



Diagnosis and Treatment of Breast Disease—Chaos or Evolution?

a report by

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The diagnosis and treatment of breast cancer has been transformed, from the aggressive treatment of what was thought to begin as a local disease to a more evolved approach to what is now known to be a systemic disease. Years ago, the only breast biopsy option available was an open breast procedure. As technology developed, the mammogram became more important, not only as a tool for screening abnormalities but also as a diagnosis device for breast disease. Today, technology has rapidly progressed to the point at which most breast biopsies are image-guided, with few breast biopsies requiring an operating room for initial definitive diagnosis.

Today's knowledge and understanding of breast cancer as a systemic disease has changed the nature of the local treatment of the primary breast tumor. The realization that amputation did not necessarily produce a cure triggered a revolution involving breast-sparing techniques, such as complete excision of the tumor and a reconstructive cosmetic procedure. This revolution has now extended to include the realm of breast radiation.

Materials and Methods

This article explores contemporary breast disease screening technology, breast biopsy techniques, and alternative uses of the resulting information in setting the foundation for breast cancer treatment. It further compares and contrasts modern conservative breast cancer treatments with a revolutionary technology that is fast evolving to help produce cosmetically desirable outcomes while curtailing the chances of local tumor recurrences.

Despite myriad advances in imaging technology, a breast biopsy remains the sole method of providing a definitive diagnosis for breast disease. Now that aggressive surgery has been shown not to cure the disease by stopping its spread at the source, biopsy techniques need to be performed alongside a comprehensive plan for surgery and radiation therapy of the residual breast tissue. The increasing use of screening mammograms combined with ultrasound (US) has led to the identification of other hidden, non-palpable abnormalities. The incorporation of magnetic resonance imaging (MRI) into the discovery process has further aided the recognition of additional non-palpable abnormalities.

Breast biopsy technology has progressed exponentially, and these technological advances, coupled with the expanding pool of knowledge concerning the nature and characteristics of breast cancer, have led to significant changes in biopsy methodologies and the amount of breast tissue removed during the biopsy procedure. It is worth noting that approximately 70% of all abnormal findings on mammograms are found to be benign on biopsy; however, the proportion of benign findings is

significantly reduced to approximately 30% when dealing with Breast Imaging Reporting and Data Systems (BIRADS) categories 4 and 5 and indeterminate calcifications. It should also be noted that, currently, the objective of a breast biopsy is to yield a definitive diagnosis at the first attempt. Achieving this objective requires judgment; interpretation of various indications on mammogram, US, and MRI reports; and complete understanding of the patient's physical examination results and medical history. Breast abnormalities do not exist in a vacuum; rather, they exist in the complex organism of an individual. As such, the patient's entire body—not just the imaging studies—should be taken into consideration when selecting a biopsy technique, with special attention being paid to the limitations of each technique.

The fine-needle aspiration (FNA) technique is no longer frequently used. This technique requires the presence of a competent cytologist, which is not possible in most communities. FNA tends to understage/miss in up to 40% of cases. In addition, this technique is not effective when used for calcifications without an associated mass (see *Figure 1*).

The increased use of US has led to a great increase in the finding of indeterminate nodules not noted on other examinations. The vast majority of such determinations are benign. The core needle is often used to biopsy these abnormalities because in most cases it facilitates the confirmation of a benign diagnosis using US guidance with local anesthesia, and thus does not leave any scars. Core-needle biopsy (CNB) tends to understage/miss in up to 20% of cases (see *Figure 1*). This technique has a low reliability rating in cases where calcifications are not associated with a mass.¹⁻³

