Breast Biopsy and Fine Needle Aspiration

This loss prevention guideline is based on a review of 218 claims involving surgical pathology and fine needle aspiration biopsy reported to The Doctors Company from 1995 to 1997.

Breast fine needle aspiration (FNA) accounted for 6 percent of 218 claims, and breast biopsy accounted for another 14 percent. If claims involving breast FNA, breast biopsy, and breast frozen section are combined, “breast specimens” accounted for 22 percent of all claims. Fifty-four percent of breast biopsy claims involved the false-negative diagnosis of breast carcinoma, while 35 percent were for the false-positive diagnosis of carcinoma.

Breast FNA
False-negative breast FNAs resulting from inadequate sampling are responsible for the majority of claims—typically in a woman with a palpable breast mass that is subsequently diagnosed as carcinoma. In many of these claims, an FNA diagnosis of “fibrocystic change” or “negative” has been made on smears that are sparsely cellular. Most of these claims could have been avoided if the diagnosis had been “nondiagnostic FNA; additional diagnostic studies recommended,” because a repeat FNA or biopsy would have been performed.

Triple Test Strategy
Every breast FNA report should include a statement reminding the clinician that breast FNA has a false-negative rate of 3 to 5 percent and a false-positive rate of 0.5 to 2 percent, the consequences of which can be minimized by applying the triple test strategy—that is, by correlating the FNA results with the mammogram/ultrasound findings and the clinical breast examination—and by performing a biopsy if these are discordant. Whenever possible, the pathologist should review the mammogram and ultrasound report(s) and discuss the physical findings with the clinician before releasing the FNA report. If the pathologist knows that there is triple test discordance, it should be stated in the report and a biopsy recommended. This strategy would eliminate most liability claims for breast FNA.

The definition of breast FNA specimen adequacy is controversial. Some experts advocate quantitative cell counting as an assessment of adequacy. Others personally examine the patient, perform the FNA, and rely on the triple test strategy to determine specimen adequacy and uncover false negatives. They contend that if an experienced aspirator feels that the lesion was adequately sampled, then the cytologic findings of paucicellular smears are consistent with a diagnosis of fibrocystic change if supported by the clinical and mammogram findings. It is important to note that pathologists who advocate this approach base the diagnosis on their clinical exam, their review of the mammogram findings, and their certainty that the lesion was sampled—not on interpretation of the FNA smears.

Unfortunately, most breast FNAs are performed by clinicians who lack formal training in this technique and do not perform the procedure frequently; they are, therefore, unable to reliably assess whether or not the mass was sampled. Their smears are referred to a pathologist who is not an expert, has not examined the patient, and may not have access to the mammogram report. In this scenario, if the FNA smears are sparsely cellular, it is hazardous for the pathologist to assume that the mass was sampled and proceed to make a diagnosis of “fibrocystic change” or “negative,” relying entirely on a comment about the false-negative rate and triple test strategy to pick up false negatives—because some of these patients will be lost to follow-up, particularly in a managed care environment where patients frequently change health plans and physicians. If, however, the pathologist interprets a sparsely cellular FNA as “nondiagnostic due to sparse cellularity,” then the clinician will be forced to repeat the FNA or to proceed to excisional or needle biopsy—and the patient will not experience a delay in the diagnosis of breast carcinoma.

Claims resulting from false-positive FNAs are usually due to interpretative errors. Most commonly, an FNA diagnosis of carcinoma is made on a mass subsequently shown to be a fibroadenoma. The claim results from either unnecessary mastectomy or axillary node sampling if breast conservation is elected. In almost every instance, these claims would have been prevented by applying the triple test strategy.

Breast FNA Key Points
1. False negatives usually result from inadequate sampling. If smears are sparsely cellular, consider a diagnosis of “nondiagnostic FNA; additional diagnostic studies recommended.”
2. The report should include a statement that breast FNA has a false-negative rate of 3 to 5 percent and a false-positive rate of 0.5 to 2 percent, the consequences of which can be minimized by applying the triple test strategy.
3. If you know there is triple test discordance, it should be stated in the report and a biopsy recommended.
4. False positives usually reflect interpretative errors. Typically, a diagnosis of carcinoma is made on a mass subsequently found to be a fibroadenoma. The triple test strategy will often prevent this misdiagnosis.
Breast Biopsy

Some breast biopsy claims involve the differentiation of low-grade ductal carcinoma in situ (DCIS) from ductal involvement by lobular carcinoma in situ (LCIS). This differentiation can be difficult and is often subjective. While the distinction is fundamentally based on morphology, the use of immunostains for E-Cadherin may be a useful diagnostic adjunct. Occasional claims involve the differentiation of DCIS from atypical duct hyperplasia (ADH), which is not surprising since poor interobserver reproducibility in the diagnosis of ductal proliferative lesions is well documented even among experts. A misdiagnosis can result in patient injury because DCIS is a premalignant lesion that is treated surgically to obtain negative margins and is sometimes treated with radiation therapy or mastectomy, whereas LCIS and ADH are regarded as markers for increased risk involving both breasts and are managed conservatively by surveillance. When considering a diagnosis of DCIS, LCIS, or ADH, it is important to keep these management differences in mind.

