THE AMERICAN SOCIETY OF Breast Surgeons - Official Statement -

Consensus Guideline on Concordance Assessment of Image-Guided Breast Biopsies and Management of Borderline or High-Risk Lesions

Purpose

To outline the recommended practice of diagnostic and screening magnetic resonance imaging (MRI) of the breast.

Associated ASBrS Guidelines or Quality Measures

1. This document replaces the previous ASBrS Statements of "Position Statement on the Use of Magnetic Resonance Imaging in Breast Surgical Oncology" (July 27, 2010) and "The Use of Magnetic Resonance Imaging in Breast Oncology" (May 6, 2007).

2. The ASBrS Choosing Wisely® Campaign endorses the statement "Don't routinely order breast MRI in new breast cancer patients." There are no other ASBrS Guidelines or Quality Measures on breast MRI.

Methods

Literature review inclusive of recent randomized controlled trials evaluating the management of various borderline and high-risk lesions (including atypical hyperplasia, lobular neoplasia, papillary lesions, radial scars and complex sclerosing lesions, fibroepithelial lesions, mucocele-like lesions, spindle cell lesions, and pseudoangiomatous stromal hyperplasia [PASH]) identified on image-guided breast biopsies. This is not a complete systematic review but a comprehensive review of the modern literature on this subject. The ASBS Research Committee developed a consensus document which the ASBS Board of Directors reviewed and approved.

Summary of Data Reviewed

Percutaneous core needle biopsy (CNB) is the preferred, initial, minimally invasive diagnostic procedure for nonpalpable breast lesions or palpable breast masses.[1] Concordance assessment of the histologic, imaging, and clinical findings determines further management. Discordance refers to the situation in which a breast CNB demonstrates benign histology, while the clinical or imaging findings are suspicious for malignancy. If there is discordance between imaging and pathology, histological evaluation is still needed. This can be accomplished either by repeat CNB, perhaps with consideration of larger gauge or vacuum-assisted device, or surgical excision.[2-5]

Some nonmalignant CNB findings are considered "borderline" because of their potential association with malignancy. Such borderline lesions include atypical ductal hyperplasia (ADH), lobular neoplasia (atypical lobular hyperplasia or lobular carcinoma in situ), papillary lesions, radial scars (complex sclerosing lesions), fibroepithelial lesions, columnar cell lesions (hyperplasia or flat epithelial atypia), spindle cell lesions, mucocele-like lesions, and pseudoangiomatous stromal hyperplasia (PASH). These lesions potentially can be upgraded to malignancy at surgical biopsy secondary to sampling volume limitations of CNB or inaccurate targeting.[2,6-7] For this reason, a CNB result with one of these histologic findings requires correlation with imaging and clinical findings to determine concordance, and to either exclude the diagnosis of a malignancy by further histological evaluation or to establish a formal plan of follow-up through risk-based, shared decision-making with the patient.[2,5-8]

If CNB was performed for mammographic calcifications, then radiographic and microscopic confirmation of calcifications in the specimen should be documented; otherwise, further efforts to identify and excise them are indicated. If imaging reveals features suspicious for malignancy, such as a spiculated or irregular mass or architectural distortion, and histology reveals a nonmalignant diagnosis, then further clinical-radiologic-pathologic correlation is needed to estimate the chance of upgrading the diagnosis to malignancy with surgical biopsy.[2, 5-7]

Management of nonmalignant lesions found on CNB should be determined on a case-by-case basis because there is variability in the imaging and pathology features for all the benign and borderline lesions discussed below and because there is a wide range of reported upgrade rates from benign to malignant disease at the time of surgical excision for these lesions.[2, 6-7]

Most of the available literature regarding upgrading rates for these lesions is retrospective. A variety of factors are reported to influence the likelihood of pathology upgrading, including year of study publication, institution, specialist pathology interpretation, persistence of the target lesion on imaging, palpability of the lesion, size and type of needle used for sampling, size of the lesion, preprocedure BI-RADS score, presence of a mass or calcifications, and patient baseline breast cancer risk. The literature is variable and there is lack of uniformity of opinion regarding the necessity of surgical excision for many of these lesions. While surgical excision is the most definitive approach, given the lack of data to guide management, close observation and careful follow-up is an acceptable option for selected patients and for lesions with a lower chance of upgrade; however, the patient should play an active role in such decisions. When opting for surveillance instead of surgical excision, patient compliance with follow-up needs to be considered.

The following sections provide a brief overview of the literature currently available regarding upgrade to malignancy and indications for surgical excision for the most common borderline lesions.

