Implementation of a Minimally Invasive Breast Biopsy Program in Countries with Limited Resources

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Abstract: Minimally invasive breast biopsy techniques, such as core needle biopsy (CNB) and fine-needle aspiration biopsy (FNAB), offer several advantages over surgical biopsy. Patients in whom minimally invasive biopsy techniques are used may undergo biopsy more quickly, are more likely to have only one surgery for treatment of the breast tumor and axillary staging, and are less likely to need reoperation after breast-conserving surgery because of positive margins. Knowledge of a diagnosis of cancer before surgery allows patients to participate in treatment decisions, and compared with surgical biopsy, minimally invasive biopsy has lower costs, produces less scarring, has nearly equivalent diagnostic accuracy, and does not require general anesthesia or sedation. Minimally invasive biopsy can permit accurate diagnosis and prompt intervention in a cost-effective manner, particularly in countries with limited resources, where patients often present with advanced-stage breast cancer. Several events characterize the implementation of a successful program in minimally invasive breast biopsy: public education about the less invasive nature of these techniques, which may encourage women to seek care at earlier stages; a change in the philosophy of medical personnel that favors involving patients in treatment decisions and acceptance of less extensive but accurate methods of diagnosis; education of medical personnel in the selection of patients for minimally invasive biopsy, performance of the biopsy, and interpretation of histologic and/or cytologic samples; quality assessment and use of the triple test (i.e., correlation of clinical, radiologic, and pathologic findings); and economical use of resources, which results from the lower costs of minimally invasive procedures and the avoidance of unnecessary surgery for benign conditions.

Key Words: accuracy, core needle biopsy (CNB), cost, excisional biopsy, fine-needle aspiration biopsy (FNAB), surgery, triple test, vacuum-assisted biopsy

A clinical diagnosis of breast cancer must be confirmed by pathologic evaluation. Minimally invasive biopsy refers to percutaneous techniques of sampling or removing suspicious areas of the breast without open surgery and excisional biopsy. These techniques include fine-needle aspiration biopsy (FNAB) and core needle biopsy (CNB).

RATIONALE FOR MINIMALLY INVASIVE DIAGNOSIS

For almost 100 years the primary treatment for breast cancer was radical surgery. We have witnessed a remarkable change in the clinical presentation, mode of diagnosis, and treatment of breast cancer during the last 30 years (1). Changes in breast cancer treatment are a consequence of the successful adoption of breast-conserving surgery, reconstructive techniques, and use of systemic therapeutics as alternatives to radical surgery (1). Patient advocacy,
increased public education and awareness, and the implementation of screening mammography are important contributing factors to this evolution (2).

Clinical reports suggest that patients in whom minimally invasive biopsy techniques are used may undergo biopsy more quickly and are more likely to have only one surgery for treatment of the breast tumor and axillary staging (3). The reoperative rate for positive margins in breast-conserving surgery is significantly lower after minimally invasive biopsy. If the diagnosis of cancer has been established, sentinel node biopsy or axillary dissection may be performed during the same procedure (3). Reduced numbers of surgical procedures have a positive impact on health care economics. In addition, general anesthesia or sedation is not required, and percutaneous techniques leave minimal scarring compared with excisional biopsy.

IMPLEMENTING A MINIMALLY INVASIVE BREAST BIOPSY PROGRAM IN COUNTRIES WITH LIMITED RESOURCES

Breast cancer is a more significant public health care problem in countries with high- or medium-level resources. The incidence of breast cancer is lower in countries with low levels of resources (4). However, between 60% and 75% of patients in such countries have advanced breast cancer (stages III and IV) at the time of diagnosis (5,6), and mastectomy is offered as the only treatment. Nevertheless, when advanced-stage cancer is suspected, it still requires accurate diagnosis and prompt intervention.