For example, an excisional biopsy is diagnosed as DCIS with involvement of the inked margins; because of a family history of breast cancer, the patient elects to have a simple mastectomy rather than a breast conserving re-excision of the biopsy site followed by radiation. The slides are subsequently reviewed by another pathologist and diagnosed as LCIS involving interlobular ducts, and a claim is filed for unnecessary mastectomy. A variation on this theme involves the diagnosis of DCIS with positive biopsy margins, resulting in re-excision of the biopsy site with axillary lymph node sampling. The patient is referred to another hospital for breast radiation where the slides are reviewed and diagnosed as ADH; a claim is filed alleging unnecessary re-excision lumpectomy and axillary dissection.

Many primary care clinicians (and some surgeons) do not fully understand the terms DCIS, LCIS, ADH, and atypical lobular hyperplasia (ALH). For this reason, the pathology report should include an explanation of the clinical significance of these terms—that is, that DCIS is a premalignant lesion placing the biopsied breast at risk, while LCIS and atypical hyperplasia are markers for risk in both breasts. It is also important to clearly state that there is no invasive carcinoma, since it is not uncommon for the “carcinoma” in DCIS or LCIS to be misunderstood as meaning the patient has cancer. These are confusing terms even for pathologists, and we should explain their meaning in our reports in order to avoid miscommunication and to prevent inappropriate management decisions.

Nineteen percent of the reviewed breast biopsy claims involved large-core (cutting) needle biopsies of palpable breast masses or stereotaxic image-guided needle biopsies of nonpalpable lesions discovered on mammography. Diagnostic errors uncovered in a review of these claims include:

1. The misdiagnosis of ductal carcinoma in situ, sclerosing adenosis, and florid adenosis as invasive ductal carcinoma.

Patient injury results if a mastectomy is performed without first performing an excisional biopsy of the lesion or if axillary lymph nodes are sampled at the time an excisional biopsy is performed.

2. The misdiagnosis of lobular carcinoma in situ involving ducts as low-grade DCIS. Since LCIS is a marker for increased risk while DCIS is a premalignant lesion, the management is totally different. Patient injury results if axillary lymph node sampling is performed at the time of excisional biopsy.

3. The failure to recognize small, easily overlooked foci of invasive lobular carcinoma.

These differential diagnostic possibilities need to be consciously considered when interpreting needle biopsies of breast lesions. If there are any reservations, a definitive diagnosis should not be made, and an excisional biopsy should be recommended. Whenever in situ carcinoma is diagnosed on needle biopsy, excisional biopsy should be performed because there may be invasive carcinoma as well. Biopsy is also recommended when atypical duct hyperplasia is diagnosed on needle biopsy, since there may be associated DCIS or invasive carcinoma. This is particularly important if image guidance is not used, since a study comparing the accuracy rates between breast biopsy techniques found that cutting needle biopsy without image guidance had a sensitivity of only 85 percent, which is considerably less than open breast biopsy (99 percent), FNA (96 percent), and the reported sensitivity of 98 percent for cutting needle biopsy with image guidance.

When invasive carcinoma is diagnosed, pathologists who are inexperienced in interpreting needle biopsies should ask a colleague to review the biopsy before releasing the report or request confirmatory biopsy before axillary lymph node sampling or mastectomy is performed.

Breast Biopsy Key Points

1. When considering a diagnosis of DCIS, LCIS, or ADH, keep the management implications in mind. In a difficult case, an E-Cadherin immunostain may be helpful.

2. The clinical significance of DCIS, LCIS, ADH, and ALH should be explained in the pathology report; i.e., DCIS is a premalignant lesion placing the biopsied breast at risk, while LCIS and atypical hyperplasia are “markers” for risk in both breasts. Specifically state that there is no invasive carcinoma.

3. When in situ carcinoma is diagnosed on breast needle biopsy, an excisional biopsy should be performed because there may be invasive carcinoma as well. Biopsy is also recommended when atypical duct hyperplasia is diagnosed, since there also may be DCIS or invasive carcinoma.

References:

By David B. Troxel, MD, Medical Director, Board of Governors.

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