Breast Cancer Underestimation Rate of Atypical Ductal Hyperplasia Diagnosed by Core-Needle Biopsy under Imaging Guidance

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Objective: *To evaluate breast cancer underestimation rate of atypical ductal hyperplasia (ADH) diagnosed by core-needle biopsy (CNB) under imaging guidance in Ramathibodi Hospital and to determine the difference between the malignant and benign groups in terms of clinical and imaging characteristics.*
Material and Method: *The pathological records of 1,521 patients who underwent CNB under imaging guidance were reviewed. Thirty-nine patients diagnosed with ADH were enrolled into the present study. Clinical data, imaging features, biopsy technique and result of excisional biopsy as well as follow-up data were retrospectively reviewed.*
Results: *Of 39 ADH cases, eight (20.5%) were found to have malignancy on subsequent excisional biopsy. The majority of these were ductal carcinoma in situ (DCIS) (62.5%). Lesion categorized as category 5 according to BI-RADS (Breast imaging reporting and data system) was the only feature which was statistically different between the benign and malignant groups. No statistically significant difference was found between the benign and malignant groups in terms of age, personal and family history of breast cancer, clinical finding, mammographic lesion type, size of lesion, image-guided technique and percentage of lesion removal.*
Conclusion: *The underestimation rate of ADH in the present study was comparable to other studies. The finding of BI-RADS category 5 in patients with ADH diagnosed from CNB is a strong indication for subsequent excisional biopsy.*

Keywords: *Breast biopsy, Core-needle biopsy, Imaging-guided biopsy, Stereotactic biopsy, Atypical ductal hyperplasia*

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Core-needle biopsy (CNB) of the breast under imaging guidance is an alternative to open surgical biopsy for the initial diagnosis of suspicious abnormalities visible on mammography or sonography. This method promises high accuracy and reliability[1-9]. Compared to open biopsy, CNB decreases physical and psychological stress of the patient, decreases operative and perioperative risks, reduces cost and minimizes postoperative scarring which may lead to impaired diagnostic assessment of future mammograms[1-4,7-11]. However, CNB under imaging guidance may not always diagnose the lesions accurately. The false negative rate of CNB averaged 2.8% (range, 0.3-8.2%)[1]. Atypical ductal hyperplasia (ADH) found from CNB is notorious for histologic underestimation of breast malignancy. ADH is a histologically borderline lesion that has some but not all the features of ductal carcinoma in situ (DCIS). The extent of involvement is also required for the diagnosis of ADH, which should involve a single duct or has

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aggregate diameter of involvement less than 2 mm[1,12-17]. Given that the extent of involvement is one of the most important histopathologic features to differentiate ADH from DCIS, the underestimation of carcinoma when ADH is retrieved by CNB may be explained by sampling error (i.e., sampling only the region of ADH in a lesion containing both ADH and carcinoma)[1,9,12].

The reports of underestimation rates of ADH come mostly from studies of stereotactic CNB because ADH usually presents mammographically as microcalcifications. The underestimation rate varies with the CNB technique: the rate is 44% (range 11%-58%) for 14-gauge core biopsy, 24% (range 0%-39%) for 14-gauge vacuum-assisted biopsy and 19% (range 10%-38%) for 11-gauge vacuum-assisted biopsy[1,12,18].

The purpose of the present study was to evaluate the cancer underestimation rate of ADH of the breast, as diagnosed by core-needle biopsy under imaging guidance in the authors' center and subsequently found to have malignancy at surgical biopsy or follow-up imaging and to determine the clinical and imaging differences between the malignant and benign groups.

Material and Method

From October 16, 1997, to September 30, 2004, 1,521 imaging guided core-needle biopsies (CNB) of the breast were performed at the breast diagnostic center, department of radiology, Ramathibodi Hospital. In this period, 1,029 patients (67.7%) underwent CNB under ultrasound guidance and the remaining 492 patients (32.2%) underwent sterotactic guided CNB. Thirty-nine ADH cases were found. Clinical data, mammographic and sonographic findings, technique of CNB and details of subsequent excisional biopsy or follow-up data were reviewed.