Indications for surgical excision for atypical ductal hyperplasia (ADH): ADH is associated with an increased risk of future breast cancer and, when identified on CNB, may be associated with malignancy. For this latter reason, ADH identified on CNB is often surgically excised; rates of upgrade to ductal carcinoma in situ (DCIS) or invasive carcinoma

are variable in the literature but are often >20%,[9-13] and on CNB it may be difficult to differentiate ADH from low- volume DCIS. Multiple factors have been associated with upgrade in the literature, as discussed above. Khoury et al created a nomogram using several such factors, designed to predict the likelihood of upgrade at surgical excision, with an area under the curve of 0.775.[14] Other authors have also suggested treatment algorithms for managing patients with atypia diagnosed on CNB. Caplain et al. reported institutional guidelines that ADH does not need to be excised if it is (a) < 6 mm in size and completely removed or (b) <6 mm in size and incompletely removed but ≤2 foci. Of 41 cases excised contrary to the guidelines, only one was upgraded at surgery, for an upgrade rate of 2%. ADH excised as prescribed by institution guidelines, by comparison, had an upgrade rate of 37%.[15] These data suggest that there may be a subset of ADH that can safely be observed. However, given the variability in the available literature, most cases of ADH should be excised.

Indications for surgical excision of lobular neoplasia (lobular carcinoma in situ [LCIS] and atypical lobular hyperplasia [ALH]): Similar to ADH, lobular neoplasias are associated with an increased risk of future breast cancer and, when surgically excised, may be associated with in situ or invasive malignancy. As with ADH, the risk of upgrade in the literature is variable[16-19] and therefore these lesions are often excised. However, there is a growing body of literature suggesting that the likelihood of upgrade is low (<5%) with small volume lobular neoplasia and in the setting of imaging-pathologic concordance.[19-21] In a recent report by MD Anderson, surgical excision is recommended in cases of discordance, and is more likely to be recommended for LCIS (versus ALH), for targeted versus incidental lesions, in cases with fewer cores taken, and for mass lesions. These same factors were associated with a risk of upgrading with surgical excision.[22]

Whether or not patients with ALH and LCIS on core biopsy specimens require surgical excision is a matter of controversy. Several recent studies suggest that when a core-biopsy-based diagnosis of lobular neoplasia is made, and no other lesions requiring excision (ADH, papilloma, radial scar) are present, and radiological–pathological concordance is present, upgrade rates are less than 5%.[23-27] As a result, we no longer advocate *routine* excision of ALH or LCIS when the radiological and pathological diagnoses are concordant, and no other lesions requiring excision are present.[22]

A number of non-classical LCIS variants, including pleomorphic, with necrosis, signet ring, or apocrine, exist. These lesions tend to have high-grade cytology and an unfavorable biomarker profile.[28] Current evidence suggests these lesions, and pleomorphic LCIS, in particular, should be treated with complete surgical excision, similar to DCIS.[29]

Indications for surgical excision for columnar cell lesions (CCL), CCL with atypia, flat epithelial atypia (FEA): CCLs are often identified with mammographic calcifications and are characterized by enlarged terminal ductal lobular units lined by columnar epithelial cells with apical snouts. Atypia may be identified with this epithelium.[25] If so, this has been termed a CCL-A or FEA.[30] Based on a systematic review of 24 studies reporting on patients with CCLs identified at needle biopsy, the upgrade rate to DCIS on excision was 1.5%, 9%, and 20% in

patients with pure CCLs, CCL-A (FEA), and CCLs with ADH.[26] Some authors recommend that CCLs with atypia (FEA) undergo or be offered excision.[31-34] Morrow et al. and other authors suggest that observation of FEA without associated ADH is a reasonable strategy, if there are no other indications for excision.[22, 35-38]

Indications for surgical excision of papillary lesions: "Papillary lesions," as a term, encompass a range of pathologies including intraductal papillomas, and these lesions may be associated with atypia. Papillary lesions with atypia are pathologically upgraded at the time of surgical excision up to 67% of the time, and surgical excision for these lesions is widely recommended.[39-42] However, literature focusing on papillary lesions without atypia is mixed, and there is yet little consensus. Reported rates of upgrade of pure papillary lesions to atypia or malignancy are highly variable, historically ranging from 5% - 20%, but trending to less than 10% in the last decade.[43-49] Most available data are retrospective, and there is little agreement between studies regarding the clinical and imaging findings predictive of upgrading at the time of surgery, making it difficult to know who is likely to benefit from surgical excision. Patient age, size of biopsy device, imaging appearance (e.g., mass versus calcifications), and lesion size have all been associated with upgrade risk, but inconsistently.[43, 45, 50-57] The decision to excise a papillary lesion without atypia needs to be individualized based on risk, including such criteria as size; symptomatology, including palpability and presence of nipple discharge; and breast cancer risk factors. Those not excised should be followed closely with imaging.[45] Palpability alone is not an absolute indication for excision. Juvenile papillomatosis (Swiss Cheese Disease) is rare, found most often in adolescents, and described in single-case reports. There are no reported series of patients diagnosed with this condition by needle biopsy who were followed without excision.

