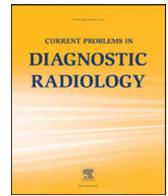




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Variability in the Management Recommendations Given for High-risk Breast Lesions Detected on Image-guided Core Needle Biopsy at U.S. Academic Institutions

Eniola Falomo, MD^{a,*}, Catherine Adejumo, MBBS^b, Kathryn A. Carson, ScM^c, Susan Harvey, MD^a, Lisa Mullen, MD^a, Kelly Myers, MD^a

^a The Russell H. Morgan Department of Radiology and Radiological Science, Johns Hopkins School of Medicine, Baltimore, MD

^b Emory University School of Public Health, Atlanta, GA

^c Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD

ABSTRACT

The purpose of this study was to describe and compare the management recommendations provided in the setting of a high-risk lesion diagnosed on core needle biopsy of the breast at academic institutions across the United States. We contacted breast imagers at U.S. academic institutions via email and asked them to complete a voluntary online survey. The survey consisted of eight questions regarding the management recommendations given when core biopsy yields various high-risk lesions. We received survey responses from 41 of the 59 institutions contacted (69% response rate). Surgical excision was the most frequently reported recommendation given for all high-risk lesions; however, the proportion varied from 95% for atypical ductal hyperplasia and papilloma with associated atypia, 76% for flat epithelial atypia, 73% for radial scar/complex sclerosing lesion, 71% for lobular carcinoma in-situ, 61% for atypical lobular hyperplasia, to 39% for intraductal papilloma without atypia. Our study demonstrates inconsistency in the management recommendations given for high-risk lesions detected on core needle biopsy at academic institutions nationally. This outcome suggests that patients may benefit from the creation of consensus recommendations for the management of high-risk lesions detected on core needle biopsy.

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Introduction

Core needle biopsy is the standard of care for lesion diagnosis in the field of breast imaging due to ample data over the past few decades demonstrating accuracy of the minimally invasive procedure.^{1,2} Core needle biopsy has widely replaced diagnostic surgical excision and plays an important role in the evaluation of breast lesions that are deemed to be suspicious following diagnostic work-up.^{1,2} For malignant and benign pathologic diagnoses obtained following a core needle biopsy, the management recommendations are straightforward. However, in some cases, pathologic results classified as high-risk breast lesions (including atypical ductal hyperplasia [ADH], atypical lobular hyperplasia [ALH], lobular carcinoma in-situ [LCIS], intraductal papilloma without atypia, intraductal papilloma with

atypia, flat epithelial atypia [FEA], and radial scar/complex sclerosing lesion) are obtained, and the appropriate management recommendations remain controversial leading to inconsistency in patient care nationally.²⁻⁸ Several prior studies have reported upgrade rates of 21%-52% for ADH,⁹⁻¹² 6%-22% for ALH,¹³⁻¹⁴ 10%-25% for LCIS,¹³⁻¹⁴ 3%-9% for intraductal papillomas without atypia,¹⁵⁻¹⁷ 23%-54% for atypical papillomas,¹⁶⁻¹⁷ 3%-13% for FEA,¹⁸⁻²⁰ and 2%-8% for radial scar/complex sclerosing lesions.²¹⁻²³

The lack of consensus on management recommendations for high-risk lesions is thought to be secondary to limitations in the available medical literature,^{2,8} including limitations in study designs and variations in the reported upgrade rates. Additionally, there is currently lack of pathological consensus regarding the diagnostic criteria for high-risk lesions, which also contributes to the lack of uniformity in management recommendations.^{8,24}

Academic institutions are often regarded as leaders in medicine and play a major role in educating the next generation of medical providers. For this project, we sought to evaluate the management recommendations for a variety of high-risk lesions detected on core needle biopsy of the breast at academic institutions across the United States. The goal of this study was to compare patterns in management recommendations at academic institutions to determine if consensus exists on the management of high-risk breast lesions in the academic community.

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This study was granted exempt status by the Institutional Review Board (IRB).

