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

Purpose: To outline the management approach for borderline and high risk lesions identified on image-guided breast biopsy.

Associated ASBrS Guidelines or Quality Measures:

1. Image-Guided Percutaneous Biopsy of Palpable and Nonpalpable Breast Lesions
2. Performance and Practice Guidelines for Stereotactic Breast Procedures
3. Concordance Assessment Following Image-Guided Breast Biopsy

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 $\leq$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	Surgical excision	Small, adequately sampled CSLs may be

lesions		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.

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