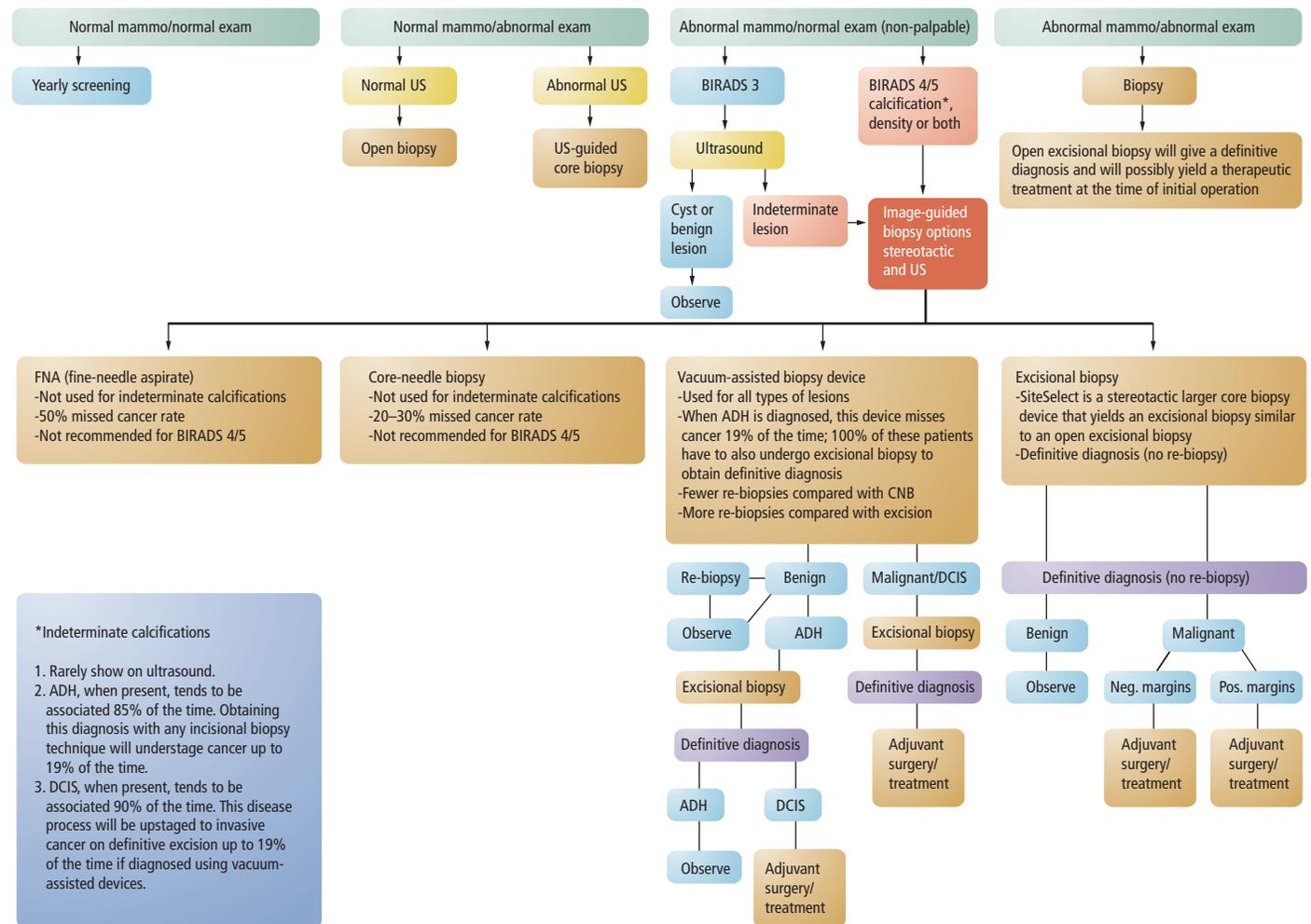
Abnormalities noted on mammogram are most often biopsied using a vacuum-assisted device. The advent of these devices has allowed the biopsy of diseased areas with minimal incision using local anesthesia. Most of these patients do not need to be taken to the operating room



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Figure 1: Decision Guide for Breast Disease Management



mammo = mammogram; US = ultrasound; BI-RADS = Breast Imaging Reporting and Data Systems; FNA = fine-needle aspiration; ADH = atypical ductal hyperplasia; CNB = core-needle biopsy; DCIS = ductal carcinoma in situ.

(OR) in order to confirm a benign finding (see Figure 1). Nonetheless, the limitations of these devices must be acknowledged. Studies demonstrate that 11-gauge tomes miss an invasive tumor 19% of the time if the diagnosis yields atypical ductal hyperplasia (ADH). This leads to a delay in obtaining a definitive diagnosis in 100% of patients with ADH diagnosed in this fashion. The time delay between biopsy and excisional surgery is considerable, often exceeding two weeks. During this time, the patient is unaware of the likelihood of cancer in her breasts. This period of anxiety and mental anguish could be avoided if a definitive diagnosis were obtained at the time of the initial biopsy. The 11-gauge tomes also understage/miss ductal carcinoma *in situ* (DCIS) 19% of the time, with DCIS being discovered at the time of definitive excision. Understaging or missing an invasive tumor prevents the surgeon from planning definitive cancer surgery. With this technique, the exact size of the cancerous lesion is unknown due to the nearly complete obliteration of the lesion.^{3,4} Additionally, the margin status of the lesion cannot be determined. The 8-gauge tome will miss to a marked degree in fewer than 19% of cases if ADH is found in the specimen. To the extent that the likelihood of a significant miss exists, this will cause delays to the definitive diagnosis in

