ANNALS OF SURGERY
Vol. 223, No. 6, 688–700

Mammographically Detected Breast Cancer

Benefits of Stereotactic Core *Versus* Wire Localization Biopsy

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Objective
The authors evaluated the differences between stereotactic core needle biopsy (SCNBx) and needle localization surgical biopsy (NLBx) in cost and treatment course for patients with mammographically detected breast cancer.

Summary Background Data
Stereotactic core needle breast biopsy is a reproducible and reliable alternative to surgical biopsy for histologic diagnosis of mammographic lesions.

Methods
Records from 52 consecutive patients with invasive breast cancer diagnosed by SCNBx (n = 21) or NLBx (n = 31) over 2 years were reviewed. Episode-of-care costs were extracted from the Barnes Hospital billing system database.

Results
At the time of excision, surgical margins were statistically more frequently positive in patients treated with NLBx (55%) than patients treated with SCNBx (0%, $p < 0.0001$). Furthermore, patients in the NLBx group undergoing breast conservation surgery required re-excision more frequently (74%) than those in the SCNBx group (0%, $p = 0.001$). There were no complications in either group after the diagnostic procedure. All SCNBx results were correct in the diagnosis of invasive breast cancer. The median cost of SCNBx was approximately $1000 less than the median cost of NLBx. This cost difference was carried through the definitive procedure, whether it was breast conservation or mastectomy.

Conclusions
This study shows the advantage of SCNBx to diagnose breast cancer and definitive operative care at a single procedure. The preoperative diagnosis of breast cancer eliminated positive operative margins and procedures to re-excise breast tissue. The use of SCNBx also saved approximately $1000 per patient compared with the use of NLBx. Our data suggest that SCNBx is the diagnostic procedure of choice for mammographically detected cancers.

Screening mammography is a valuable technique for detecting small nonpalpable breast cancers, and it has been shown to have a marked impact on survival from breast cancer in a randomized clinical trial.[1] Tabar et al.[1] showed in one large study in Sweden that after 13 years of follow-up, breast cancer mortality was reduced by 30% using mammography every 2 years. With acceptance of the effectiveness of screening mammography has come a large increase in the number of mammograms performed and, thus, a large increase in the number of breast biopsies performed for mammographic abnormalities. Approximately 500,000 breast biopsies initiated by mammographic findings are performed in the United States each year; 60% to 90% of lesions are benign.[2] The surgical biopsy represents the largest fraction of induced costs of screening.[3]

Stereotactic core needle biopsy (SCNBx) is becoming accepted as an alternative to needle localization surgical biopsy (NLBx) for diagnosis in many circumstances. It decreases the time required for arranging and performing biopsy, diminishes the potential for complications and disfigurement for potentially benign lesions, decreases trauma to the patient, and shortens recovery time. The SCNBx procedure is more reliable and accurate than is stereotactic fine needle aspiration (SFNA)[4] and appears to rival the accuracy of NLBx, although there has been some controversy as to whether SCNBx is equivalent to NLBx.[5] We reviewed the literature regarding the accuracy of SCNBx and NLBx and evaluated the differences between SCNBx and needle localization surgical biopsy in cost and treatment course for patients with mammographically detected nonpalpable breast cancer.

MATERIALS AND METHODS

Records from 21 consecutive patients with invasive breast cancer diagnosed by SCNBx from December 1993 to September 1995 from 1 hospital (Barnes Hospital, St. Louis, MO) were reviewed. Records from 31 consecutive patients with invasive breast cancer diagnosed by NLBx between May 1993 and May 1995 and managed by 1 of 4 surgeons (D.R., J.L., J.A.N., G.M.D.) at the same hospital were reviewed for comparison. Patients with ductal carcinoma *in situ* (DCIS) only were excluded. Mammographic lesions were categorized as probably benign, indeterminate, or high-suspicion lesions based on the mammographic characteristics. All patients in this study had indeterminate or high-suspicion mammographic abnormalities. The indications for SCNBx were identical to the indications for NLBx, and the decision to perform one or the other was determined primarily by patient or referring physician preference. The data extracted from the records included demographic characteristics, prebiopsy mammographic evaluations, biopsy procedure and pathology reports, definitive therapy operative and pathology reports, and the hospital course.

