Stereotactic Breast Biopsy: A Surgical Series

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Background: Stereotactic core needle biopsy (SCNB) is increasing in popularity and is currently being performed by both radiologists and surgeons. It has been shown to be accurate and cost effective, but the appropriate use of SCNB in the probably benign mammographic lesion has not been determined. Nor has it been determined whether a learning curve affects performance of the procedure.

Study Design: The records of all patients undergoing SCNB by the author from August 1993 through May 1996 were reviewed. Two hundred forty-two patients underwent 244 procedures. Indications for biopsy, results, and complications were examined.

Results: Probably benign mass was the most common indication for biopsy (45%), and microcalcifications were the indication for biopsy in 24%. A diagnosis of cancer was made in 11.1%. Patients with microcalcifications and probably benign masses were diagnosed with cancer in 18.4 and 1.8%, respectively. Three of eight patients undergoing open biopsy for atypical hyperplasia were diagnosed with cancer. Accuracy rate for the entire series was 97.7%. The effect of operator experience on the indication for SCNB was studied. As experience increased from the first to the last third of the study, microcalcifications as an indication increased from 23.5–37.5%. During this same time period, "probably benign" mass decreased from 53.1–32.5%.

Conclusion: This study demonstrates that accuracy of this surgical series is comparable to other published series. Biopsies for more difficult lesions were noted to increase as operator experience increased. It was likely that this "learning curve" was owing to improvements in technique and an increased confidence in the accuracy of the procedure. With an incidence of cancer of less than 2% in patients with a probably benign mass, interval mammography represents for many, a cost-effective alternative. (J Am Coll Surg 1997;185:224–228. © 1997 by the American College of Surgeons)

Stereotactic core needle biopsy (SCNB) of the breast has been shown to be accurate and cost effective (1–3). For many, it has become a reliable alternative to open biopsy for mammographically detected lesions (4, 5). The procedure, although pioneered by radiologists, is now performed by radiologists and surgeons (6). Whether this trend will continue or whether one specialty will become the primary provider of SCNB has yet to be determined. In addition to which specialty will perform the procedure, the use of SCNB for the probably benign mammographic lesion has also generated controversy. Whether core biopsy should replace the interval mammogram for these low-risk lesions has not been decided. This study was undertaken to examine the accuracy of a surgical series of SCNB, and to determine whether a learning curve might exist for the physician performing it. It was also hoped that some insight might be gained about the role of SCNB in the diagnosis of probably benign mammographic lesion.

Methods

The author began to perform stereotactic core needle biopsy in August 1993. From August 1993 through May 1996, 242 consecutive patients underwent 244 procedures. These patients comprise the study group. The records of these patients were reviewed for the indications that led to the decision to biopsy, the results of the biopsies, and any complications that occurred. Data were analyzed using the Pearson chi-square test, and significant differences were defined as $p < 0.05$. All procedures were performed on a dedicated prone stereotactic table (Fischer Imaging Corp, Denver, CO). Until early in 1996 all biopsies were performed with a spring-loaded 14-gauge needle. Subsequently a mammotome (BiopsysMedical Inc, Irvine, CA) was used for microcalcifications and a 14-gauge needle continued to be used for a majority of the other lesions. A minimum of 5 core biopsy samples were taken from each patient. More biopsy samples were taken if necessary to demonstrate calcifications. All specimens were submitted in formalin for permanent section.

Table 1. Indications for Stereotactic Biopsy and the Incidence of Cancer

Indication for biopsy	No. of patients (%)	No. of cancers (%)
Suspicious/indeterminate mass	49 (20.3)	9 (18.4)
Microcalcifications	58 (24.0)	10 (17.2)
Mass and calcifications	7 (2.9)	2 (28.6)
Probably benign mass	109 (45.0)	2 (1.8)
Asymmetric density	15 (6.2)	3 (20.0)
Architectural distortion	4 (1.6)	1 (25.0)
Total	242 (100)	27 (11.2)

Table 3. Indications for Open Surgical Biopsy After Stereotactic Core Biopsy and Incidence of Cancer

