Stereotactic Core Needle Biopsy of Nonpalpable Breast Lesions

Initial Experience With a Promising Technique

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Objectives: To evaluate the correlation between the pathological findings of stereotactic core needle biopsy (SCNB) and the prebiopsy mammographic findings, as well as the pathological findings of lesions that were subsequently removed by surgical excision.

Design: A retrospective review of 97 consecutive patients who underwent 100 SCNBs of suspicious nonpalpable mammographic lesions. The criterion standard is surgical excisional biopsy with needle localization. Mammographic findings were graded according to the American College of Radiology Breast Imaging Reporting and Data System. The pathological findings of SCNB were categorized into 4 groups: benign and specific, benign and nonspecific, premalignant, and malignant. Surgical excision of the lesion was performed if the pathological finding on SCNB was nonconcordant with the prebiopsy mammogram and when premalignant or malignant lesions were found. The pathological findings of lesions that were subsequently removed by surgical excision were compared with those of SCNB.

Setting: Community-based private multispecialty ambulatory practice.

Patients: A population-based sample composed of 97 patients who had grade III, IV, or V lesions on routine screening mammograms.

Intervention: Stereotactic core needle biopsy of nonpalpable mammographic lesions.

Main Outcome Measures: Percentage of patients whose SCNB results were concordant with the mammographic findings and the pathological findings on subsequent surgical excision.

Results: Concordance between SCNB and mammography occurred in 97% of biopsy specimens. Concordance between the pathological findings of SCNB and those of surgically excised lesions occurred in 92.5% of biopsy specimens. We had 1 false-negative result. We had no false-positive diagnosis of cancer with SCNB.

Conclusion: On the basis of accumulating literature and our own initial experience, SCNB is a promising, safe, and cost-effective procedure.

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WITH THE realization that mammography significantly reduces breast cancer mortality, an increasing number of women are undergoing screening mammography followed by biopsy of suspicious lesions. The reported biopsy yield of cancer is 10% to 40%,1-4 which means that up to 90% of women who are exposed to the discomfort, morbidity, and cosmetic effects of surgical biopsy have benign lesions. When the cost of surgical biopsy, and the fact that scarring from surgical biopsy interferes with subsequent mammography, are added to those factors, the need for a less invasive and less expensive procedure becomes obvious.

Stereotactic core needle biopsy (SCNB) has been recently introduced as an alternative to the traditional surgical excisional biopsy with needle localization. Studies continue to appear in the literature reporting the accuracy,5-19 safety, and cost-effectiveness20-22 of this procedure. In this study, we report our initial experience with this technique. We assessed the accuracy of SCNB in our institution by determining the concordance rate between the pathological findings of SCNB and those of surgically excised lesions occurred in 92.5% of biopsy specimens. We had 1 false-negative result. We had no false-positive diagnosis of cancer with SCNB.
PATIENTS AND METHODS

PATIENT SELECTION

All patients who had undergone routine screening mammography between June 1996 and March 1997 who had nonpalpable mammographic lesions were assigned 1 of 5 grades of suspicion of malignancy based on the American College of Radiology Breast Imaging Reporting and Data System.23 Patients with grade IV (suspicious abnormality) and grade V (highly suggestive of malignancy) lesions underwent SCNB. Patients with grade III lesions underwent SCNB, at the discretion of the surgeon, if they were apprehensive about having their mammographic abnormalities observed especially in the presence of strong risk factors for breast cancer.24

