

# Correlation between core biopsy and excisional biopsy in breast high-risk lesions

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## Abstract

**Background:** The purpose of the current study was to compare the prevalence of invasive or in situ cancer at excisional biopsy in patients with image-guided core needle biopsy (CNB)-proven atypical ductal hyperplasia (ADH), atypical lobular hyperplasia (ALH), or lobular carcinoma-in-situ (LCIS). Factors affecting the upgrade rate to malignancy were also identified.

**Methods:** Patients diagnosed with ADH, ALH, or LCIS on image-guided CNB (stereotactic or ultrasound) from 1995 to 2005 were identified through radiologic and surgical databases. Patients who subsequently underwent excisional biopsy of their lesion were included in the study. The imaging, medical records, and pathology of these patients were reviewed.

**Results:** Ninety-six patients with either ADH (61/96, 63%), ALH (19/96, 20%), or LCIS (16/96, 17%) on image-guided CNB proceeded to excisional biopsy. Malignancy was detected on excisional biopsy in 31% of patients with ADH, 16% of patients with ALH, and 25% of patients with LCIS. There were no significant differences between the 2 groups in terms of age, parity, hormonal status, or previous benign breast biopsies. The presence of a mass on mammography was associated with an increased upgrade rate to malignancy, while biopsies performed using vacuum-assisted devices, larger gauge biopsy needles, and greater number of cores were associated with a lower upgrade rate.

**Conclusions:** Our data suggest that excisional biopsy is warranted in all patients with CNB diagnoses of ADH, ALH, or LCIS to exclude the presence of cancer. © 2006 Excerpta Medica Inc. All rights reserved.

*Keywords:* Atypical ductal hyperplasia; Atypical lobular hyperplasia; Lobular carcinoma in situ

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Percutaneous core needle biopsy (CNB) has become the standard of care for the pathologic evaluation of clinically occult breast lesions. While this minimally invasive method of diagnosis represents a practical approach for further surgical treatment planning, it also results in the identification of nonmalignant lesions where management is less clear. These include atypical ductal hyperplasia (ADH), atypical lobular hyperplasia (ALH), and lobular carcinoma in situ (LCIS). ADH has been well studied; upgrade to ductal carcinoma-in-situ (DCIS) or invasive cancer in the final excisional specimen has been reported in 19% to 87% of

patients [1–6]. As a result, there is a general consensus in regard to the need to perform excisional biopsy when ADH is diagnosed at CNB [7]. In contrast, the treatment of patients with ALH or LCIS diagnosed at CNB is not well established, and few guidelines exist [8–11]. The purpose of the current study was to retrospectively determine the frequency of invasive cancer or DCIS at excisional biopsy in women with a diagnosis of ALH or LCIS at CNB and to compare this to similar women with a diagnosis of ADH. In addition, factors affecting the upgrade rate to malignancy at excisional biopsy were identified.

## Materials and Methods

Institutional review board approval was obtained prior to the commencement of this retrospective study. Written informed consent of patients was not required. We retrospec-

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tively reviewed the pathology results of all image-guided breast CNBs (of screen detected abnormalities) performed between January 1995 and December 2005 to identify those patients diagnosed with ADH, ALH, or LCIS. Procedural variables were recorded and included image modality employed (stereotactic or ultrasound), biopsy device (tru-cut or vacuum-assisted), biopsy needle size (14-, 11-, or 9-gauge), and number of core biopsy specimens obtained per lesion. The biopsy technique used was individually determined according to available technology and judgment of our breast radiologists. All patients with DCIS or invasive cancer on the CNB specimen were excluded. Only those patients who had subsequent excisional biopsy of their lesion were included in the study. Patients with pure ALH or LCIS on CNB were categorized as such; those with ALH or LCIS and concurrent ADH on CNB were categorized as ADH, representing the higher risk lesion (2 patients had ADH and ALH and 1 patient had ADH and LCIS; none of these 3 patients were upgraded on final excisional pathology). Pathology from the excisional biopsies were categorized as malignant (DCIS or invasive) or nonmalignant. Breast imaging and medical records were reviewed and recorded. All data were transferred to a single spreadsheet (Excel; Microsoft, Redmond, WA). Statistical calculations were performed using software (StatView; Abacus Concepts, Berkeley, CA). For all analyses, results were considered statistically significant if the *P* value was .05 or less.