* Reprint request: Eniola Falomo, MD, The Russell H. Morgan Department of Radiology and Radiological Science, Johns Hopkins School of Medicine, 601 North Caroline Street, Baltimore, MD 21287

E-mail address: eobadin1@jhmi.edu (E. Falomo).

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Materials and Methods

Study Setting and Participants

This study was granted exempt status by the Institutional Review Board (IRB). Survey responses were collected over a 3-month period (from November 2016 to January 2017). We were guided by a list of academic programs offering breast imaging fellowships in the United States, as provided on the Society of Breast Imaging (SBI)'s website.²⁵ We attempted to contact breast imagers at all of these

academic institutions via email and asked them to voluntarily complete a brief survey.

Survey Instrument

The survey was created and administered using Survey Monkey (www.surveymonkey.com). The survey consisted of a total of nine questions (Fig 1). The first question asked for the name of the institution, while the remaining questions asked about the management recommendations typically given when a core biopsy yields various

Your completion of this survey or questionnaire will serve as your consent to be in this research study

Please answer the following questions based on your **usual** recommendations in the **clinical** setting

1) Name of institution (confidentiality will be maintained):

2) When a core biopsy reveals ADH, what is your typical management recommendation?

- a) Surgical excision
- b) Short-interval follow-up
- c) Return to screening
- d) It depends on certain factors (please specify: _____)

3) When a core biopsy reveals ALH, what is your typical management recommendation?

- a) Surgical excision
- b) Short-interval follow-up
- c) Return to screening
- d) It depends on certain factors (please specify: _____)

4) When a core biopsy reveals LCIS, what is your typical management recommendation?

- a) Surgical excision
- b) Short-interval follow-up
- c) Return to screening
- d) It depends on certain factors (please specify: _____)

5) When a core biopsy reveals Intraductal Papilloma without atypia, what is your typical management recommendation?

- a) Surgical excision
- b) Short-interval follow-up
- c) Return to screening
- d) It depends on certain factors (please specify: _____)

6) When a core biopsy reveals Intraductal Papilloma with atypia, what is your typical management recommendation?

- a) Surgical excision
- b) Short-interval follow-up
- c) Return to screening
- d) It depends on certain factors (please specify: _____)

7) When a core biopsy reveals Flat Epithelial Atypia (FEA), what is your typical management recommendation?

- a) Surgical excision
- b) Short-interval follow-up
- c) Return to screening
- d) It depends on certain factors (please specify: _____)

8) When a core biopsy reveals Radial Scar/Complex Sclerosing Lesion, what is your typical management recommendation?

- a) Surgical excision
- b) Short-interval follow-up
- c) Return to screening
- d) It depends on certain factors (please specify: _____)

9) Do your breast imaging colleagues at your institution typically give the same recommendations?

- a) Yes
- b) No

FIG 1. Survey questions.

high-risk lesions. Specifically, institutions were asked for their typical management recommendation when a core biopsy yields the following results: ADH, ALH, LCIS, intraductal papilloma without atypia, intraductal papilloma with atypia, flat epithelial atypia, and

radial scar/complex sclerosing lesion. Participants were also asked whether colleagues at their institution typically give the same recommendation.