Indications for surgical excision of radial scars (complex sclerosing lesions): Complex sclerosing lesions (CSLs), which include radial scars, may be identified incidentally at the time of CNB or may present as suspicious, spiculated masses on breast imaging. They are found to have associated malignancy from zero to upwards of 25% at the time of surgical excision, with most studies reporting rates close to 10%.[58-62] Older age, imaging appearance, lesion size, and biopsy needle size have been noted as factors associated with upgrade,[62-64] but as with other high-risk lesions, these findings are not consistent in the literature.[65] Most CSLs should be excised, although imaging follow-up is reasonable for small, image-detected radial scars that are completely removed or well-sampled with large-gauge devices and in the setting of imaging- pathology concordance.

Indications for surgical excision of fibroepithelial lesions: Fibroepithelial lesions include fibroadenomas and phyllodes tumors of varying malignant potential. Lesions diagnosed as fibroadenomas do not require routine excision, and obvious phyllodes tumors do require excision with negative margins. [66]

Fibroepithelial lesions not further defined, and cellular fibroadenomas in which there is potentially a missed diagnosis of phyllodes tumor, are more problematic. Several authors have reviewed CNB findings associated with the finding of phyllodes tumor on surgical excision and identified increased stromal cellularity, stromal mitoses, stromal overgrowth, fragmentation, nuclear pleomorphism, and infiltration of adipose tissue associated with

upgrade at surgery.[67-70] Lesions with these features usually require surgical excision for definitive diagnosis. Other authors have shown no consistent imaging or clinical findings that predict final surgical pathology of a fibroadenoma versus a phyllodes tumor, including lesion size.[71-74] However, Resetkova et al. found that in 58 patients with indeterminate lesions not excised but followed with imaging, none progressed with a median follow-up of 24 months, suggesting that close follow-up is reasonable for these lesions. In addition, of their 43 excised lesions, 13 were found to be benign phyllodes tumors; none were malignant or borderline.[74] Therefore, although a minority of indeterminate fibroepithelial lesions are found at excision to be phyllodes tumors, the finding of borderline or malignant phyllodes tumors is rare, and close imaging follow-up is a reasonable approach.

Indications for surgical excision of mucocele-like lesions: Mucocele-like lesions (MLL) are rare lesions characterized by dilated ducts lined with epithelium and filled with mucin. The epithelium can be associated with a range of pathologic abnormalities, including atypia and DCIS.[75] In addition, there is concern it may be a precursor lesion to mucinous DCIS or mucinous carcinoma.[76] Given the lack of supporting data, Ha et al. recently reported a series of 35 MLLs, 12 of which had associated atypia on CNB. All 12 of these underwent surgical excision, and one (8%) was found to have DCIS. Ten were found at surgical excision to have additional atypia; one had only benign findings. Of the 12 MLLs diagnosed as benign at CNB and subsequently excised, 4 (33%) were upgraded at surgery, all to atypia.[77] The rate of upgrade from benign MLL on CNB to malignancy at surgical excision is overall low in the literature (often <5%).[78,79] The authors recommended excising all lesions with associated atypia with consideration of excision of benign MLLs should the finding of atypia change management.

More recently, Diorio et al. reported on 35 women who underwent excision of needle biopsy-detected MLL.[80] Only 2 (5.7%) of the 35 were upgraded, both to DCIS. They concluded that a policy of routine excision of all MLL was not indicated.

Indications for surgical excision of spindle cell lesions: The term "spindle cell lesion" refers to a spectrum of breast pathologies, from benign to malignant, including hemangiomas, fibromatosis, PASH, leiomyosarcoma, and spindle cell sarcoma, among others. This guideline focuses on the most commonly seen nonmalignant lesions.

Hemangiomas are benign, and given their often superficial location, often present as palpable masses and may have overlying skin discoloration. When imaging, exam, or needle biopsy findings are inconclusive for angiosarcoma, or when the lesion enlarges, surgical excision should be performed; otherwise, observation is appropriate.[81]

Fibromatosis (desmoid tumor) is a benign but infiltrative spindle cell lesion. These tumors are rarely seen in the breast and may be incidental or associated with trauma, prior surgery, Gardner's syndrome, or Familial Adenomatous Polyposis.[81,82] When fibromatosis is identified on core biopsy, surgical excision is recommended with wide margins to prevent local recurrence.[8283,84]Unfortunately, local recurrence rates are high, and surgical resection with widely negative margins can be morbid. Additional adjuvant therapies may be used but are beyond the scope of this guideline.[85,86]

PASH may present as a painless mass or as an imaging abnormality. These lesions are characterized by myofibroblast proliferation, and because there are no characteristic radiology or exam findings to definitively make the diagnosis, biopsy is needed.[81] When these lesions are identified on CNB, and imaging is considered concordant (mammographically, this often appears as a developing mass or asymmetry), surgical excision is not necessary. However, suspicious imaging findings, interval growth, and symptomatic lesions should undergo excision.[87,88]

ASBrS Recommendations for Image-Guided Breast Biopsies and High-Risk Lesions

The following general policy considerations of selective versus routine excision can be applied to any borderline or high-risk lesion.