Episode-of-care resource consumption data for biopsy and definitive therapy were extracted from the Barnes Hospital billing system database. Figures for selected cost centers (such as radiology, anesthesiology, and operating room) were recorded separately and analyzed in addition to the total cost for the episode of care. Preoperative tests were included. Professional fees and outpatient clinic visit costs were not included.

Stereotactic breast biopsy was performed using a dedicated prone biopsy table (Lorad, Danbury, CT). The patient was placed in the prone position, and the lesion was identified using digital mammography. The breast was cleansed and prepared using povidone–iodine solution. The predetermined point of biopsy was marked on the stereo images, and computer-generated coordinates for the lesion were made. Local anesthetic was infiltrated into the skin and subcutaneous tissue. A small incision was made in the skin, and a 14-gauge needle in an automated longthrow biopsy gun (Manan, Northbrook, IL) was placed in the incision. The needle was positioned according to the coordinates, prefire stereo pair images were obtained to validate needle position, and biopsy specimens then were obtained. A median of 5 cores was obtained with a range of 3 to 8. Digital stereo pair images were obtained after the first and last biopsy to confirm that the lesion had been traversed. A typical procedure took 40 to 50 minutes, although the actual biopsy procedure time was shorter. On occasion, the procedure was performed on the same day as was the mammogram.

Data were evaluated for statistical difference with Fisher's exact test for comparison of ratios and the Mann–Whitney *U* test for comparison of nonparametric data.

RESULTS

The median age of the SCNBx group was 66 years (range, 50–86), which is statistically different from the NLBx group (median, 57; range, 37–82 years, $p < 0.05$).

Table 1 lists the mammographic findings leading to biopsy in these patients. Because the inclusion criteria stipu-

Presented at the 107th Annual Session of the Southern Surgical Association, December 3–6, 1995, Hot Springs, Virginia.

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Accepted for publication January 23, 1996.

Table 1. MAMMOGRAPHIC FINDINGS LEADING TO BIOPSY

	Diagnostic Procedure	
	SCNBx (N = 23 lesions)	NLBx (N = 32 lesions)
Abnormality		
Mass	18	24
Microcalcifications	1	2
Mass + microcalcifications	4	6
Suspicion for malignancy		
High suspicion (BI-RADS 5)	15	19
Indeterminate (BI-RADS 3-4)	8	13

SCNBx = stereotactic core needle biopsy; NLBx = needle localization surgical biopsy; BI-RADS = Breast Imaging Reporting and Data System.

Table 2. PATHOLOGIC FINDINGS FROM BIOPSY AND DEFINITIVE THERAPY

	Diagnostic Procedure	
	SCNBx (N = 21 patients)	NLBx (N = 31 patients)
Histologic classification		
Ductal adenocarcinoma	19	27
Lobular adenocarcinoma	1	2
Tubular adenocarcinoma	1	2
DCIS present	12	23
Multicentric disease	3	2
Tumor size median (range)	10 mm (2–30 mm)	8 mm (1–26 mm)
Positive lymph nodes	3	2
Stage		
I	17	27
II	4	4

SCNBx = stereotactic core needle biopsy; NLBx = needle localization surgical biopsy; DICS = ductal carcinoma *in situ*.

lated invasive carcinoma, few patients presented with microcalcifications in this study. Two patients in the SCNBx group had two mammographic lesions in different areas of the breast; both lesions in both patients were biopsied by SCNBx. One patient in the NLBx group also had two mammographic lesions; these lesions were biopsied by two separate NLBxs. The distribution of abnormalities and initial suspicion for malignancy by mammogram were rather similar for both the SCNBx and NLBx groups. Most invasive cancers were high-suspicion lesions on mammogram before biopsy for both groups, although a substantial number of invasive cancer diagnoses arose from indeterminate mammograms.

Histopathologic findings from biopsy and definitive therapy are catalogued in Table 2. All SCNBx and NLBx results were correct in the diagnosis of invasive breast cancer. There was one discrepancy in the SCNBx group; the biopsy was interpreted as invasive lobular carcinoma, but the mastectomy specimen was found to have invasive ductal carcinoma and DCIS with possible lobular carcinoma *in situ* as well. Two patients received a diagnosis of invasive carcinoma without histologic classification on SCNBx. In addition to the histologic classification, a Page & Anderson grade was given on SCNBx specimens for 17 patients. The biopsy grade was the same as the final grade in 11 patients and different from the final grade in 6 patients. Finally, estrogen receptor/progesterone receptor status was accurately determined by immunocytochemistry for nine patients from SCNBx specimens.