## Results

In 3486 consecutive patients, a review of results at image-guided CNB performed between January 1995 and December 2005 revealed that 111 patients (0.32%) had a diagnosis of ADH (70/111, 63%), ALH (21/111, 19%), or LCIS (20/111, 18%). Of the 111 patients, 96 of those with either ADH (61/96, 63%), ALH (19/96, 20%), or LCIS (16/96, 17%) proceeded to excisional biopsy. It is unclear from the retrospective records why the remaining 15 patients did not undergo excisional biopsy. There were no definitive clinical, imaging, or pathologic features to suggest why excision was not performed. Only those 96 patients who had a subsequent excision were included in the study. Patient and lesion variables are summarized in Table 1. All patients were female, with a mean age of 57 years (range 37 to 90 years). Malignant disease was detected on excisional biopsy in 31% of patients with ADH (19 of 61), 16% of patients with ALH (3 of 19), and 25% of patients with LCIS (4 of 16). The majority of patients with upgraded ADH had DCIS on final excisional specimen (14 of 19, 74%). All 3 patients with upgraded ALH had invasive cancers (2 lobular, 1 mixed ductal and lobular). The 4 patients with upgraded LCIS included 1 DCIS, 2 invasive ductal, and 1 invasive lobular on final excisional pathology.

No specific clinical parameters predicted a higher rate of upgrade to malignancy at surgical excision. The mean age of women with malignant disease (58 years, range 38 to 90 years) was not significantly different from those without malignancy (57 years, range 37 to 83 years). There were no significant differences between the 2 groups in terms of parity, hormonal status (pre- or postmenopausal  $\pm$  hormone-replacement therapy), or history of benign breast biopsies. A final diagnosis of malignancy was more common in

Table 1

Upgrade rates for ADH, ALH, and LCIS lesions (N = 96) by patient, mammographic, and stereotactic biopsy variables

Variable	No malignancy	Malignancy upgrade	<i>P</i> value
Age (y)	57	58	NS
Nulliparous	8%	7%	NS
Premenopausal	27%	19%	NS
Postmenopausal + HRT	8%	6%	NS
Previous benign breast biopsy	4%	4%	NS
Previous personal or family history of breast cancer	17%	38%	NS
Mean lesion size (mm)	9.2	8.7	NS
Lesion type			<.05
Calcifications only	87%	54%	
Mass +/- calcifications	13%	46%	
Biopsy device			<.05
14-gauge tru-cut	56%	44%	
14-gauge vacuum-assisted	73%	27%	
11-gauge vacuum-assisted	79%	21%	
9-gauge vacuum-assisted	85%	15%	
No. of cores/lesion			<.05
$\leq 5$	52%	48%	
$> 5$	82%	18%	

NS = not significant; HRT = hormone-replacement therapy.

women with a previous personal or family history of breast cancer (10 of 26 [38%] patients with malignant findings vs. 12 of 70 [17%] patients without malignancy), but the difference did not reach statistical significance (*P* = .10).

All biopsied lesions had a BI-RADS classification of 4, except for 2 lesions that were BI-RADS 3 [12]. The two patients with BI-RADS 3 classification requested CNB due to uneasiness with 6-month imaging follow-up; both of these patients had ADH on CNB and neither upgraded to malignancy on surgical excision. There was no significant difference between the mean diameter of the mammographic abnormality in patients with a final diagnosis of malignancy (8.7 mm, range 3 to 26 mm) compared with patients without malignancy (9.2 mm, range 3 to 25 mm) (*P* = .88). Of the patients with malignancy on excisional biopsy, 12 of 26 (46%) patients had a mass with or without calcifications on mammogram, compared with 9 of 70 (13%) patients without malignancy (*P* < .05). Upgrade to malignancy at excisional biopsy was more likely if the image-guided biopsy was performed with a 14-gauge tru-cut type needle (11 of 25, 44%) compared to a 14-gauge vacuum-assisted device (3 of 11, 27%), an 11-gauge vacuum-assisted device (10 of 47, 21%), or a 9-gauge vacuum-assisted device (3 of 13, 15%) (*P* < .05). Upgrade to malignancy at excisional biopsy was also more likely when fewer than 5 cores were acquired (14 of 29, 48%) compared with 5 or more cores (12 of 67, 18%) (*P* < .05). However, even with the increased use of vacuum-assisted devices with larger cores and increasing numbers of specimens, the upgrade rate at excisional biopsy persisted at 15% to 27%. In fact, 2 of the 3 ALH upgraded lesions and 3 of the 4 LCIS upgraded lesions were diagnosed at CNB with vacuum-assisted devices, using  $\geq 11$  gauge biopsy needles, with  $\geq 5$  cores acquired.

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