1. A policy of routine excision of every borderline or high-risk lesion included in this statement is not recommended.

2. Patients with suspicious clinical or imaging findings, discordant with CNB histology, should be recommended for excision.

3. A policy of selective excision for the remaining patients is recommended.

4. Estimates of the risk of upgrade to malignancy are improved with multi-disciplinary input to include breast radiology, breast surgery, and pathology.

5. The final decision to excise depends on shared decision making with the patient and includes the following steps:

    - careful clinical imaging pathology concordance assessment
    - patient-specific estimates of the risk of upgrade to malignancy if excision performed
    - consequences of delay in cancer diagnosis (if no excision is performed) for the individual patient taking into account the patient's co-morbidities and estimated life expectancy
    - patient breast cancer risk factors
    - disclosure of operative and cosmetic risks
    - the importance of clinical and imaging surveillance for at least 2 years if the target lesion is not excised
    - whether the patient can or will comply with follow-up

6. A summary of individual recommended management for each borderline or high-risk lesion is presented in the table below. These recommendations assume that the pathology and imaging results are deemed concordant.

Lesion	Recommendation	Exceptions / Notes
ADH	Surgical excision	Small volume ADH if completely excised on CNB may be observed based on risk factor assessment and multidisciplinary input
LCIS / ALH	Excise or observation with clinical and imaging follow up	Excision is necessary if pathology is discordant, limited sampling, or other high risk lesion is present
Pleomorphic LCIS	Surgical excision	Similar for necrosis and other non-classical lesions
Pure FEA or CCL	Observation with clinical and imaging follow up	Excise if concurrent ADH
Papillary lesions	Excision or clinical and imaging follow up	Excise palpable lesions and those with atypia Incidental, benign papillary lesions can be followed
Complex sclerosing lesions	Surgical excision	Small, adequately sampled CSLs may be observed
Fibroadenoma	Surgical excision or clinical observation	
Fibroepithelial lesions with concern for Phyllodes	Surgical excision	Concerning characteristics can include stroma mitoses, stromal overgrowth, nuclear pleomorphism, fragmentation, adipose tissue infiltration or other pathologist concerns
Mucocele-like lesions	Surgical excision or follow-up	Benign MLLs can be observed if atypia would not alter patient management
Desmoid tumors or fibromatosis	Wide local excision	High risk of local recurrence
PASH	Clinical observation	

A more detailed description of the data summarized above is provided below:

1. Atypical Ductal Hyperplasia (ADH)
    a. Surgical excision is recommended for most ADH diagnosed on CNB
    b. Small-volume ADH, and ADH completely excised with CNB, may be observed when the imaging and pathology are concordant. Consideration of breast cancer risk factors and multidisciplinary input is crucial for making this determination.

2. Lobular neoplasia including LCIS and ALH
    a. Lobular neoplasia found on CNB should be excised if the imaging and pathology are uncertain or discordant.
    b. For small-volume lesions of lobular neoplasia with imaging-pathology concordance, and without other atypical or high risk lesion present, observation can be offered using shared decision-making.
    c. For lobular lesions not excised, clinical and imaging follow-up is recommended. Multidisciplinary input is crucial for making this determination.

3. Pleomorphic LCIS, LCIS with necrosis, and other non-classical lesions should be recommended to undergo surgical excision.

4. Indications for surgical excision of columnar cell lesions
    a. Surgical excision is recommended for flat epithelial atypia (FEA) with ADH, identified on CNB.
    b. Observation and follow-up is a reasonable option for pure FEA.
    c. Surgical excision is unnecessary for cases of pure columnar cell hyperplasia identified on CNB.

5. Indications for surgical excision of papillary lesions
    a. Due to lack of reliable clinical and imaging characteristics predictive of upgrading, most papillary lesions should be offered excision, especially with the presentation of a palpable mass lesion or pathology-imaging discordance.
    b. Given significant disagreement seen in retrospective data in the literature, small, incidental benign papillary lesions with imaging concordance may be offered close clinical follow-up.

6. Indications for surgical excision of complex sclerosing lesions
    a. Given a typically suspicious imaging appearance and a chance of upgrading, surgical excision should be considered for most CSLs.
    b. CSLs may not require excision if they are small, adequately sampled, and in the setting of pathology-imaging concordance.

7. Indications for surgical excision of fibroepithelial lesions
    a. Fibroepithelial lesions, favoring fibroadenomas and without stroma mitoses, stromal overgrowth, nuclear pleomorphism, fragmentation, adipose tissue infiltration or a pathologist "comment of concern," can safely be observed. Optional to excise if symptomatic, enlarging, diagnosis is unclear or at patient request.

b. Fibroepithelial lesions favoring phyllodes tumors or with the above-mentioned features should be considered for excision; the likelihood of identifying a benign phyllodes tumor is close to 50%.

8. Indications for surgical excision of mucocele-like lesions
   a. Surgical excision is recommended for MLLs with atypia identified on CNB.
   b. Surgical excision is recommended for benign MLLs if the finding of atypia would alter patient management.