DATA COLLECTION

A retrospective review of the medical records was performed to collect the following data: risk factors for breast cancer, type of mammographic lesion (mass vs microcalcification), Breast Imaging Reporting and Data System grade, pathological findings of SCNB and those of lesions that were surgically removed, and clinically significant complications (hematoma requiring drainage or infection requiring hospitalization). We adopted the method described by Burbank25 to classify pathological findings as follows: malignant; premalignant; benign and nonspecific; and benign and specific. Nonconcordance between mammography and SCNB was defined as benign pathological findings on SCNB when the mammographic lesion was grade V. The findings of SCNB were also compared with those of surgically excised specimens, and nonconcordance was defined as the presence of malignant or premalignant pathological findings in surgically excised lesions when SCNB showed benign pathological findings (false negative), or the presence of benign pathological findings in surgically excised lesions when SCNB showed premalignant or malignant pathological findings (false positive). Patients whose mammographic findings were grade III or IV and who had benign pathological findings on SCNB were entered into an imaging follow-up program consisting of a mammogram at 3 to 6 months; if the lesion is unchanged or smaller, this is followed by another mammogram in 6 months. If the lesion appears larger, surgical excisional biopsy is performed. If the lesion is smaller or unchanged on the second mammogram, routine screening is resumed.

RESULTS

One hundred SCNBs were performed from June 1996 to March 1997. Ninety-four patients had unilateral and 3 patients had bilateral mammographic lesions. The average age was 58 years (range, 30-85 years). Thirty-six women (37%) were 50 years old or younger and 61 (63%) were older than 50 years. Fifty-six patients had mass lesions and 44 patients had microcalcification. Five patients had grade V lesions, 91 patients had grade IV lesions, and 4 patients had grade III lesions on mammography (Table 1). Of the 100 SCNBs performed, pathological findings were benign in 76 biopsy specimens (76%); 13 were benign and specific and 63 were benign and nonspecific (Table 2). Premalignant pathological changes were found in 8 biopsy specimens (8%), and pathological findings were malignant in 16 (16%). The positive predictive value, defined as the biopsy yield of premalignant and malignant lesions, was therefore 24%. The 4 patients with grade III mammographic lesions were found to have benign and nonspecific pathological findings on SCNB. During the above period, 4 mammographic lesions could not be localized stereotactically, SCNB was aborted, and excisional biopsy was performed. Excisional biopsy in those 4 patients disclosed nonproliferative fibrocystic changes in 2 patients and proliferative fibrocystic changes in 2 patients. Our patients had no clinically significant complications from SCNB.

Excisional biopsy was performed in 27 patients (Table 3): 24 patients had premalignant and malignant pathological findings on SCNB and 3 patients had nonconcordance between the mammographic findings and the pathological findings of SCNB. Of the 3 patients with nonconcordance with mammographic findings, 2 patients had benign pathological findings (normal and atrophic breast tissue) and 1 patient had malignant pathological findings (invasive ductal carcinoma) on excisional biopsy. Of the 24 patients with premalignant and malignant lesions, nonconcordance occurred in 1 pa-
tient who had premalignant pathological findings on SCNB (atypical ductal hyperplasia) and was found to have benign and nonspecific pathological findings (fibrocystic change) in the surgically excised specimen. Therefore, concordance between the pathological findings of SCNB and those of surgically excised specimens occurred in 25 (93%) of 27 patients. The false-negative, or cancer “miss,” rate was 1.0%.

**COMMENT**

The increasing need for a minimally invasive and relatively low-cost technique to biopsy mammographic lesions prompted the introduction of SCNB in the United States in 1990. Encouraged by the increasing number of studies reporting the accuracy and safety of the procedure, we introduced SCNB in our practice in June 1996. After having performed 100 consecutive biopsies, we began to collect standard outcome statistics and we report our initial results.

We selected patients who otherwise would have undergone excisional biopsy with needle localization, namely, patients with grades IV and V mammographic lesions. In this study, the 4 patients with grade III lesions had strong risk factors for breast cancer and were reluctant to have their mammographic findings observed. The minimally invasive nature and relatively low cost of SCNB did not lower our threshold for biopsy of “probably benign lesions.” We do not exclude patients with highly suspicious lesions, as recommended by some authors, since some of them will have benign pathological findings and can be spared surgical biopsy. Making the diagnosis of cancer by SCNB allows better planning of treatment, including a more aggressive local resection, than simply an excisional biopsy and also axillary lymph node sampling in the same setting. We do not exclude patients with small breasts or posterior lesions. A lesion consisting of a small cluster of microcalcification can be completely removed by SCNB, making subsequent identification of the area difficult if
the lesion is found to be malignant and wire-guided lumpectomy must be performed. We have found that even when the lesion appears to be completely removed on the postbiopsy mammogram, local bleeding at the biopsy site is apparent on subsequent mammograms and serves as a marker of the site of the lesion. The coordinates of the lesion are also saved in the computer and can be used to retarget the lesion. Another option is to mark the biopsy site with small surgical clips or medical carbon.25 The other concern with small clusters of calcification is that cancer might be missed or underestimated, but this risk was shown to be small.26 Whenever SCNB is performed on microcalcification, we examine the tissue removed by specimen radiography to verify the presence of calcium.27,28