100% of patients diagnosed with ADH using the 8-gauge tome. A finding of DCIS may also be upstaged to invasive cancer on definitive excision (see Figure 1). Again, the exact size is lost with this technique as the lesion is usually nearly completely obliterated and the margin status cannot be determined, leading the treating physician to perform an image-guided or open excisional biopsy in order to obtain a definitive diagnosis.

The excisional biopsy is considered to be the 'gold standard' because it enables pathologists to examine the specimen intact, devoid of shred artifacts, and without resorting to extrapolation. An excisional biopsy is not defined by the volume of contiguous tissue removed; rather, it is defined as the complete removal of the abnormal area as one intact specimen,⁷⁻⁹ revealing the size, volume, and margin status of the lesion. The size/volume of tissue removed varies widely depending on the size of the abnormality. Whether the excision is image-guided or not has no bearing on the physical nature of the specimen being removed for examination. SiteSelect is a large-core excisional breast biopsy device that uses stereotactic technology to completely excise the abnormal lesion in one contiguous piece, yielding a definitive diagnosis.^{5,6} SiteSelect can be

WHAT IS THE CURRENT STANDARD OF CARE FOR BREAST DISEASE MANAGEMENT?

The prevailing technology, used to perform thousands of breast biopsies each year...

*** Does Not Provide Definitive Diagnosis:**

Can not diagnose *ADH, ALH, Radial Scar, IDC/ILC, LCIS, and DCIS* when using a *Vacuum assisted* breast biopsy device.

*** Provides Only A Limited Histological Evaluation:**

Can not determine the lesion *Size, Margin* status, and *Architecture* when retrieving multiple fragmented samples

*** Provides Only Shredded Samples of Tissue for Biopsy:**

Have you ever permanently lost the *Histology* information of a suspected cancerous lesion due to suctioning and shredding of the tumor into pieces during a biopsy?

*** Does Not Localize the Sample:**

Have you ever missed a tumor due to the biopsy needle moving the lesion?

DO THESE ISSUES CONCERN YOU?
...THERE IS AN ALTERNATIVE
SiteSelect® Breast Biopsy System
CERTAINTY IN ITS DIAGNOSIS
Elegant in its Simplicity

PROVEN TECHNOLOGY

♀ Definitive Diagnosis the first time (on all abnormalities)

♀ Virtually 100% Specificity and 100% Sensitivity

♀ Histology information similar to open excision biopsy

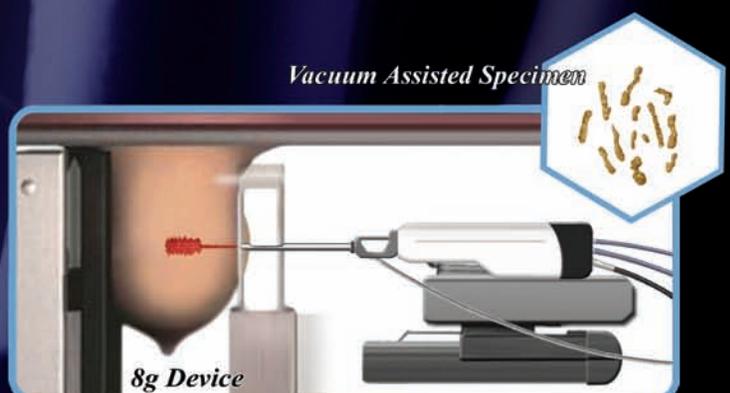
♀ One contiguous core of specimen preserving the lesion architecture with artifact free margins (no RF artifact)

♀ Hemostasis is consistent with all open or image guided/Stereotactic biopsy procedures depending on size

SiteSelect® is recommended for *BIRADS 4, 5*, and all *Indeterminate Microcalcifications*

Simple, Fast, Accurate

Minimally Invasive SiteSelect® Excision



All Data on file. For Publications, Researches, and Abstracts on SiteSelect® Biopsy system visit our website at: siteselectmedical.com
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best characterized as a needle localization excisional biopsy performed on a stereotactic table rather than in the OR (see *Figure 1*). The exact size, volume, and margin status of a lesion can be determined via this biopsy technique.