Of the patients who received breast conservation, 5 of 7 (71%) patients whose cancer was diagnosed by SCNBx had coincident DCIS, and 14 of 19 (74%) patients whose cancer was diagnosed by NLBx had coincident DCIS in addition to invasive cancer.

All three patients with two separate mammographic lesions had multicentric disease, but one additional patient in the SCNBx group and one additional patient in the NLBx group were found to have multicentric disease. Tumor size, lymph node metastasis, and stage of the cancer were similar between the SCNBx and NLBx groups.

Table 3 lists the clinical course for the SCNBx and NLBx groups. At the time of excision, surgical margins were statistically more frequently positive in patients who received NLBx (55%) than in patients who received SCNBx (0%).

Table 3. CLINICAL COURSE

	Diagnostic Procedure		
	SCNBx (N = 21)	NLBx (N = 31)	p Value
Margins after first excision			
Positive*	0	17	<0.0001
1–3 mm	1	6	
3–5 mm	2	1	
≥5 mm	14	1	
Negative, not specified	4	6	
Breast conservation			
N	7	19	
Reexcision	0	14	0.0012
Axillary dissection only	0	5	
Mastectomy			
N	14	12	

SCNBx = stereotactic core needle biopsy; NLBx = needle localization surgical biopsy.
* Tumor 1 mm or less from margin.

Table 4. HOSPITAL COSTS OF STEREOTACTIC CORE NEEDLE BIOPSY *VS.* NEEDLE LOCALIZATION SURGICAL BIOPSY

	Diagnostic Procedure			
	SCNBx Cost ($) Median (Range)	NLBx Cost ($) Median (Range)	Difference ($)	p Value*
Cost of Dx procedure	549 (484–670)	1570 (1018–2099)	1021	<0.0001
Dx procedure + BC	3861 (3513–4626)	5030 (4294–6338)	1169	0.0001
SCNBx + BC *vs.* NLBx + axillary dissection only	3861 (3513–4626)	5084 (4294–6338)	1223	0.01
Dx procedure + mastectomy	4189 (3262–8125)†	6053 (4707–9448)‡	1863	0.02

SCNBx = stereotactic core needle biopsy; NLBx = needle localization surgical biopsy; BC = breast conservation.
* Mann-Whitney *U* Test.
† One patient excluded for unrelated cost (extensive work-up diagnosed gout).
‡ One patient excluded for excessive cost (>$20,000) due to complication (myocardial infarction) after definitive therapy.

Furthermore, the distance of the tumor from the surgical margin for patients in the SCNBx group was greater as a whole than the distance for patients in the NLBx group in whom margins were negative and the distance was specified.

Patients in the NLBx group undergoing breast conservation surgery also required re-excision more frequently (74%) than did those in the SCNBx group (0%). Only five patients (26%) received axillary dissection alone as the second operation in the NLBx group. All other patients in the NLBx group received either re-excision of the NLBx site with axillary dissection or mastectomy.

Table 4 lists the hospital costs of SCNBx versus NLBx. The median cost of SCNBx was approximately $1000 less than the median cost of NLBx; this was statistically significant. This cost difference was carried through the definitive procedure regardless if breast conservation or mastectomy followed the diagnosis.

The need for re-excision of breast tissue at the second operation in the NLBx group did not add demonstrably to the monetary cost, as those NLBx patients who required axillary dissection only at the second operation had no difference in cost from the NLBx/breast conservation group as a whole. The NLBx/axillary dissection only subgroup still had a substantially higher cost than did the SCNBx group ($p = 0.01$).

Table 5 lists the breakdown of the hospital cost in greater detail. For both breast conservation and mastectomy, the SCNBx group had lower costs in operating room, recovery room, and anesthesia than did the NLBx group within their respective form of definitive therapy. The radiology costs were greater in the SCNBx group versus those in the NLBx group.

DISCUSSION

This study presents data regarding the treatment course and treatment cost for patients with invasive breast cancer diagnosed by SCNBx of the breast and by conventional NLBx. There appear to be advantages to using the SCNBx to diagnose nonpalpable breast cancer. There was a substantial and statistically significant improvement in the surgical margins achieved when the diagnosis of breast cancer was known before operation, and the need for re-excision of breast parenchyma as a part of breast conservation was eliminated. Most patients required only one trip to the operating room for their definitive operation rather than separate trips for the biopsy and the definitive procedure. Finally, the cost of diagnosis and definitive surgical treatment was decreased by approximately $1000 per patient. The use of SCNBx for these patients requires the surgeon to understand several important issues.