9. Indications for surgical excision of spindle cell lesions
   a. Because there are multiple types of benign spindle cell lesions, the need for surgical excision is variable and depends on the specific pathology.
   b. Fibromatosis or a "desmoid" tumor identified on CNB requires wide local excision; local recurrence is common.
   c. PASH typically does not require surgical excision unless the pathology-imaging is discordant or the lesion increases in size.

- References -

1. Silverstein MJ, Recht A, Lagios MD, et al. Image detected breast cancer: state-of-the-art diagnosis and treatment. *J Am Coll Surg*. 2009;209:504-520.
2. Johnson NB, Collins LC. Update on percutaneous biopsy of non-malignant breast lesions. *Adv Anat Pathol*. 2009;16:183-195.
3. The American Society of Breast Surgeons. Performance and Practice Guidelines for Stereotactic Breast Procedures. Revised April 2010. Official Statements. http://www.breastsurgeons.org/statements/index.php. Accessed August 31, 2015.
4. American College of Radiology. Practice Guidelines for the Performance of Stereotactically Guided Breast Interventional Procedures. Revised 2014. Guidelines. http://www.acr.org/~/media/ACR/Documents/PGTS/guidelines/Stereotactically_Guided_Breast.pdf. Accessed August 31, 2015.
5. Landercasper J, Linebarger J. Contemporary breast imaging and concordance assessment. *Surg Clin N Am*. 2011;91:33-58.
6. Masood S, Rosa M. Borderline breast lesions: diagnostic challenges and clinical implications. *Adv Anat Pathol*. 2011;18:190-198.
7. Corben AD, Edelweiss M, Brogi E. Challenges in the interpretation of breast core biopsies. *Breast J*. 2010;16(suppl 1);S5-S9.
8. Neal L, Tortorelli CL, Nassar A. Clinician's guide to imaging and pathologic findings in benign breast disease. *Mayo Clin Proc*. 2010;85(3):274-279.
9. Ely KA, Carter BA, Jensen RA, Simpson JF, Page DL. Core biopsy of the breast with atypical ductal hyperplasia. A probabilistic approach to reporting. *Am J Surg Pathol*. 2001;25:1017–1021.
10. Wagoner MJ, Laronga C, Acs G. Extent and histologic pattern of atypical ductal hyperplasia present on core biopsy specimens of the breast can predict ductal carcinoma in situ. *Anat Pathol*. 2009;131;112–121.
11. Ko E, Han W, Lee JW, et al. Scoring system for predicting malignancy in patients diagnosed with atypical ductal hyperplasia at ultrasound-guided core biopsy. *Breast Cancer Res Treat*. 2008;112;189–195.
12. Margenthaler JA, Duke D, Monsees BS, Barton PT, Clark C, Dietz JR. Correlation between core biopsy and excisional biopsy in breast high-risk lesions. *Am J Surg*. 2006;192:534–537.
13. Menes TS, Rosenberg R, Balch S, et al. Upgrade of high-risk breast lesions detected on mammography in the breast cancer Surveillance Consortium. *Am J Surg*. 2014;207;24–31.
14. Khoury T, Chen X, Wang D, et al. Nomogram to predict the likelihood of upgrade of atypical ductal hyperplasia diagnosed on a core needle biopsy in mammographically detected lesions. *Histopathol*. 2015;67:106-120.
15. Caplain A, Drouet Y, Peyron M, et al. Management of patients diagnosed with atypical ductal hyperplasia by vacuum-assisted core biopsy: a prospective assessment of the guidelines used at our institution. *Am J Surg*. 2014;208:260-267.
16. Hwang ES, Nyante SJ, Chen Y, et al. Clonality of lobular carcinoma in situ and synchronous invasive lobular carcinoma. *Cancer*. 2004;100:2562–2572.
17. Cohen MA. Cancer upgrades at excisional biopsy after diagnosis of atypical lobular hyperplasia or lobular carcinoma in situ at core-needle biopsy: some reasons why. *Radiol*. 2004;231:617–621.