Breast lesions were categorized by the radiologists who performed CNB according to Breast Imaging Reporting and Data System (BI-RADS)[19]. Maximum diameter of the lesions was determined by mammogram. If the lesion was mammographically invisible, the maximum diameter determined by ultrasound was used.

The choice of guidance modality was mainly based on the type of lesion. The lesion which was clearly visible by ultrasound would be biopsied under ultrasound guidance because it was easier to perform, took less time and had lower cost than stereotactic guidance[20,21]. Stereotactic CNB was reserved for lesions which were invisible or inadequately visualized on ultrasound such as microcalcifications or small architectural distortion.

Sonographically guided biopsy was performed freehand with high-resolution sonographic equipment (HDI 5000; Phillips ultrasound, Bothell, WA, USA) with a 14-gauge cutting needle (MDTECH; Gainesville, FL, USA) and a long-throw, spring loaded automated gun (Magnum; Bard Peripheral Technologies, Covington, GA, USA). Six core samples were routinely obtained for noncalcified masses. Before March 2000, stereotactic CNB was performed by 14-gauge-automated technique. After that time, the authors used 11-gauge directional vacuum assisted biopsy instrument (Mammotome^{R}, Biopsys Ethicon Endo-Surgery, Cincinnati, OH, USA). Twelve core samples were routinely obtained using this technique. The authors did not aim to remove all suspicious microcalcifications, but to obtain an adequate specimen for pathologic diagnosis. Specimen radiography was performed for all calcified lesions.

For the 20 ADH cases who had undergone 14 and 11-gauged stereotactic biopsies, immediate mammograms after CNB from the archives of the machine were reviewed. If such data were unavailable, consecutive follow-up mammograms were used. For the remaining cases who had undergone CNB under ultrasound guidance, the immediate post-biopsy images were reviewed. The extent of lesion removal was classified as follows: 100% removal, 90-99% removal, 50-89% removal and less than 50% removal.

The authors examined clinical and imaging follow-up data of patients in whom excisional biopsy was not performed. The latest follow-up mammogram and sonogram of this group of patients were compared to the immediate postbiopsy films and the visualized lesions were noted as "stable", "regression", "disappear" or "progression"

Data were entered into a computerized spreadsheet for statistical analysis with the software Statistical Package for Social Sciences (SPSS) version 11.5. Statistical testing was performed using either Student's t-test, Wilcoxon ranksum test, Pearson Chi-square test or Fisher's exact test when appropriate. Statistical significance was defined as a p-value of less than 0.05.

Results

Of the 39 cases identified as having ADH, 22 cases underwent further excisional biopsy. Of these 22 cases, eight had malignancies, eight had benign pathology and six had ADH. Cancer underestimation

Table 1. Demographic and clinical data

Demographic	Total (n = 39)	No cancer (n = 31)	With cancer (n = 8)	p-value*
Age (years): Mean (SD), (range)	52 (8.04), (35-69)	51.4 (8.24), (35-69)	54.75 (7.03), (46-69)	0.35
History of contralateral cancer: n (%)	6 (15)	5 (16)	1 (13)	0.99
Family history of cancer: n (%)	1 (3)	0 (0)	1 (13)	0.21
Palpable lesions: n (%)	7 (18)	5 (16)	2 (25)	0.62

* p-value according to t-test, chi-square test and Fisher's exact test as appropriate

Table 2. Imaging findings

Findings	Total (n = 39)	No cancer (n = 31)	With cancer (n = 8)	p-value*
Type of lesions				0.12
Masses: n (%)	17 (44)	15 (48)	2 (25)	
Calcifications: n (%)	17 (44)	14 (45)	3 (38)	
Masses with calcifications: n (%)	3 (8)	1 (3)	2 (25)	
Architectural distortion: n (%)	2 (5)	1 (3)	1 (13)	
Category				0.01
4	33 (85)	29 (94)	4 (50)	
5	6 (15)	2 (7)	4 (50)	
Size of lesions (cm): median, (range)	1 (0.3-3.0)	1 (0.3-2.5)	1.45 (0.6-3.0)	0.75