Most of the biopsies in this study were performed with the mammotome because of its greater tissue acquisition properties and the fact that the device remains in the breast while the tissue is harvested.29,30 In the 12 biopsies performed with the biopsy gun, a 14-gauge needle was used and we obtained at least 10 cores per lesion. The use of a smaller-gauge needle by other investigators5,8,11,31,32 was associated with less successful results. Similarly, the fewer cores obtained, the higher the likelihood of missing a lesion.16

For invasive cancer, all pathology reports documented the histological type, the presence or absence of coexistent ductal carcinoma in situ (DCIS), and blood vessel and/or lymphatic vessel invasion. For DCIS, the architectural type and nuclear grade were reported. We followed the pathological classification described by Burbank24 because it provides a good guide to the action that needs to be taken after biopsy. In this classification, comedo DCIS and noncomedo morphologic characteristics with low nuclear grade were included within the malignant group because of their high potential for progression to infiltrating ductal carcinoma.33 Low-nuclear-grade DCIS and atypical ductal hyperplasia (ADH) are both included in the premalignant group because of the difficulty in making a clear distinction between those 2 entities.34 None of the specimens removed by SCNB during this study was described as “insufficient material.”

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Table 1. Mammographic Findings in 97 Patients

<table>
<thead>
<tr>
<th>Grade</th>
<th>Assessment</th>
<th>No. of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Negative; nothing to comment on</td>
<td>0</td>
</tr>
<tr>
<td>II</td>
<td>Benign finding</td>
<td>0</td>
</tr>
<tr>
<td>III</td>
<td>Probably benign</td>
<td>4</td>
</tr>
<tr>
<td>IV</td>
<td>Suspicious abnormality</td>
<td>91</td>
</tr>
<tr>
<td>V</td>
<td>Highly suggestive of malignant neoplasm</td>
<td>5</td>
</tr>
</tbody>
</table>

Table 2. Pathological Findings in 100 SCNBs*

<table>
<thead>
<tr>
<th>Category</th>
<th>No. of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benign and specific</td>
<td>13</td>
</tr>
<tr>
<td>Fibroadenoma</td>
<td>5</td>
</tr>
<tr>
<td>Lymph node</td>
<td>4</td>
</tr>
<tr>
<td>Lipoma</td>
<td>1</td>
</tr>
<tr>
<td>Hematoma</td>
<td>1</td>
</tr>
<tr>
<td>Fat necrosis</td>
<td>1</td>
</tr>
<tr>
<td>Cyst</td>
<td>1</td>
</tr>
<tr>
<td>Benign and nonspecific</td>
<td>63</td>
</tr>
<tr>
<td>Fibrocystic disease</td>
<td>21</td>
</tr>
<tr>
<td>Normal or atrophic breast tissue</td>
<td>17</td>
</tr>
<tr>
<td>Usual ductal hyperplasia</td>
<td>10</td>
</tr>
<tr>
<td>Usual lobular hyperplasia</td>
<td>0</td>
</tr>
<tr>
<td>Focal fibrosis</td>
<td>6</td>
</tr>
<tr>
<td>Sclerosing adenosis</td>
<td>5</td>
</tr>
<tr>
<td>Other nonspecific breast background lesion</td>
<td>4</td>
</tr>
<tr>
<td>Premalignant</td>
<td>8</td>
</tr>
<tr>
<td>ADH/papillomatosis</td>
<td>5</td>
</tr>
<tr>
<td>DCIS, noncomedo morphologic characteristics</td>
<td>2</td>
</tr>
<tr>
<td>with low nuclear grade</td>
<td></td>
</tr>
<tr>
<td>Atypical lobular hyperplasia</td>
<td>1</td>
</tr>
<tr>
<td>LCIS</td>
<td>0</td>
</tr>
<tr>
<td>Malignant</td>
<td>16</td>
</tr>
<tr>
<td>Infiltrating ductal carcinoma</td>
<td>10</td>
</tr>
<tr>
<td>Variants of infiltrating ductal carcinoma</td>
<td>0</td>
</tr>
<tr>
<td>Infiltrating lobular carcinoma</td>
<td>3</td>
</tr>
<tr>
<td>DCIS, comedo morphologic characteristics</td>
<td>3</td>
</tr>
<tr>
<td>DCIS, noncomedo but intermediate to high nuclear grade</td>
<td>0</td>
</tr>
</tbody>
</table>