18. Levine P, Simsir A, Cangiarella J. Management issues in breast lesions diagnosed by fine needle aspiration and percutaneous core biopsy. *Am J Clin Pathol*. 2006;125(suppl):S124–S134.
19. Bowman K, Munoz A, Mahvi DM, Breslin TM. Lobular neoplasia diagnosed at core biopsy does not mandate surgical excision. *J Surg Res*. 2007;142:275–280.
20. Rendi MH, Pintzis SM, Lehman CD, Calhoun KE, Allison KH. Lobular in situ neoplasia on breast core needle biopsy: imaging implication and pathologic extent can identify which patients require excisional biopsy. *Ann Surg Oncol*. 2012;19:914–921.
21. Middleton LP, Sneige N, Coyne R, et al. Most lobular carcinoma in situ and atypical lobular hyperplasia diagnosed on core needle biopsy can be managed clinically with radiologic follow-up in a multidisciplinary setting. *Cancer Med*. 2014;3:492-499.
22. Morrow M, Schnitt SJ, Norton L. Reviews: Current management of lesions associated with an increased risk of breast cancer. *Nat Rev Clin Oncol*. 2015;12: 227–238.
23. Middleton LP, Sneige N, Coyne R, et al. Most lobular carcinoma *in situ* and atypical lobular hyperplasia diagnosed on core needle biopsy can be managed clinically with radiologic follow-up in a multidisciplinary setting. *Cancer Med. 2014;*3:492–499.
24. Murray, MP, Luedtke C, Liberman L, et al. Classic lobular carcinoma *in situ* and atypical lobular hyperplasia at percutaneous breast core biopsy: outcomes of prospective excision. *Cancer*. 2013;119:1073–1079.
25. Rendi MH, Dintzis SM, Lehman CD, Calhoun KE, Allison KH. Lobular *in-situ* neoplasia on breast core needle biopsy: imaging indication and pathologic extent can identify which patients require excisional biopsy. *Ann Surg Oncol*. 2012;19: 914–921.
26. Shah-Khan MG, Geiger XJ, Reynolds C, et al. Long-term follow-up of lobular neoplasia (atypical lobular hyperplasia/lobular carcinoma *in situ)* diagnosed on core needle biopsy. *Ann Surg Oncol*. 2012;19**:**3131–3138.
27. Subhawong AP, Subhawong TK, Khouri N, Tsangaris T, Nassar H. Incidental minimal atypical lobular hyperplasia on core needle biopsy: correlation with findings on follow-up excision. *Am J Surg Pathol. 2010;*34:822–828.
28. Chen YY, Hwang ES, Roy R, et al. Genetic and phenotypic characteristics of pleomorphic lobular carcinoma in situ of the breast. *Am J Surg Pathol*. 2009;33:1683-1694.
29. Downs-Kelly E, Bell D, Perkins GH, Sneige N, Middleton LP. Clinical implications of margin involvement by pleomorphic lobular carcinoma in situ. *Arch Pathol Lab Med*. 2011;135:737-743.
30. Tavassoli FA, Devilee P, eds. *WHO Classification Tumours of the Breast and Female Genital Organs*. 1st ed. Lyon: IARC Publications; 2003.
31. Fraser JL, Raza S, Chorny K, et al. Columnar alteration with prominent apical snouts and secretions: a spectrum of changes frequently present in breast biopsies performed for microcalcifications. *Am J Surg Pathol*. 1998;22:1521–1527.
32. Verschuur-Maes A, van Deurzen C, Monninkhof E, van Diest P. Columnar cell lesions on breast needle biopsies: is surgical excision necessary? A systematic review. *Ann Surg*. 2012;255:259-265.
33. Lavoué V, Roger CM, Poilblanc M, et al. Pure flat epithelial atypia (DIN 1a) on core needle biopsy: study of 60 biopsies with follow-up surgical excision. *Breast Cancer Res Treat*. 2011;125:121–126.
34. Solarzano S, Mesurolle B, Omeroglu A, et al. Flat epithelial atypia of the breast: pathologic-radiology correlation. *AJR Am J Roentgenol*. 2011;197:740-746.
35. Uzoaru I, Morgan BR, Liu ZG, et al. Flat epithelial atypia with and without atypical ductal hyperplasia: to re-excise or not. Results of a 5-year prospective study. *Virchows Arch*. 2012;461(4):419-423.
36. Noel JC, Buxant F, Engohan-Aloghe C. Immediate surgical resection of residual microcalcifications after a diagnosis of pure flat epithelial atypia on core biopsy: a word of caution. *Surg Oncol*. 2010;19: 243–246.
37. Piubello Q, Parisi A, Eccher A, et al. Flat epithelial atypia on core needle biopsy: which is the right management? *Am J Surg Pathol*. 2009;33:1078–1084.
38. Prowler VL, Joh JE, Acs G, et al. Surgical excision of pure flat epithelial atypia identified on core needle breast biopsy. *Breast*. 2014;23:352–356.
39. Renshaw AA, Derhagopian RP, Tizol-Blanco DM, Gould EW. Papillomas and atypical papillomas in breast core needle biopsy specimens. *Am J Clin Pathol*. 2004;122:217–221.
40. Agoff SN, Lawton TJ. Papillary lesions of the breast with and without atypical ductal hyperplasia. *Am J Clin Pathol*. 2004;122:440–443.
41. Sohn V, Keylock J, Arthurs Z, et al. Breast papillomas in the era of percutaneous needle biopsy. *Ann Surg Oncol*. 2007;14:2979–2984.
42. Sydnor MK, Wilson JD, Hijaz TA, Massey HD, Shaw de Paredes ES. Underestimation of the presence of breast carcinoma in papillary lesions initially diagnosed at core-needle biopsy. *Radiol*. 2007;242:58–62.
43. Cyr AE, Novack D, Trinkaus K, et al. Are we overtreating papillomas diagnosed on core needle biopsy? *Ann Surg Oncol*. 2010;18:946-951.
44. Holley SO, Appleton CM, Farria DM, et al. Pathologic outcomes of nonmalignant papillary breast lesions diagnosed at imaging-guided core needle biopsy. *Radiol*. 2012;265:379-384.
45. Foley NM, Racz JM, Al-Hilli Z, et al. An international multicenter review of the malignancy rate of excised papillomatous breast lesions. *Ann Surg Oncol*. 2015;22(suppl 3):S385-S390.
46. Glenn ME, Throckmorton AD, Thomison JB, Bienkowski RS. Papillomas of the breast 15 mm or