Accuracy

Accuracy has been the greatest focus of comparison between SCNBx and NLBx. This is vitally important because SCNBx can only be used in place of NLBx if the patient still receives timely, appropriate therapy. Table 6 lists the literature that has evaluated the reproducibility and accuracy of SCNBx to diagnose both benign and malignant breast lesions found on mammograms.[4,6–16] Only cases in which surgical follow-up was performed, not clinical follow-up alone, are shown. Histologic agreement here is the definitive histopathologic diagnosis (such as fibroadenoma or invasive ductal carcinoma) on SCNBx, which agrees with the final surgical pathologic analysis. The SCNBx "true" miss rate is the percentage of patients who received a diagnosis by SCNBx that would not have led to timely, appropriate therapy and is roughly equivalent to the false-negative rate plus the false-positive rate. Diagnoses such as insufficient samples, "benign nondiagnostic," and incor-

Table 5. BREAKDOWN OF HOSPITAL COSTS BY CATEGORY

	SCNBx + BC ($)*	NLBx + BC ($)*	SCNBx + MRM ($)*	NLBx + MRM ($)*
Hospital room/board	636 (254–746)	651 (329–1574)	954 (205–1615)	972 (651–1937)
Operating room	1188 (917–1517)	1868 (1577–2273)	1529 (1023–3725)	2443 (1701–4802)
Recovery room	295 (243–348)	413 (303–659)	288 (199–591)	421 (362–632)
Anesthesia	443 (276–517)	530 (340–720)	405 (318–961)	598 (446–795)
Radiology	747 (411–860)	293 (223–953)	474 (380–1092)	270 (223–813)
Surgical pathology	383 (342–478)	334 (154–535)	395 (224–602)	382 (200–726)

SCNBx = stereotactic core needle biopsy; BC = breast conservation; NLBx = needle localization surgical biopsy; MRM = mastectomy.
*Median (range).

rect benign diagnoses (*e.g.*, fibroadenoma, which was actually fibrocystic disease) that would have led to the correct therapy even if surgical confirmation was not performed were not included as true misses. In many (but certainly not all) of these cases, further diagnostic workup would have to have been performed.

Two special situations should be recognized. First, diagnosis of atypical hyperplasia on SCNBx has been

Table 6. ACCURACY OF STEREOTACTIC CORE NEEDLE BIOPSY: REVIEW OF LITERATURE

Study	No. of cases (Surgical Confirmation Only)	Number of Cancers	Needle Size (gauge)	Histologic Agreement (%)	SCNBx "True" Misses (%)	Comment
Parker et al. (1990)[6]	102	16	14–20	87	1	1 insufficient tissue; 1 cancer found by SCNBx was missed by NLBx but confirmed by MRM; 1 missed DCIS
Dowlatshahi et al. (1991)[7]	250	76	20	67	7.6	43 insufficient samples, 11 of which were cancers; only 2–3 cores taken
Parker et al. (1991)[8]	102	23	14	96	2	2 fibroadenoma were normal; 1 read as normal was carcinoma
Dronkers (1992)[9]	53	45	18	91	3.7	3 insufficient samples, 2 of which were cancer
Elvecrog et al. (1993)[10]	100	36	14	94	1	One miss was microcalcifications; no specimen radiograph
Gisvold et al. (1994)[11]	160	65	14	87	4.3	
Mikhail et al. (1994)[12]	60	26	14	95	0	3 patients had small malignant lesions on biopsy only, not in mastectomy specimen
Parker et al. (1994)[13]	1363	910	14	90	1.1	25% of cancer found by US guided CNBx; 9.2% included atypical hyperplasia with DCIS and/or invasive cancer
Sullivan (1994)[4]	50	NA	14	98	0	1 patient had atypical hyperplasia in 3 cores, actually invasive cancer
Cross et al. (1995)[14]	66	NA	14	100	0	
Pitre et al. (1995)[15]	30	8	NA	100	0	
Iorianni et al. (1995)[16]	102	20	14	81	0	13 "benign nondiagnostic" were fibroadenoma or fibrocystic disease; 2 read as DCIS had invasive cancer as well.