* SCNB indicates stereotactic core needle biopsy; ADH, atypical ductal hyperplasia; DCIS, ductal carcinoma in situ; and LCIS, lobular carcinoma in situ. Positive predictive value (malignant plus premalignant) was 24%.
We defined the positive predictive value as the biopsy yield of premalignant and malignant lesions, since surgical excision is required if either of the 2 is present. The need for biopsy of premalignant lesions particularly applies to ADH, since it has been shown that, on surgical excision, carcinoma was present near the site of the SCNB in 50% of patients with ADH.10,11,26 Nonconcordance of the pathological results with the imaging findings was found in 1 series35 to be associated with the presence of cancer on repeated biopsies in 47% of cases. In our series, nonconcordance between mammographic findings and pathological findings of SCNB occurred in 3 patients (3%) (Table 3). On subsequent surgical excision, 1 patient, who had a spiculated mass on the mammogram and a diagnosis of lipoma by SCNB, was found to have invasive ductal carcinoma. That biopsy was performed with a 14-gauge needle. This is the only cancer “miss” in this series. The second patient, who had microcalcification on the mammogram, had normal breast tissue on surgical excision. Specimen radiography verified the presence of calcium in the tissue removed by SCNB. The pathologist did not identify any microcalcification in the specimen removed by surgical excision. We believe that the lesion was probably completely removed by the SCNB. The third patient, who had a nodule on the mammogram, was found to have atrophic breast tissue on surgical excision. One patient had microcalcification on the mammogram and ADH with some features of DCIS (ie, premalignant) on SCNB. On subsequent surgical excision, that patient was found to have nonproliferative fibrocystic change, no evidence of ADH, and no evidence of microcalcification. Again, we believe that the lesion was probably completely removed by the SCNB. However, we listed that as nonconcordance between the pathological findings of SCNB and those of surgical excision.

Our initial experience with SCNB shows a false-negative, or cancer “miss,” rate of 1%, which compares favorably with the 5.4% rate reported in the literature.20 It also compares favorably with the 6% false-negative rate of excisional biopsy reported in the literature.20 Some investigators reported a false-negative rate of excisional biopsy as low as 0.5%,37,38 and as high as 20%.1,39 This discrepancy relates to difference in technique and individual variations between different institutions.37 We realize that, to determine the actual false-negative rate, a follow-up of at least 2 years is needed for all patients with benign pathological findings on SCNB.7 The final results of the Radiologic Diagnostic Oncology Group V—a study supported by the National Cancer Institute to evaluate automated core biopsy of the breast—will not be available for several more years. We, therefore, perform surgical excisional biopsy whenever suspicion of cancer, based on mammographic findings and the patient’s risk factors, persists despite the presence of benign pathological findings on SCNB. By adhering to this protocol, the 1 cancer that was missed on SCNB in this series was detected immediately, without delay in diagnosis.