smaller: 4-year experience in a community-based dedicated breast imaging clinic. *Ann Surg Oncol*. 2015;24:1133–1139.

47. Cheng TY, Chen CM, Lee MY, et al. Risk factors associated with conversion from nonmalignant to malignant diagnosis after surgical excision of breast papillary lesions. *Ann Surg Oncol*. 2009;16:3375–3379.
48. Fu CY, Chen TW, Hong ZJ, et al. Papillary breast lesions diagnosed by core biopsy require complete excision. *Eur J Surg Oncol*. 2012;38;1029–1035.
49. Rizzo M, Linebarger J, Lowe MC, et al. Management of papillary breast lesions diagnosed on core-needle biopsy: clinical pathologic and radiologic analysis of 276 cases with surgical follow-up. *J Am Coll Surg*. 2012;214:280–287.
50. Gendler LS, Feldman SM, Balassanian R, et al. Association of breast cancer with papillary lesions identified at percutaneous image-guided breast biopsy. *Am J Surg*. 2004;188:365–370.
51. Ivan D, Selinko V, Sahin AA, et al. Accuracy of core needle biopsy diagnosis in assessing papillary breast lesions: histologic predictors of malignancy. *Mod Pathol*. 2004;17:165–171.
52. Ashkenazi I, Ferrer K, Sekosan M, et al. Papillary lesions of the breast discovered on percutaneous large core and vacuum-assisted biopsies: reliability of clinical and pathological parameters in identifying benign lesions. *Am J Surg*. 2007;194:183–188.
53. Arora N, Hill C, Hoda SA, et al. Clinicopathological features of papillary lesions on core needle biopsy of the breast predictive of malignancy. *Am J Surg*. 2007;194:444–449.
54. Kil WH, Cho EY, Kim JH, Nam SJ, Yang JH. Is surgical excision necessary in benign papillary lesions initially diagnosed at core biopsy? *Breast*. 2007;17:258–262.
55. McCulloch GL, Evans AJ, Yeoman L, et al. Radiological features of papillary carcinoma of the breast. *Clin Radiol*. 1997;52:865–868.
56. Liberman L, Tornos C, Huzjan R, et al. Is surgical excision warranted after benign, concordant diagnosis of papilloma at percutaneous breast biopsy? *AJR Am J Roentgenol*. 2006;186:1328–1334.
57. Sakr R, Rouzier R, Salem C, et al. Risk of breast cancer associated with papilloma. *Eur J Surg Oncol*. 2008;34:1304–1308.
58. Becker L, Trop I, David J, et al. Management of radial scars found at percutaneous breast biopsy. *Can Assoc Radiol J*. 2006;57:72–78.
59. El-Sayed ME, Rakha EA, Reed J, et al. Predictive value of needle core biopsy diagnoses of lesions of uncertain malignant potential (B3) in abnormalities detected by mammographic screening. *Histopathol*. 2008;53:650–657.
60. Rakha EA, Lee AHS, Jenkins JA, et al. Characterisation and outcome of breast needle core biopsy diagnoses of lesions of uncertain malignant potential (B3) in abnormalities detected by mammographic screening. *Int J Cancer*. 2010;58:626-632.
61. Kirwan SE, Denton ERE, Nash RM, Humphreys S, Michell MJ. Multiple 14G stereotactic core biopsies in the diagnosis of mammographically detected stellate lesions of the breast. *Clin Radiol*. 2000;55:763–766.
62. Bianchi S, Gianotti E, Vanzi E, et al. Radial scar without associated atypical epithelial proliferation on image-guided 14-gauge needle core biopsy: analysis of 49 cases from a single-centre and review of the literature. *Breast*. 2012;21:159-164.
63. Matrai C, D'Alfonso TM, Pharmer L, et al. Advocating non-surgical management of patients with small, incidental radial scars at the time of core needle biopsy: a study of 77 cases. *Arch Pathol Lab Med*. 2015:139:1137-1142.
64. Nassar A, Conners AL, Celik B, et al. Radial scar/complex sclerosing lesions: a clinicopathologic correlation study from a single institution. *Ann Diagn Pathol*. 2015;19:24-28.
65. Heller SL, Elias K, Gupta A, et al. Outcome of high-risk lesions at MRI-guided 9-gauge vacuum-assisted breast biopsy. *AJR Am J Roentgenol*. 2014;202:237-245.
66. Van Osdol A, Landercasper J, Andersen JJ, et al. Determining whether excision of all fibroepithelial lesions of the breast is needed to exclude phyllodes tumor: upgrade rate of fibroepithelial lesions of the breast to phyllodes tumor. *JAMA Surg*. 2014;149:1081-1085.
67. Jacobs TW, Chen YY, Guinee DG, et al. Fibroepithelial lesions with cellular stroma on breast core needle biopsy: are there predictors of outcome on surgical excision? *Am J Clin Pathol*. 2005;124:342–354.
68. Lee AH, Hodi Z, Ellis IO, et al. Histological features useful in the distinction of phyllodes tumour and fibroadenoma on needle core biopsy of the breast. *Histopathol*. 2007;51:336–344.
69. Yasir S, Gamez R, Jenkins S, Visscher DW, Nassar A. Significant histological features differentiating cellular fibroadenoma from phyllodes tumor on core needle biopsy specimens. *Am J Clin Pathol*. 2014;142(3):362-369.
70. Johnson NB, Collins LC. Update on percutaneous needle biopsy of nonmalignant breast lesions. *Adv Anat Pathol*. 2009;16:183-195.
71. Yilmaz E, Sal S, Lebe B. Differentiation of phyllodes tumors versus fibroadenomas. *Acta Radiol*. 2002;43:34–39.
72. Chao TC, Lo YF, Chen SC, et al. Sonographic features of phyllodes tumours of the breast. *Ultrasound Obstet Gynecol*. 2002;20:64–71.
73. Bode MK, Rissanen T, Apaj-Sarkkinen M. Ultrasonography and core needle biopsy in the differential diagnosis of fibroadenoma and tumor phyllodes. *Acta Radiol*. 2007;48:708–713.
74. Resetkova E, Khazai L, Albarracin CT, Arribas E. Clinical and radiologic data and core needle biopsy findings should dictate management of cellular fibroepithelial tumors of the breast. *Breast*. 2010;16:573-580.
75. Schnitt SJ, Collins LC. *Biopsy Interpretation of the Breast*. Philadelphia: Lippincott Williams & Wilkins; 2009.