Indications	No. of patients	No. with cancer (%)
Lack of correlation	4	2 (50)
Atypical hyperplasia	8	3 (37.5)
Patient factors	2	0
Technical factors	5	1 (20.0)
Increase size of mass	2	0
No calcium in specimen	1	0
Other	1	0
Total	23	6 (100)

Results

The indications for stereotactic biopsy and the incidence of cancer for each indication are shown in Table 1. For this study, probably benign mass was defined as a sharply circumscribed mass (round, oval, or lobular) with no malignant characteristics. This indication was the most common, accounting for over 108 (44.6%) of all patients with 2 such patients (1.8%) showing malignancy. In many instances, patient preference led to stereotactic biopsy in place of interval mammography. The results of stereotactic biopsy for probably benign lesions are shown in Table 2. Fibrocystic change and fibroadenoma made up more than 60% of these lesions. Microcalcifications accounted for approximately 58 (24%) of the series with suspicious or indeterminate lesions making up slightly more than 49 (20%). The incidence of cancer for these indications was 17.2% and 18.4%, respectively. Biopsy specimens from 2 of 7 patients with mass and calcifications showed malignancy. Four of the remainder showed fibrocystic change, and there was 1 fibroadenoma showing nondystrophic calcifications. In 19 of the 58 patients with microcalcifications biopsies were performed with the mammotome, but in the remaining 39 patients, a standard 14-gauge needle with multiple

Table 2. Results of Stereotactic Core Biopsies

Results	No. of patients (%)
Cancer in situ	10 (4.1)
Invasive cancer	17 (7.0)
Fibroadenoma	43 (17.8)
Benign	30 (12.4)
Fibrocystic change	90 (37.2)
Atypical hyperplasia	12 (5.0)
Cyst	11 (4.5)
Papilloma	2 (0.8)
Radial scar	1 (0.4)
Calcium in skin	2 (0.8)
Intramammary node	4 (1.7)
Not completed (technical)	20 (8.3)
Total	242 (100)

passes was used. The single failure to show microcalcifications in the specimen x-ray occurred in the group in which a 14-gauge needle was used. No conclusions could be reached regarding the efficacy of these two biopsy techniques. The results of SCNB are shown in Table 2. A diagnosis of carcinoma was made in 11.1%, 10 patients had carcinoma in situ, and 17 patients showed invasive carcinoma. A benign diagnosis was reported in 181 patients (74.8%), with atypical hyperplasia reported in 12 patients. Twenty-two procedures were not completed. Of these, clustered calcifications were noted in the skin in 2 patients before placement of the needle, and in 20 patients biopsy could not be completed for technical reasons. In a majority of these patients it was because the mammographic lesion could not be visualized. In most instances this represented asymmetric densities or extremely fine calcifications. Seventeen of these procedures occurred early in the study, while only 3 occurred in the last 12 months of the study. Of the 20 patients whose procedures were not completed for technical reasons, 15 were followed by interval mammogram and 5 underwent open biopsy. Fourteen of the 15 patients not undergoing biopsy had at least 1 mammogram with no detrimental changes. The remaining patient had a well defined mass that was noted not to be present on the scout film before the patient's biopsy. Of the 5 patients undergoing open biopsy, 4 had benign tumors and 1 had a malignant tumor. The 1 malignant tumor in this group was found in a 41-year-old woman who underwent SCNB for an asymmetric density. A hematoma developed rapidly after the first core was taken, and the procedure was terminated. She did not require an operation to resolve the complication but was noted to have cancer at an open biopsy 1 week later.

Twenty-three patients underwent open surgical biopsy within several weeks following SCNB. The indications for open biopsy are listed in Table 3. A total of 6 (26.1%) patients were diagnosed with cancer in this group. Two of the 4 patients whose

Table 4. Indications for Stereotactic Biopsy as a Function of the Number of Procedures Performed

