopsies	
Mean (SD)	14 (3.49)
Median (Interquartile range)	12 (12-16)
Range (minimum-maximum)	8-20
Number of calcified core specimen	
Mean (SD)	4 (2.78)
Median (Interquartile range)	4 (2-6)
Range (minimum-maximum)	0-11
Lesion was removed	
Radiologist satisfy	63 (98%)
Radiologist not satisfy	1 (2%)

**Table 4.** Initial biopsy reports and final diagnosis

Characteristics & findings (n = 64)	Summary n (%)
Initial biopsy report	
Benign lesions	43 (67)
High risk (atypical ductal or lobular hyperplasia)	8 (13)
Malignancy	13 (20)
Final diagnosis	
Benign lesion	42 (66)
High risk	5 (8)
Malignancy	17 (26)

**Table 5.** Agreement between initial core needle biopsy (CNB) diagnosis and final diagnosis

CNB\Final	Benign	High risk	Malignancy	Total
Benign	42	0	1	43
High risk	0	5	3	8
Malignancy	0	0	13	13
Total	42	5	17	64

Crude agreement: 93.8% (95% CI 84.8 to 98.3), expected agreement: 50.5%, kappa: 0.874 (95% CI 0.684 to 1.0), p-value < 0.001

agreement rate (93.8%, 60/64) and kappa 0.874 for breast lesion diagnosis are high. The false negative rate was 4.5%, which is acceptable.

Leifland et al reported 90% sensitivity of stereotactic core needle biopsy in 2003, which was similar to the presented data<sup>(7)</sup>.

**Table 6.** Various underestimation rates

Final\CNB lesion	Benign lesion (n = 43)	ADH (n = 6)	DCIS (n = 9)
Benign	42	0	0
High risk	0	3 (ADH)	0
DCIS	0	1	9
IDC	1	1	0
DCIS with IDC	0	1	0
Underestimation rate (95% CI)	1/43 = 2.3% (0.1% to 12.3%)	3/6 = 50.0% (11.8% to 88.2%)	0

CNB = core needle biopsy; ADH = atypical ductal hyperplasia; DCIS = ductal carcinoma in situ; IDC = invasive ductal carcinoma

Pfiral et al showed a 3.3% false negative rate from a retrospective review of 318 lesions which underwent stereotactic 11-gauge vacuum-assisted core needle biopsy in 2002<sup>(8)</sup> and Lee et al showed 2% false negative rate from a review of 355 cases that underwent stereotactic core needle biopsy in 1999<sup>(6)</sup>. The present study had a slightly higher false negative rate compared to these studies, which may be explained by a smaller population.

There was one false negative lesion in the present study but delayed diagnosis for malignancy did not occur because the radiologist who performed the procedure recommended the surgeon for further excisional biopsy, according to a discordant pathological result and radiographic findings.

One of the ADH underestimated cases had been recommended by the radiologist who performed the procedure for further biopsy because of inadequate specimens. Thus, delayed diagnosis of malignancy was not encountered.

Concerning this information, even if the result of the present study shows relatively high accuracy of the stereotactic core needle biopsy, a comparison between pathologic result and radiographic findings as well as review of the adequacy of the specimens after core needle biopsy are still necessary to avoid false negative and underestimated lesion as well as delayed diagnosis of malignancy.

In the present study, the underestimate rate for ADH lesion is 50% (3 of 6 lesions) higher than the previous study by Wiratkapun et al at Ramathibodi Breast diagnostic center in 2005, which reported 20.5% underestimated rate for ADH lesions in all imaging-guided core needle biopsy and 20% if concerning only stereotactic core needle biopsy<sup>(5)</sup>. However, due to the small number of population and wide range of 95% CI

of this underestimate rate (95% CI 11.8 to 88.2), use of this statistical parameter is limited. Nevertheless, according to these present data, surgical excision is recommended to all lesions diagnosed ADH from core needle biopsy.

The present study has certain limitations. First, there was a small population (64 including cases) this could be the reason that there was no DCIS underestimated lesion in the present study.

Second, in cases included in the present study were not consecutive. Benign biopsy results that were not proven by surgical biopsy and did not have at least a 2-year follow up were excluded. Therefore, a selection bias may exist, and it is possible that there were more false-negative diagnosis in the excluded cases.

### Conclusion

Vacuum-assisted core needle biopsy is an accurate method for evaluating breast lesions. This procedure is an alternative to surgical excision for assessing these lesions.

However, to avoid false negative and underestimated lesion as well as delayed diagnosis for malignancy, comparison between pathologic result and radiographic findings as well as review of the adequacy of the specimens after core needle biopsies are necessary. Excisional biopsy is recommended for all lesions diagnosed ADH from core needle biopsy, regarding to the high underestimation rate.

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## การวิเคราะห์ความถูกต้องในการตัดเนื้อเต้านมออกตรวจโดยใช้เทคนิค vacuum-assisted stereotaxis

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**วัตถุประสงค์:** เพื่อศึกษาถึงความถูกต้องในการตัดเนื้อเต้านมออกตรวจโดยใช้เทคนิค vacuum-assisted stereotaxis

**วัสดุและวิธีการ:** ได้ทำการศึกษาผู้ป่วยที่ได้รับการตัดเนื้อเต้านมออกตรวจด้วยวิธีนี้ที่ศูนย์วินิจฉัยเต้านม ภาควิชารังสีวิทยา คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี ในช่วงระหว่างวันที่ 1 มกราคม พ.ศ. 2546 ถึง วันที่ 31 ธันวาคม พ.ศ. 2548 จำนวน 64 รอยโรค จากผู้ป่วยหญิง 64 ราย ผู้ป่วยที่ผลพยาธิวิทยาไม่ใช่มะเร็งเต้านม (benign) จะต้องมีการติดตามผลอย่างน้อย 2 ปี (ถึงปี พ.ศ. 2550) จึงจะแน่ใจได้ว่าไม่เป็นมะเร็งจริง

**ผลการศึกษา:** จาก 64 รอยโรค พบมะเร็งเต้านมร้อยละ 20, รอยโรคความเสี่ยงสูง (high risk lesions) ร้อยละ 13, ไม่ใช่มะเร็ง (benign) ร้อยละ 37 the crude agreement rate คิดเป็นร้อยละ 93.8 (60 จาก 64 รอยโรค) ผู้ป่วย 3 ใน 6 ราย ที่ได้รับการวินิจฉัยว่าเป็น atypical ductal hyperplasia (ADH) พบมะเร็งเต้านมจากการผ่าตัด คิดเป็น under estimation rate ร้อยละ 50 ไม่พบ under estimation rate ในผู้ป่วยที่ได้รับการวินิจฉัยว่าเป็น ductal carcinoma in situ (DCIS) ใน 43 รอยโรคที่ผลการตัดชิ้นเนื้อตรวจไม่ใช่มะเร็ง (benign) พบมะเร็งเต้านมจากการผ่าตัด 1 รอยโรค คิดเป็นผลลบลง (false negative rate) ร้อยละ 6 ความไว (sensitivity) ร้อยละ 96

**สรุป:** การตัดเนื้อเต้านมออกตรวจด้วยเทคนิค vacuum-assisted stereotaxis เป็นวิธีที่มีความถูกต้องสูง อย่างไรก็ตาม แนะนำให้ผ่าตัดในผู้ป่วยที่ได้รับการวินิจฉัยว่าเป็น ADH เนื่องจากมีโอกาสเป็นมะเร็งเต้านมสูง