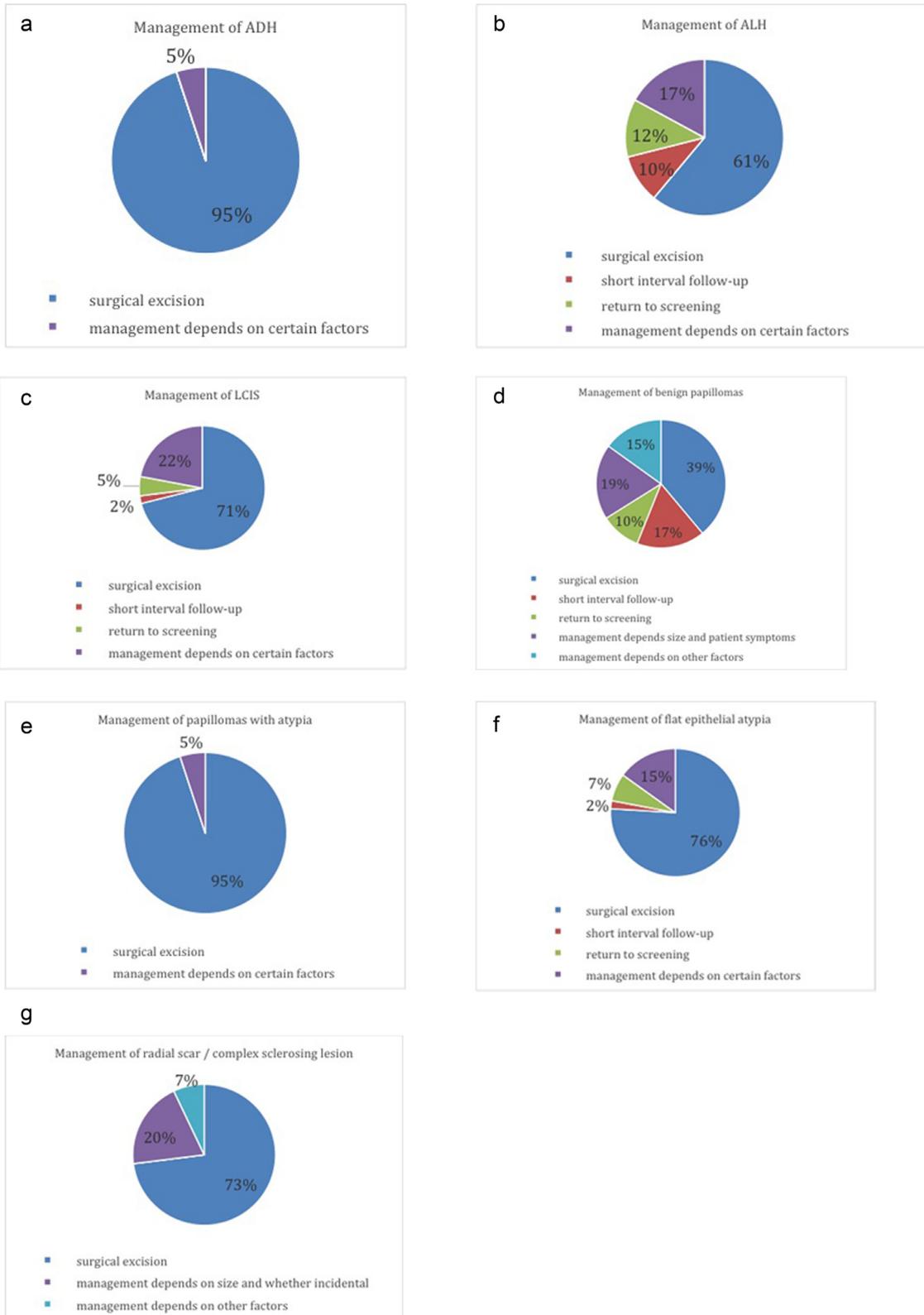


FIG 2. Management recommendations made by breast imagers at 41 academic institutions when core biopsy yields (a) ADH (atypical ductal hyperplasia), (b) ALH (atypical lobular hyperplasia), (c) LCIS (lobular carcinoma in situ), (d) benign papilloma, (e) papilloma with atypia, (f) flat epithelial atypia or (g) radial scar/complex sclerosing lesion. While the vast majority of breast imagers at academic institutions across the United States recommend surgical excision for ADH and papillomas with atypia, management recommendations for other high-risk lesions are highly variable. (Color version of figure is available online.)

Data Analysis

The completed survey data were manually entered into an Excel spreadsheet for review (Microsoft, Redmond, Washington). If multiple completed surveys were inadvertently received from the same institution, the responses from the first completed survey were used for the primary analysis. The percent of institutions recommending each management type was calculated for each pathology result. To evaluate for regional variations in the management recommendations given for high-risk lesions, the association between management type and geographic region was assessed using Fisher's exact test. For those institutions from which we received multiple responses, we looked at agreement in recommendations within each institution. Statistical analysis was performed using SPSS Statistics (IBM, version 24) and SAS version 9.4 (SAS Institute, Inc., Cary, NC). Statistical significance was set at $P < 0.05$.