Indications	Group 1 patients 1–81 (%)	Group 2 patients 82–162 (%)	Group 3 patients 163–242 (%)
Suspicious or indeterminate mass	15 (18.5)	20 (24.7)	15 (18.8)
Microcalcifications	9 (11.1)	19 (23.5)	30 (37.5)
Mass and calcifications	4 (4.9)	2 (2.5)	1 (1.3)
Probable benign mass	43 (53.1)	39 (48.1)	26 (32.5)
Asymmetric density	9 (11.1)	1 (1.2)	5 (6.3)
Architectural distortion	1 (1.2)	0	3 (3.8)
Total	81 (100)	81 (100)	80 (100)

core biopsy did not correlate with mammographic findings were found to have cancer. One patient's tumor was found to be malignant when SCNB was not completed because of a complication. The remaining 3 cancers were diagnosed from a group of 12 patients noted to have atypical hyperplasia on core biopsy (Table 3). Eight of the 12 patients with atypical hyperplasia underwent open biopsy; 3 were diagnosed with cancer. All had ductal carcinoma in situ, 1 with microinvasion. Those who did not undergo open biopsy had very mild atypia or focal atypia.

To study whether the experience of the operator affected the indications for biopsy, the series was divided into three groups (Table 4). Group 1 represents the first 81 procedures. Group 2 is comprised of the second 81 procedures, and group 3 the final 80 procedures. As the series progressed, there was a significant difference noted in the number of procedures done for both microcalcifications and probably benign mass (p = 0.002). Microcalcification as an indication for SCNB was noted to be 11.1% in the first 81 procedures. This indication had increased to 23.5% in group 2, and to 37.5% in the final 80 patients. Similarly, probably benign mass as an indication decreased steadily over the study period, beginning at 53.1% for the first group and accounting for 32.5% of the last 80 procedures.

Of the entire series of 242 patients, 171 (70.7%) returned for mammographic followup. Average followup time for the entire group was 9.0 months. Excluding patients diagnosed with cancer and those not having a repeat mammogram, average followup time was 12.8 months (range, 6–39 months). Of the 220 patients whose biopsies were successfully completed, the results of SCNB were noted to be true negative in 188 (85.4%), true positive in 27 (12.3%), and false negative in 5 (2.3%). All 5 patients with false-negative biopsy specimens promptly underwent open biopsy, and a diagnosis was made with minimum delay.

Discussion

This study consisted of 242 patients undergoing stereotactic breast biopsy by one surgeon. The accuracy rate for this study was 97.7% (number of cases diagnosed correctly/total number of patients in the study) and is comparable to other surgical and radiologic series (4, 5, 7). There was no false positive finding, but there were 5 false negative findings. All 5 patients with falsely negative pathologic reports underwent open biopsy almost immediately to confirm the diagnosis. There was one complication in the series, which did not require surgery for management. In dealing with microcalcifications, only 1 of 58 procedures failed to demonstrate calcifications on specimen radiograph. This single patient underwent open biopsy, and the specimen was benign. Nineteen of the 58 patients with microcalcifications had the biopsy performed with the mammotome, and in the remaining 39 patients, biopsies were performed with a standard 14-gauge needle and multiple punctures. The single failure to show microcalcifications occurred in the group in which a 14-gauge needle was used. No conclusions could be reached regarding the use of these two biopsy techniques.

Based on this study, the diagnosis of atypical hyperplasia continues to demonstrate high rates of carcinoma when open biopsy was performed. In our series three of eight patients undergoing open biopsy for atypical hyperplasia were diagnosed with cancer. This is consistent with other studies showing a 30–50% malignancy rate when open biopsy is carried out for atypical hyperplasia (7, 8). Whether all patients with atypical hyperplasia require open biopsy is unclear. For example, should patients with very mild or focal atypia undergo open surgery? This issue of focal atypia has not received mention in other series. In our series four patients with these findings did not undergo open biopsy. None as yet has been diagnosed with cancer, but followup is short.

Table 5. Indications for Stereotactic Biopsy as a Function of the Time Period in Which It Was Performed

Indications	Period 1 8/93–6/95 (%)	Period 2 7/95–6/96 (%)
Suspicious or indeterminate mass	35 (21.3)	14 (18.4)
Microcalcifications	29 (17.7)	29 (38.2)
Mass and calcifications	6 (3.7)	1 (1.3)
Probably benign mass	83 (50.6)	24 (31.6)
Asymmetric density	10 (6.1)	5 (6.6)
Architectural distortion	1 (0.6)	3 (3.9)
Total	164 (100)	76 (100)