In the setting of predominantly advanced breast cancer, minimally invasive biopsy can play an important role by providing a diagnosis before therapy, be it systemic chemotherapy or surgery, in a cost-effective fashion. The following events characterize successful implementation of a minimally invasive biopsy program:

- Public education and participation: Cancer detection at an earlier stage must be an important objective of any cancer intervention. Use of minimally invasive biopsy techniques may encourage earlier intervention in a population that is frightened about radical, disfiguring, and/or expensive surgery.
- Change in philosophy of medical personnel: To some degree, minimally invasive biopsy is patient-driven in that the patient hopes to avoid surgery, scarring, and other feared outcomes. Medical professionals should be open to patient participation in their care. Medical professionals must develop an emphasis on prompt, expedient, and cost-effective diagnosis before the treatment of breast cancer. Extensive surgery is not necessary for diagnosis and should be avoided.
- Education of medical personnel: Introduction of minimally invasive biopsy requires training of medical personnel in patient selection, performance of the biopsy, and interpretation of the histologic and/or cytologic samples. Table 1 (7–16) shows the relative degree of difficulty, accuracy, and cost of minimally invasive biopsy techniques and open surgery. Learning how to analyze and integrate biopsy information is critical to the success of a minimally invasive biopsy program.
- Quality assessment: In minimally invasive biopsy, only a sample of the breast abnormality is collected. Sampling error may lead to an erroneous diagnosis. Therefore it is critical to recognize the limitations of minimally invasive biopsy methods. The diagnosis of cancer may be underestimated in the presence of certain histologies, such as atypical ductal hyperplasia, atypical lobular hyperplasia, radial scar, and papillary lesions (17). Excisional biopsy is recommended if the minimally invasive biopsy is nondiagnostic or shows any of the aforementioned pathologic findings. Just as important is interpretation of minimally invasive biopsy in the context of clinical and imaging findings as part of the triple test (i.e., correlation of clinical, radiologic, and pathologic findings). Any discrepancy or suspicious finding should prompt excisional biopsy.

| Method                        | Degree of difficulty | Diagnostic accuracy (%) | Nondiagnostic rate (%) | Cost     |
|-------------------------------|----------------------|-------------------------|------------------------|----------|
| FNAB                          | ++                   | 90–96                   | 2–50                   | $        |
| 14-G core needle biopsy       | ++                   | 94–99                   | 1–10                   | $$       |
| VAC biopsy                    | ++++                 | 99                      | 1                      | $$$      |
| Surgical biopsy, office settinga | +                   | >99                     | <1                     | $        |
| Surgical biopsy, operating rooma | +                   | >99                     | <1                     | $$$      |

FNAB, fine-needle aspiration biopsy; VAC, vacuum-assisted core. Relative degree of difficulty ranges from least difficult (+) to most difficult (++++). Relative cost ranges from least costly ($) to most costly ($$$$).
aSurgical expertise required.
even in the face of a benign pathologic result. Use of clinico-radiologic-pathologic correlation provides a high degree of diagnostic certainty (18). Access to breast imaging may be limited in countries with limited resources. It is difficult to measure the contribution of breast imaging to the triple test because the accuracy of physical examination and minimally invasive biopsy in the absence of imaging has not been scientifically studied in comparison with the gold standard of surgical biopsy.

- Economical use of resources: Minimally invasive biopsy has an immediate salutary effect on the economy of health care when compared with open surgery. A number of factors contribute to this. First, benign breast conditions are four times more prevalent than breast cancer. A benign diagnosis saves the costs of open surgery in patients with benign breast disease (19). Second, the direct cost of minimally invasive biopsy is less than that of open surgery (20). In addition, processing of cytology samples for FNAB is less expensive than histologic processing of samples for core biopsy or surgical biopsy (7).

MINIMALLY INVASIVE PROCEDURES: FNAB VERSUS CNB

Medical professionals generally agree that FNAB should be regarded as the initial diagnostic procedure for palpable breast lesions. FNAB is a technique for obtaining cellular material using a 21-gauge or smaller needle. Usually FNAB is performed with a 10 or 20 cc syringe using special syringe holders. Diagnosis on FNAB is primarily based on cytologic examination of the aspirate.