SCNBx = stereotactic core needle biopsy; NLBx = needle localization surgical biopsy; MRM = mastectomy, median (range); DCIS = ductal carcinoma *in situ;* US = ultrasound; CNBx = core needle biopsy; NA = not applicable.

found frequently to be cancerous on surgical confirmation and should always be excised.[4,17,18] In one study, 9 of 16 specimens diagnosed as atypical hyperplasia on SCNBx were found to be cancerous after surgical biopsy.[17] Second, DCIS diagnosed by SCNBx is associated with invasive cancer on surgical confirmation in a significant proportion of cases. Jackman et al.[17] showed that 8 of 43 SCNBx biopsies with DCIS had associated invasive cancer identified at excision. These lesions would have been excised anyway but might have led to another separate procedure (axillary dissection) when the invasive cancer was identified in the excised specimen. Lesions diagnosed incorrectly as atypical hyperplasia or DCIS without invasion as above were not considered true misses on Table 6 because subsequent excision and appropriate definitive therapy are assumed.

The technique of SCNBx is important in ensuring accuracy. Initial studies in this field used smaller gauge[18–20] core biopsy needles; this resulted in a higher insufficient sample rate as well as poorer histologic agreement and has largely been abandoned. The 14-gauge needle allows for a good core to be visualized grossly when the sample is sufficient. Whereas the two early studies with smaller core needles[7,9] had substantial numbers of insufficient samples (6–17%), more recent studies with larger needles and more cores per sample have decreased this to <1%. Thus, in reports since 1993, the insufficient sample rate has been reduced to nearly 0% and the histologic agreement rate is greater than 87%, with a rate of diagnosis that would have led to correct therapy approaching 100% in most studies.

There have been essentially no false-positives reported; that is, there have been no cancers seen on core biopsy that were not confirmed by surgery or thought strongly to be present in the core despite absence from the surgical specimen after definitive therapy (very rare). This means no patient would receive an unnecessary axillary dissection or mastectomy if definitive therapy is based on the result of the SCNBx.

Comparison with Stereotactic Fine Needle Aspiration

It has become clear that SCNBx is superior to SFNA, which has higher false-negative and inadequate sampling rates, as well as an occasional false-positive result. Approximately one quarter to one third of patients with SFNA receive a nondiagnostic or erroneous result.[4] Furthermore, SFNA cannot diagnose invasion or grade and has poor ability to make a definitive benign diagnosis. Also, there is a lack of widespread cytologic expertise, which is needed for histopathologic assessment of SFNA but not needed for SCNBx.

Comparison with NLBx

The SCNBx miss rate is of greatest concern because patients with unsampled cancers would not receive timely, appropriate therapy. The SCNBx miss rate has been compared favorably with NLBx, which frequently has been quoted to have a miss rate (the rate of missing the intended lesion at biopsy) from 0.2% to 20% when compared with SCNBx.[13] However, a recent review of 17 studies in the literature summarized the average miss rate to be 2.8%.[19] In most cases, the NLBx miss should have been immediately evident from a specimen radiograph after excision and would then prompt further tissue sampling and possibly further localization. However, a specimen radiograph may not be taken, the lesion may not be identifiable for biopsy after the breast parenchyma is disturbed, or the specimen radiograph may actually give false confirmation of a successful biopsy when the lesion actually was missed. Thus, only lesions that are missed and do not receive specimen radiograph or lesions that are missed despite a specimen radiograph should be included in the true miss rate.

In one study, the records of patients with NLBx in which specimen radiograph and postprocedure mammogram were always performed were reviewed. In this study, postoperative mammogram 3 months later showed that 3 of 192 NLBxs missed the lesion despite having been confirmed as being present in the specimen radiograph, and another 5 were missed that were known to have been missed by specimen radiograph and the lesion still was not biopsied. This would give a true miss rate of 4.2%, which could be reduced to 1.6% if lesions that were known to have been missed were repeatedly biopsied with ultimate success.[20]

It is clear that although NLBx is considered the "gold standard," it is not perfect, and if SCNBx can approach a true miss rate as low as 1% to 3% as seen in the most recent studies, it can replace NLBx for first-line histopathologic diagnosis of nonpalpable mammographic lesions. Furthermore, NLBx can be used for questionable cases after SCNBx is performed. However, accuracy remains a concern; even a slightly greater miss rate may have a substantial impact on the value of the test because the margin of benefit is narrow for earlier detection.[5]