In conclusion, SCNB appears to be an accurate, safe, and cost-effective procedure for evaluation of nonpalpable mammographic lesions. Long-term follow-up is needed to determine the actual false-negative rate of the procedure. Until those results are available, SCNB should not completely replace surgical excisional biopsy.

REFERENCES


**DISCUSSION**

Peter J. Deckers, MD, Farmington, Conn: This is a very important addition to our diagnostic armamentarium in the treatment of breast cancer. I have jotted down a few comments and in the interest of time I would like to read these.

I have had the privilege in the last 2 years of discussing 2 papers on breast cancer, 1 last year from Rhode Island and this one this year with which I have no disagreement. This is a very important contribution. It is very clear, straightforward, and should be read by everybody.

Most would accept, I believe, that the diagnosis of any malignancy at an early stage is usually associated with a survival benefit. As such, early diagnosis is our aim and certainly is the goal of any screening tool. Mammography is the reference standard screening tool in the management of breast diseases. It has been shown in 50- to 70-year-old females that early detection of breast cancer by mammography practiced at regular intervals reduces breast cancer mortality by about one third, and though results in females 40 to 49 years of age are less clear, most would now accept that the benefit of reduced mortality in this younger age group is about one half of that seen in the group over 50 years of age. This is especially true in these younger screened women who are followed as they must be for at least 10 years. The conclusion must be that mammography, while not perfect (in that one fourth of invasive cancer in women under 50 and one 10th of invasive cancer in women between 50 and 70 are still not detected), despite that, mammography is a very valuable screening tool.

Now approximately 10% of screening mammograms, as was suggested, are read as abnormal, and though most of these determinations are benign, much anxiety is produced in the patient and some should be produced in her physician as well. Additional tests, which are costly, are usually ordered. Many of these abnormalities could be managed by expectant observation with repeat mammograms in 6 months. This is done in some centers, but in many other centers, for fear of litigation, it is not done, and there is a knee-jerk willingness to proceed immediately to open surgical biopsy. In fact, the number is even higher than a million. Close to a million and a half women each year in the United States still undergo open surgical biopsy with or without preoperative needle localization. Therefore, given the fact that we have about 180 000 new invasive and in situ cancers per year in the United States, only 12% of all of these biopsies are positive for cancer and 88% are negative.

If one focuses presumably on nonpalpable grade IV or grade V mammographic abnormalities, the yield from surgical biopsy in young women ages 40 to 50 should be 2 cancers, 1 in situ and 1 invasive, per 8 biopsies, whereas in women over 50 the yield should be twice that amount. If you accept that, still in each group, this data implies that 75% and 50%, respectively, of the open biopsies we do are negative. Now the question is: can most open surgery be prevented in the majority of patients with occult mammographically detected abnormalities? I believe it not only can but should be.

Stereotactic core needle biopsy is a reliable alternative that is simpler. As was stated, it’s at least two-thirds less costly, it’s less invasive, and it’s as reliable. During the past 4 years in my practice using this technique for occult solid lesions and for new microcalcifications not classically malignant but of concern in women over 40 years of age, I have not to this point, at least to my knowledge, had a false-positive or a false-negative diagnosis of cancer. Though, like in this particular study, 75% of my over 300 consecutive core needle biopsies were benign and therefore might have been managed expectantly, this diagnostic test provided much earlier relief of anxiety for all concerned—for me and for the patient—with minimal trauma and no complications. That is something I can’t say for my surgical experience, and I suspect you can’t say it either.

In short, in my opinion, stereotactic core needle biopsy is more than a promising technique. It is or should be the accepted standard of care in 1997 for occult nondiagnostic but worrisome solid lesions and new microcalcifications in the female breast.

By way of contrast, in apparent disagreement or slight disagreement with the authors, in my opinion if an occult mammographically detected lesion is solid and highly suggestive of cancer or there is microcalcification that is diagnostic or highly suspicious of cancer, open surgical excision, not core biopsy, is the correct first appropriate approach. Therefore, I favor core needle biopsy for what these authors refer to as grade III and
certainly all grade IV mammographic abnormalities, not for grade V abnormalities, despite the fact that I accept that a few of them will probably be benign.