* p-value according to Wilcoxon ranksum test and Fisher's exact test as appropriate

Table 3. Core-needle biopsy procedures and results

	US guide (14-G-needle) n = 19	Stereotactic CNB (14-G-needle) n = 5	Stereotactic Vacuum assisted CNB (11-G-needle) n = 15
Number of core specimens: median (range)	6 (6-8)	6 (6-9)	12 (9-20)
Malignancy: n (%)	4 (21)	1 (20)	3 (20)

rate in the authors' study was 20.5% (8 out of 39 cases). Histologic findings of malignancies included ductal carcinoma in situ (DCIS) in five (62.5%), DCIS with microinvasion in one (12.5%) and invasive ductal carcinoma in two (25%). The stage of invasive ductal carcinoma was stage I in one patient, while in the remaining patient the stage of cancer was unknown. Demographic data sorted according to pathologic findings are shown in Table1. Imaging findings are shown in Table 2. Imaging-guided CNB procedures and pathological result are shown in Table 3. Core-needle biopsy procedures for the malignant and benign groups are shown in Table 4.

Table 4. Comparison of extent of lesions removed between malignant and benign groups

	Malignancy (n = 8)	Benign (n = 31)
Number of core specimens: median (range)	6 (6 - 20)	6 (6 - 15)
Amount of lesions removed		
100%: n (%)	0 (0)	3 (10)
90-99%: n (%)	1 (13)	3 (10)
50-89%: n (%)	2 (25)	9 (29)
< 50%: n (%)	5 (63)	16 (52)

Among 39 cases diagnosed of ADH, seventeen patients were followed-up without performing intervention procedure. In this group of patients, the radiologists did not recommend further biopsy in 7 cases because the lesions were completely removed and/or only mild focal atypia was present. The remaining 10 cases were followed up by surgeon's preference regardless of recommendation for surgical biopsy by the radiologists. The interval of mammographic follow-up ranged from six to 52 months (median: 16.5

months). Of these 17 followed-up cases, seven lesions were stable. Six lesions disappeared. Three lesions regressed and one lesion progressed. The latter case was followed for four years and the amount of microcalcifications was only slightly increased.

The details of eight patients in whom cancer was found were shown in Table 5.

Several risk factors were compared between the malignant and benign groups. These factors consisted of age, personal history of breast cancer, family history of breast cancer, clinical findings, type of lesion, BI-RADS category, size of lesion, imaging-guided technique and percentage of lesion removed. Of these risk factors BI-RADS category 5 lesion was the only factor significantly associated with the finding of malignant lesions (p-value = 0.01).

Discussion

Atypical ductal hyperplasia (ADH) is a histologically borderline lesion that has some but not all the features of ductal carcinoma in situ (DCIS) or is a lesion fulfilling all the criteria of DCIS but involving only a single duct[1,9,12-17]. ADH diagnosed with CNB is the prototypic high-risk CNB lesion[1-3,9,12-18,22-26]. Subsequently surgical biopsy is usually recommended regardless of the type of core biopsy device used[1-3,9,12-18,22,26]. It is one of the most common causes of rebiopsy in patients who have undergone CNB[1,2,4,9]. ADH also has a relatively high frequency of associated coexistent carcinoma[22]. Women with a diagnosis of ADH are at increased risk for breast cancer. The risk is about 4-5 times greater than that in the general population[14,22,23]. The family history of breast cancer is also important: a positive family history in association with a diagnosis of ADH has been shown to increase the risk of breast cancer to 8-10 times above baseline. Similarly, a personal history of breast cancer connotes a 2-14-fold increased risk of developing contralateral breast cancer, depending on age[23].

Since ADH is a clinically silent lesion, its true prevalence is unknown. It has been reported in 10-12% of surgical biopsy specimens of the breast performed for another abnormality[14,15,22]. In the literature, the reported prevalence of ADH found on stereotactic CNB was 3-5% (ranging between 1.7-9.5%)[13,14,16,18,23-26]. In the authors' imaging-guided CNB, the authors found a 2.6% prevalence of ADH (39 of 1,521 cases), a slightly lower prevalence compared to other studies.