When case mix was examined over time (Table 5) it was noted that significantly more patients had biopsies for microcalcifications as case numbers increased. Conversely, probably benign lesions were biopsied much less frequently as time passed. It is likely that this change in case mix reflected the learning curve. In this instance, however, the learning curve might represent a curve of confidence as well as technical skills. With increasing experience and the associated increase in confidence in the accuracy of core biopsy, there was a shift toward using SCNB in cases that were technically more difficult and potentially more serious in outcome. Early in the series, larger, more easily biopsied lesions were selected until a certain comfort level was achieved. Of equal importance in the learning curve is case selection. All mammographic abnormalities are not easily visualized on stereotactic images. Only 3 of the 20 procedures that could not be completed were performed in the last 12 months of the study.

Brenner and colleagues also noted increasing accuracy with increased operator experience in all lesions, but this was most notable in patients with microcalcifications (9). Additionally, as the use of ultrasonographically-guided core biopsy began in the middle of 1995, many lesions including fibroadenomas were biopsied using this technique. This might have had an additional effect on decreasing the relative mix of suspicious and benign lesions.

In my study only 2 of 109 (1.8%) probably benign lesions were malignant. This figure is similar to those of Sickles (10) and Varas and colleagues (11) who reported for probably benign lesions a cancer rate of 1.4% and 1.6%, respectively. Certainly, the cost of SCNB cannot compare with the cost of an interval mammogram. It is likely that most physicians would accept a 1–2% cancer rate in this group of patients with interval mammographic surveillance. Yet all do not agree with Sickles that the followup mammogram is the procedure of choice for the probably benign lesion

(12, 13). In our study, the malignancy rate of 1.8% does not support the wholesale use of SCNB for these lesions. Additionally, the true denominator (total number of patients who were followed during this same time period with repeat mammogram) for this study is not known. It is therefore probable that the malignancy rate is considerably lower for this total group of patients. Cost, however, is not the only issue. The anxiety of women awaiting interval mammography cannot be quantified, nor is it likely that what Sickles calls a "confident and competent" explanation will satisfy all patients (14). Moreover, the threshold for reporting a lesion as "probably benign" might differ among radiologists. Each of these factors must be considered when advising a patient on treatment options. If cost was not a factor, SCNB is an almost ideal procedure for obtaining a diagnosis of the probably benign mammographic lesion. It is accurate, minimally invasive, and causes minimal discomfort. It is performed in the outpatient setting with a local anesthetic and is associated with no cosmetic deformity. In addition, it will provide the 1–2% of patients who indeed have cancer with an earlier diagnosis. Patients must therefore be individualized, with cost, patient, and physician factors all taken into consideration. Based on our study, however, a majority of these patients should be adequately treated with an interval mammogram.

There is little argument that SCNB for suspicious or indeterminate lesions is indeed appropriate and cost effective. A decrease in the overall number of operative procedures and a reduction in the reexcision rate has been reported in support of image-directed core biopsy (15, 16), but it has been argued in dealing with suspicious lesions that definitive breast conservation surgery can be performed as a surgical biopsy, saving the cost of SCNB. In performing definitive surgery as a surgical biopsy, one relinquishes the possible benefits of preoperative surgical planning. Some may feel that certain breast tumors, such as those with an extensive intraductal component and invasive lobular carcinoma, require larger volume excisions than other histologic types. If such a philosophy is followed, some of the resections will be for benign disease, and the patient will be left with at least some breast deformity. A preoperative needle biopsy allows a patient adequate time to make an informed decision. One might argue that patient education can occur in the preoperative setting, not unlike the days of operative frozen section and immediate mastectomy, but making an informed decision before a definitive diagnosis of cancer and making a decision after confirming the diag-

nosis are not equivalent. Good planning before a definitive operation seems a desirable outcome, as is giving a woman adequate time and information to make an educated decision about treatment options.

This study of SCNB demonstrates accuracy comparable to other surgical and radiologic series. It was also noted that as the operator experience increased, the incidence of the more difficult biopsies such as those for microcalcifications increased. This suggests a learning curve for using the technique and in confidence in the procedure. Based on cost and the accuracy of diagnosing the lesion that is likely to be benign, many of these lesions can best be treated with interval mammography, but patient anxiety and the physician's confidence in the mammographic interpretation of probably benign lesions must be considered.

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