It is important to recognize the difference between FNAB and CNB. In contrast to FNAB, which provides material for cytologic evaluation, CNB yields tissue fragments for histologic evaluation. The accuracy of FNAB and CNB in palpable breast lesions is well established. FNAB is more accurate, has a low false-negative rate, and is a painless procedure in the workup of palpable breast lesions (21–24). CNB is the preferred procedure for sampling of nonpalpable breast lesions.

Advantages of breast FNAB include
- Cost-effectiveness.
- Minimal physical and psychological discomfort to the patient.
- Elimination of a two-stage procedure.
- Rapid reporting and bedside diagnosis.
- Active participation of the patient in treatment planning.
- Therapeutic procedure for evacuation of breast cysts.
- An alternative procedure when surgical biopsy is not possible.
- An effective means of tumor sampling for prognostic testing and monitoring the effect of therapy.

FNAB has a low incidence of complications, although occasionally hematoma formation, bleeding, or infection may occur. Pneumothorax is a very rare complication (25,26). Vasovagal reactions, ranging in severity from syncope to mild lightheadedness, can occur. Tumor implantation after FNAB is extremely rare.

HOW TO ESTABLISH A BREAST FNAB SERVICE

First, it is important to ensure that the physicians who perform FNABs are thoroughly familiar with the technique as well as its indications and interpretation. Aside from traditional training and participation in various workshops, personal experience is the most significant factor contributing to the success of this procedure. Continuous and consistent practice by simulating FNAB on surgical specimens and preparing smears and imprints is the most effective way of developing proficiency in the technique and subsequently in the interpretation of FNABs. The ability to recognize the differences between the interpretive criteria for exfoliative cytology and for FNAB is also essential.

Second, the necessity of establishing an FNAB service has to be justified. The merits and pitfalls of the procedure must be made clear to patients and health care providers. They must be convinced that FNAB is an attractive alternative to surgical biopsy because it is more convenient for patients. Lectures, interdepartmental conferences, and brochures explaining the merits of FNAB are important vehicles for educating the public and medical community.

Third, the physicians who perform FNABs must be identified—surgeons, oncologists, radiologists, or pathologists. There are many factors that influence this decision, including the geographic proximity of clinic patients and the availability of qualified pathologists. The possibility of involving other health care providers in performing FNABs is also a realistic possibility. However, many investigators have unequivocally shown that pathologists obtain the best FNAB results (27,28).

Complete familiarity with the clinical picture of the patient and examination of the mass and the gross appearance of the aspirate complements the interpretation of cytologic material when making a definitive diagnosis. An immediate interpretation provided by a pathologist at the bedside can significantly reduce the number of insufficient samples and false-negative diagnoses, and speed diagnosis
and therapy. To achieve this type of immediate evaluation, an FNAB cart can be assembled and either stationed at a clinic or wheeled to the patient’s bedside. The cart should contain a microscope, different stains, fixatives, syringes, needles, syringe holders, slides, and the other accessories necessary for performing FNABs and processing the aspirated material.

Unfortunately implementation of the system described above may not be feasible in many institutions. An alternative approach is to make sure that the other individuals performing FNAB procedures are adequately trained in all aspects of sampling the lesion and preparing the smears. If possible, they should be provided with a technician to assist them in processing the aspirated material. Another alternative is collecting the aspirated material into appropriate fixative. This permits the preparation of high-quality smears by trained technologists, no matter who does the aspiration (29).

Initially surgeons may be reluctant to prescribe a definitive therapy based on cytologic diagnosis alone. For this reason they should be allowed to challenge the cytologic diagnosis by an excisional biopsy and/or frozen section for a short period of time. Once trust between pathologist and surgeon is firmly established, the technique of FNAB will be viewed as a reliable diagnostic procedure.

CONCLUSION

Use of minimally invasive biopsy techniques offers a reliable diagnosis of breast diseases in a cost-efficient manner. Educating medical personnel in these techniques and in the integration of clinical, imaging, and pathologic information is essential for success. A philosophical change that encourages patient involvement in health care decisions may facilitate implementation of minimally invasive biopsy in countries with limited resources.

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