ADH is not always evident on mammograms. In patients in whom mammographic findings can be directly attributed to ADH, calcifications are the most common findings, followed by the finding of a breast mass[9,12-14,16,18,22,24-26]. ADH patients in the presented series was equal to the microcalcifications or masses.

The BI-RADS was developed to standardize the terminology in imaging reports, assessment of the findings, and the recommendation of actions to be taken[19]. Lesions categorized as BI-RADS category 5 have a high probability (95%or greater) of being cancerous. In the present study, the authors found that BI-RADS category 5 lesion was the only factor which showed significant association with the finding of malignant lesions.

The technique of CNB also affects the accuracy of CNB in the diagnosis of ADH. The

Table 5. Detail of malignant cases

Case	Imaging feature	Size (cm)	BI-RADS Category	Imaging guidance	Needle	Extent of removal (%)	Pathology
1	Clusters of pleomorphic calcifications	0.6	4	Mammotome	11 G	90	DCIS
2	Cluster of pleomorphic calcifications	1.1	5	Mammotome	11 G	50-89	DCIS
3	Cluster of pleomorphic calcifications	2.0	4	Mammotome	11 G	<50	DCIS
4	Mass	0.9	4	US	14 G	<50	IDC, stage I
5	Mass	1.5	4	US	14 G	<50	DCIS
6	Calcified mass	1.4	5	US	14 G	<50	DCIS with microinvasion
7	Calcified mass	1.6	5	US	14 G	<50	DCIS
8	Architectural distortion	3.0	5	Stereotactic	14 G	<50	IDC, unknown stage

Abbreviations: US = Ultrasound, G = gauge, DCIS = Ductal carcinoma in situ, IDC = Invasive ductal carcinoma

published literature concluded that the high accuracy rate of the diagnosis of ADH using 11-gauge, vacuum assisted stereotactic CNB is because a larger volume of specimen can be obtained[1,12,13,17,24]. The highest diagnostic yield reported was achieved with 12 specimens per lesion for stereotactic CNB[27]. In the authors' center, 12 core specimens are also routinely obtained for stereotactic vacuum assisted CNB. The higher percentage of lesion removed after CNB also increases the accuracy of diagnosing ADH[1,18,25]. In the present study, the benign and malignant groups were similar in terms of guidance modality, biopsy techniques and extension of removal.

Although most ADH cases underwent subsequent excisional biopsy, 15 to 30% of the patients found to have ADH on CNB were not performed this procedure[16,18]. Reasons for not performing excisional biopsy include advanced patient age, very small size of lesion, patient refusal or practice preference[16]. In the present series, 25.6% of the patients did not have excisional biopsy regardless of the recommendation of the radiologists who performed CNB. No malignancy was found in the follow-up imaging studies in this group. The median interval of imaging follow-up in this group was 16.5 months.

Overall cancer underestimation rate of ADH cases in the present series was 20.5%, comparable to previously published studies[1,4,9,12-18,22,24,25]. Except for the finding of BI-RADS category 5, no clinical, mammographic, or biopsy features could be used to predict subsequently detected malignancy. In one case, although the mammographic finding was category 4, the pathologist recommended rebiopsy because the tissue was insufficient to provide a definite diagnosis. This reflects the need for close cooperation between radiologists, surgeons and pathologists. Recently published data suggest that not all lesions diagnosed as ADH from CNB should be biopsied. Patients with mild ADH found on CNB, not associated with a personal or family history of breast cancer, may not need excisional biopsy if all calcifications have been removed[18,23]. This finding could be applied if there exists good cooperation between radiologists (who will determine the extent of lesions removed as well as the discordance between imaging and histologic findings), pathologists (who will characterize the degree and extent of atypia) and surgeons (who will perform clinical examination and send the patient for imaging follow-up)

In the underestimated cases, the most common malignancy is DCIS[9,12,14-16,18,23,25,26]. DCIS was also the most frequently encountered malignancy in the present series (5 from 8 cases or 62.5%), followed by invasive ductal carcinoma (one case with stage I disease and the another with unknown stage, 25%) and one case of DCIS with microinvasion (13%). These findings suggest the existence of curable diseases in cases of ADH underestimation.