Finally, stereotactic core needle biopsy has been, is, and I believe always will be in the appropriate province of the diagnostic radiologist. For the sake of controversy, I don’t believe that surgeons playing with this technology on 1 or 2 cases per month in an office setting for purely economic reasons is appropriate and I believe they will obtain invariably inferior results, patients will suffer by delayed diagnosis and its consequences, and the purpose of mammography and stereotactic core will have been defeated.

John Sutton, MD, Lebanon, NH: As an extension of Dr. Decker’s last comment, should the surgeon be totally removed out of this loop? Should the diagnostic radiologist do the mammogram, see the finding, arrange the biopsy, perform it, get the results, and then contact the surgeon, or should the surgeon have any input to the decision making?

Robert M. Quinlan, MD, Worcester, Mass: I notice that your pickup on malignancies was 16%. Do you have any historical data on how many were positive when you were doing needle localization and excision? You have to keep an eye on radiologists as well as you have to keep an eye on the surgeons. If our pickup rate with needle localization and excision was 30% and now it is 16%, there is in that a possibility that we might be doing too many stereotactic core biopsies and lowering our pickup rate.

The other question is related to your premalignant lesions. Several of our patients that have had premalignant lesions, up to 50%, will have in situ disease; so when we see a premalignant lesion on stereotactic biopsy, we automatically go to needle localization and excision, and I’m sure you had set out that way. Would you continue to do that even though you didn’t find DCIS?

Thomas Colacchio, MD, Lebanon: Were you able to compare the difference between the cost of stereotactic biopsy and then the recommended follow-up vs frequent unilateral mammography as the follow-up?

Dr. Seoudi: I will start with Dr. Decker’s comments. The 2 main issues are: should stereotactic biopsy be done on lesions that consist of a small cluster of microcalcifications, and whether it should be done on highly suggestive mammographic lesions. The argument is, if the lesion consists of a small cluster of microcalcifications, it might be completely removed by the stereotactic biopsy, making it difficult to relocalize the lesion if the pathology is malignant. We did not find that to be a problem. There is always a small amount of bleeding that serves as a marker of the site of the biopsy. [SLIDE] This is an example of a small cluster of microcalcification and this is the local bleeding that occurs, which can be localized by wire when we go back to perform the definitive local excision. Also we can leave surgical clips or medical carbon at the site.

The other issue is about highly suggestive mammographic lesions. The argument is, if the lesion is highly suggestive, should we add a step by doing the stereotactic biopsy or go straight to needle localization biopsy, which might serve as the definitive local surgical treatment. There is a significant proportion of those patients who turn out to have benign pathology and should not be denied the benefit of the stereotactic biopsy. Also, it has been shown in 1 study that patients who undergo stereotactic biopsy have an average of 1.25 surgical procedures and patients who undergo excisional biopsy with wire localization have an average of 2.01 surgical procedures.

Cost-effectiveness: the procedure will not be cost-effective if the threshold to biopsy probably benign lesions is lowered. In this series we stick with the same protocol that we had before starting to use stereotactic biopsy. Only patients with suspicious and highly suggestive lesions undergo stereotactic biopsy.

Should the surgeon be removed? I don’t think so. This is a joint effort between the radiologist, the surgeon, and the pathologist.

The positive predictive value of 16%. We have not evaluated our positive predictive value of excisional biopsy with needle localization. However, since we did not change our indications for biopsy of mammographic lesions, we do not believe the positive predictive value of needle localization biopsy to be significantly different from that of stereotactic biopsy.

Premalignant lesions: we do not accept a diagnosis of premalignant lesion on stereotactic biopsy as the final diagnosis. For example, in Burbank’s classification, DCIS with comedo necrosis and low nuclear grade, and atypical hyperplasia are included in the premalignant group. Because of the frequent association of the former with invasive cancer and the difficulty of distinguishing the latter from DCIS, we always follow by performing excisional biopsy with needle localization.