Results

We attempted to contact all of the 72 academic institutions listed on SBI's website and were able to obtain the contact email addresses for breast imagers at 59 of the listed U.S. academic breast imaging programs. We contacted breast imagers at these 59 academic institutions via email, and 41 responded (69% completion rate). The percent of institutions recommending each management option is shown in Figure 2. While the majority of institutions reported recommending surgical excision for ADH and atypical papillomas (95% for both), there was wide variation in the management recommendations given for the other high-risk lesions (Fig 2). For example, surgical excision of benign papillomas is recommended at 16 (39%) of the surveyed institutions, short interval follow-up at 7 (17%), return to screening at 4 (10%) and case-by-case management at 14 (34%).

Thirty-seven of the 41 institutions (90%) reported that management recommendations are consistent among their colleagues within their department, including the 7 institutions from which multiple surveys were received. Despite these 7 institutions reporting uniform recommendations, 6 (86%) had conflicting responses for at least one management recommendation and 3 (43%) had conflicting responses on three recommendations. These differences in responses obtained from the same institution were often major differences, e.g. return to screening versus surgical excision.

Surveys were completed by breast imagers at academic institutions located in the following regions across the United States: 15 (37%) in the Northeast, 11 (27%) in the South, 10 (24%) in the Midwest, and 5 (12%) in the West. There were no statistically significant differences in management recommendations across geographic regions for any lesion type ($P > 0.05$ for all). The only two institutions that considered avoiding excision of ADH are both located in the South; however, this did not reach statistical significance ($P = 0.06$).

Discussion

The results of our study highlight the variations that exist in the management recommendations given by breast imagers at academic institutions across the United States after the diagnosis of a high-risk lesion on a core needle biopsy. The management recommendations for ADH and atypical papillomas were the most consistent, with 95% of academic breast imagers recommending surgical excision. This is not surprising since ADH and atypical papillomas are the high-risk lesions that tend to be associated with the highest reported upgrade rates in the medical literature (several prior studies reported upgrade rates of up to 52% for ADH, and up to 54% for atypical papillomas).^{9–12,16,17} The management recommendations given for the other high-risk lesions evaluated in this study were much more variable. This observed variation might be due to controversy in the management of high-risk lesions resulting from limitations in the available medical literature, as

well as lack of pathological consensus regarding the diagnostic criteria for high-risk lesions.

Although most of the survey respondents reported having consistent management recommendations amongst their colleagues at their institution, we found that when looking at the seven academic institutions from which we received multiple responses, the majority of them ($n = 6$; 86%) did not give the same management recommendations in their survey responses. This suggests that breast imagers may be unaware of the recommendations that fellow colleagues at their academic institutions give when they encounter the diagnosis of a high-risk lesion on a core needle biopsy.

We need to strive to achieve the right balance in our management recommendations for high-risk lesions. With surgical excision, there is a risk of potential surgical complications, while avoiding surgical excision could result in a missed cancer diagnosis. These variations in management recommendations that exist between institutions can have a negative impact on patient care, as patients sometimes transfer their care to another institution due to various factors, e.g. moving to a different city, new job, insurance changes, or simply to obtain a second opinion. Receiving different management recommendations for the same pathologic diagnosis at different institutions can be very confusing for patients, and could decrease the level of confidence that they have in their physicians. Additionally, variations that exist within the same institution (i.e. intra-institutional variations) could make it more difficult for the trainees who are at that institution to learn, as consistency can help to improve the learning process.

The role that academic institutions play in training the next generation of breast imaging specialists gives them the opportunity to influence the way that high-risk lesions are managed. We need to work together to reach a consensus regarding the management of high-risk lesions, with the help of large well-designed prospective multi-institutional research trials.

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