The authors' current investigation is limited by the low prevalence of ADH as diagnosed by imaging-guided CNB and lack of independent pathologic review.

Conclusion

Cancer underestimation rate of ADH diagnosed by CNB under imaging guidance in the present series was 20.5%, which was comparable to other series. All of malignancies were found on subsequent surgical biopsy and the majority of these were DCIS, which carried good prognosis. No malignancy was found in the follow-up group. BI-RADS category 5 lesions was the only factor found to be associated with the finding of malignant lesions. This finding strongly indicates that subsequent excisional biopsy should be performed for BI-RADS category 5 lesions in patients with ADH diagnosed by CNB.

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มะเร็งเต้านมที่พบใน Atypical ductal hyperplasia ที่ได้รับการวินิจฉัยโดยวิธีเจาะตรวจชิ้นเนื้อโดยการนำด้วยคลื่นเสียงความถี่สูงและแมมโมแกรม

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บทนำ: *Atypical ductal hyperplasia (ADH) ที่ได้รับการวินิจฉัยโดยการเจาะตรวจชิ้นเนื้อ มีความเสี่ยงที่จะพบมะเร็งเต้านม ซึ่งอาจเป็นจากชิ้นเนื้อส่วนที่ได้ไม่มีมะเร็งอยู่ หรือมีความผิดปกติทางพยาธิวิทยาคล้ายมะเร็งแต่ปริมาณชิ้นเนื้อจำกัดทำให้ไม่สามารถให้การวินิจฉัยได้ถูกต้อง ดังนั้นในทางปฏิบัติจะแนะนำให้ทำ excisional biopsy ต่อไป*

วัตถุประสงค์: *เพื่อศึกษาอัตราการพบมะเร็งเต้านมในผู้ป่วยที่ได้รับการวินิจฉัย ADHโดยการเจาะตรวจชิ้นเนื้อและศึกษาเปรียบเทียบความแตกต่างระหว่างกลุ่มที่พบมะเร็งเต้านมกับกลุ่มที่ไม่พบมะเร็งเต้านม*

วัสดุและวิธีการ: *ศึกษาข้อมูลผู้ที่ได้รับการเจาะตรวจชิ้นเนื้อเต้านมภายใต้การนำด้วยคลื่นเสียงความถี่สูงและแมมโมแกรมที่ศูนย์ตรวจวินิจฉัยเต้านม ภาควิชารังสีวิทยา คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี 1,521 ราย พบ atypical ductal hyperplasia 39 ราย ได้ทำการศึกษาข้อมูลย้อนหลังด้านคลินิก ลักษณะทางรังสีวินิจฉัย เทคนิคการเจาะตรวจชิ้นเนื้อ และ ผลพยาธิวิทยาของ excisional biopsy หรือ ติดตามผลการรักษา*

ผลการศึกษา: *พบมะเร็งเต้านมในผู้ป่วย 8 ราย (20.5%) ผู้ป่วยส่วนใหญ่เป็นมะเร็งเต้านมชนิด ductal carcinoma in situ (DCIS) 5 ราย (62.5%) พบว่าผู้ป่วยที่มีความผิดปกติจัดอยู่ใน category 5 ตาม BI-RADS (breast imaging reporting and data system) มีความเสี่ยงต่อมะเร็งเต้านมอย่างมีนัยสำคัญทางสถิติ*

สรุป: *อัตราการพบมะเร็งเต้านมจากการศึกษานี้มีค่าใกล้เคียงกับการศึกษาอื่นๆ ที่ผ่านมา ผู้ป่วยที่มีความผิดปกติจัดอยู่ใน category 5 ตาม BI-RADS จำเป็นต้องได้รับการทำ excisional biopsy ต่อไป เนื่องจากมีความเสี่ยงสูงที่จะพบมะเร็งเต้านม*