76. Leibman AJ, Staeger CN, Charney DA. Mucocelelike lesions of the breast: mammographic findings with pathologic correlation. *AJR Am J Roentgenol*. 2006;186:1356–1360.

77. Ha D, Dialani V, Mehta TS, et al. Mucocele-like lesions in the breast diagnosed with percutaneous biopsy: is surgical excision necessary? *AJR Am J Roentgenol*. 2015;204:204-210.

78. Edelweiss M, Corben AD, Liberman L, et al. Focal extravasated mucin in breast core needle biopsies: is surgical excision always necessary? *Breast J*. 2013;19:302–309.

79. Rakha EA, Shaaban AM, Haider SA, et al. Outcome of pure mucocele-like lesions diagnosed on breast core biopsy. *Histopathol*. 2013;62:894–898.

80. Diorio C, Provencher L, Morin J. Is there an upgrading to malignancy at surgery of mucocele-like lesions diagnosed on percutaneous breast biopsy? *Breast J*. 2016; 22:173-179.

81. Schickman R, Leibman AJ, Handa P, Kornmehl A, Abadi M. Mesenchymal breast lesions. *Clin Radiol*. 2015;70:567-575.

82. Lattin GE, Jesinger RA, Mattu R, et al. Diseases of the male breast: radiologic–pathologic correlation. *Radiographics*. 2013;33:461–489.

83. Schwarz GS, Drotman M, Rosenblatt R, et al. Fibromatosis of the breast: case report and current concepts in the management of an uncommon lesion. *Breast J*. 2006;12:66–71.

84. Neuman HB, Brogi E, Ebrahim A, et al. Desmoid tumors (fibromatoses) of the breast: a 25- year experience. *Ann Surg Oncol*. 2007;15:274–280.

85. Salas S, Dufresne A, Bui B, et al. Prognostic factors influencing progression-free survival determined from a series of sporadic desmoid tumors: A wait-and-see policy according to tumor presentation. *J Clin Oncol*. 2011;29:3553–3558.

86. Crago AM, Denton B, Salas S, et al. A prognostic nomogram for prediction of recurrence in desmoid fibromatosis. *Ann Surg*. 2013;258:347–353.

87. Neal L, Sandhu NP, Hieken TJ, et al. Diagnosis and management of benign, atypical, and indeterminate breast lesions detected on core needle biopsy. *Mayo Clin Proc*. 2014; 89:536-547.

88. Gresik CM, Godellas C, Aranha GV, Rajan P, Shoup M. Pseudoangiomatous stromal hyperplasia of the breast: a contemporary approach to its clinical and radiologic features and ideal management. *Surgery*. 2010;148:752–757.

This statement was developed by the Society's Research Committee and on November 2, 2016, was approved by the Board of Directors.