There is no single biopsy technique that is suitable for all abnormalities. Nonetheless, if the abnormality reported in an imaging study is a non-palpable mass, the potential delays inherent in using alternative image-guided biopsies, waiting for pathology reports, arranging for the referral, and the appointment with a surgeon can be avoided by simply excising the abnormality using SiteSelect. However, there are cases in which an open excisional biopsy may be the best option.

Discussion

The breast disease management production line starts with a palpable mass on physical examination or an abnormal imaging study, or both. When the mammogram test reveals abnormality in a patient she is informed of the need for further testing, which could take anywhere from one to four weeks to schedule and complete. She is then advised to undergo an image-guided biopsy procedure. This is often scheduled with a radiologist, a process that could take an average of two weeks. By the time the pathology is relayed to the patient, another week has gone by. The patient is usually called and told the diagnosis. If it is cancer, DCIS, or ADH, she is recommended to promptly seek the counsel of a surgeon.

A conservative estimate is that the above process could take up to seven weeks before the patient is adequately advised of her final results, assuming that there are no insurance authorization glitches or clerical blunders. This is in addition to the lead time for visiting a surgeon, which could easily take a week or more. By this time, the patient will have devoted nearly two months to obtaining a diagnosis and scheduling the appointment for definitive treatment. No-one up to this point has examined her with the study results in mind. The patient has not received information or counseling regarding the biopsy procedure, alternative devices or techniques, and the limitations thereof. Finally, she receives definitive treatment. Additional pre-operative tests and scheduling the surgery necessitates further delays of another week or two. While such delays may not markedly influence the final treatment outcome, they could be frustrating or even devastatingly terrifying for the average patient.

Naturally, no single biopsy method can be suitable for all situations. In other words, one size does not fit all. Nonetheless, regardless of the methodology employed, it appears that there may be distinct advantages to involving a breast specialist at the inception of the biopsy process. Such an approach, along with selecting the most suitable biopsy

approach, could potentially shorten the diagnosis process and thus spare the patient significant grief and agony. It can also be readily demonstrated that this approach would be less costly than the practice detailed above. If the suspicious lesion noted on mammogram/US is palpable, the breast specialist can make an accurate judgment about the likelihood of a tissue being malignant. In cases of smaller lesions, it is advisable to promptly remove any and all abnormalities without frittering away valuable time. More often than not, such an excision would produce a definitive diagnosis.

On the other hand, if the lesion is not palpable, but either is of a suspicious density (BIRADS category 4 or 5) or involves indeterminate calcifications, it should be completely excised in one piece by image guidance in order to arrive at a definitive diagnosis at the first attempt. If the correct size of device is chosen, the procedure may yield a therapeutic excision, as evidenced by the clear margin status on the pathological examination.⁶ The smaller biopsy devices, such as vacuum-assisted devices or small-core needles, may result in misinformation, requiring a repeat biopsy in order to verify the results obtained at the first attempt.^{3,4} However, the smaller biopsy devices are adequate tools for exhibiting that a BIRADS category 3 is benign and requires no further treatment.

Indeterminate calcifications noted on mammogram categorized as BIRADS category 4 or 5 can be difficult to judge and accurately diagnose for three reasons. First, when ADH is present, it is associated with indeterminate calcifications on mammogram about 85% of the time. Second, when DCIS is present it is associated with indeterminate calcifications on mammogram about 90% of the time.⁶ Finally, the calcifications may or may not be directly involved in the disease process. Indeterminate calcifications need to be completely excised as one contiguous piece of tissue to avoid understaging of the disease process. Nothing can be assumed about any calcifications left behind in the biopsied area of the breast tissue.

Conclusions

The decision as to which biopsy technique to use should be based on the nature of the visible abnormality on the imaging study combined with the patient's history and physical examination results. In reality, the choice of biopsy technique is a new challenge confronting every patient. The decision on which biopsy approach to be used differs among patients based on the probability of discovering a malignancy and the plan for any subsequent definitive surgery. The goal is not to treat the image, but rather to treat the patient. With the complex set of currently available alternatives, a breast specialist should be in charge of the overall process of diagnosis and treatment of those patients who have an abnormal breast examination, an abnormal imaging study, or both. ■

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