Indications

There has been some controversy regarding the indications for SCNBx. Radiologists recommend biopsy based on the level of suspicion associated with a mammographic lesion.[4] Lesions can be classified as probably benign, indeterminate, and high-suspicion lesions based on their mammographic characteristics. The American

College of Radiology Breast Imaging Reporting and Data System (BI-RADS) suggests a standardized method of breast imaging reporting and can be correlated with this classification.[21] Probably benign masses (BI-RADS 2) have round contours, well-circumscribed borders, no calcifications, and remain unchanged on repeat mammogram. Microcalcifications also can be characterized morphologically using spot-compression and magnification mammography. The likelihood of malignancy can be stratified by experienced radiologists. For example, clusters of tiny, round calcifications also may be considered probably benign. The likelihood of malignancy in well-studied, probably benign lesions is <2%. Indeterminate lesions (BI-RADS 3–4) do not have the characteristic morphologies of breast cancer but are sufficiently suspicious to recommend biopsy. High-suspicion lesions (BI-RADS 5), such as spiculated masses, do have characteristic morphologies of breast cancer and have a high probability of being cancerous, on the order of approximately 80%.[4,21,22]

Probably Benign Lesions (BI-RADS 2)

Lesions classified by mammographic evaluation as probably benign should usually undergo periodic mammographic follow-up rather than biopsy, because 1) it is less expensive than SCNBx; 2) most lesions that are actually malignant will be identified by mammographic follow-up before any other sign or symptom of breast cancer; and 3) lesions that are identified by follow-up to be cancer have an extremely good prognosis, with little benefit from an earlier diagnosis by SCNBx. However, SCNBx should be considered in patients who cannot be followed and in patients with extreme anxiety that would be alleviated by a negative biopsy.[23]

Indeterminate Lesions (BI-RADS 3–4)

Indeterminate mammographic lesions are generally considered to be the lesions most appropriately biopsied by SCNBx.[4,10] Patients with these lesions would most likely benefit from early detection by SCNBx. Based on the accuracy of the SCNBx, definitive benign diagnosis by SCNBx should eliminate the need for surgical biopsy. The frequency of benign diagnoses in this group would provide the greatest overall cost advantage.

The use of SCNBx for indeterminate lesions depends greatly on the accuracy of SCNBx. A lesion diagnosed as benign will receive only clinical and mammographic follow-up without surgical confirmation if the lesion is consistent with the initial mammographic findings. Any further surgical follow-up of benign lesions eliminates the cost advantage and actually increases the cost. For lesions that are shown to be malignant, however, the cost advantage is maintained, and in this study, SCNBx eliminated positive margins and re-excision of tissue and allowed for a single definitive operation.

High-Suspicion Lesions (BI-RADS 5)

Although the use of SCNBx for probably benign and indeterminate mammographic lesions seems clear, its role for high-suspicion mammographic lesions has been more controversial. Surgeon preference plays a large role in whether these lesions receive NLBx or SCNBx. The rationale for NLBx is that because high-suspicion lesions are more likely to be cancerous, they would have to be excised anyway, and SCNBx would be an additional procedure and expenditure.[4,10] However, our study suggests that the best approach is initial SCNBx. If patients who have approximately an 80% chance of having cancer have NLBx for diagnosis, then approximately 80% of them will require a second operating room visit for definitive therapy. If the patient has SCNBx that shows malignancy, then she can consider her treatment options, review the implications of the various management strategies (mastectomy with or without various reconstructions, tylectomy with radiation, *etc.*), and make one definitive operating room visit. This is particularly advantageous for women who choose breast conservation.

Overall, 55% of patients who received NLBx in our study had positive margins, and an additional 19% of patients had tumor within 3 mm of the margins. This is consistent with most studies of margins for NLBx, with positive margins or residual cancer seen in 45% to 83% of patients (Mokbel et al., 45%[24]; Lee and Carter, 54%[25]; Solin et al., 63%[26]; Tafra et al., 76%[27]; and Ngai et al., 83%[28]). In addition, in our study, a mammographic diagnosis of high suspicion did not seem to significantly reduce the number of positive margins; 10 of 19 (53%) of high-suspicion lesions still had positive margins. However, a histologic diagnosis of invasive cancer by SCNBx completely eliminated positive margins in those women who chose breast conservation, and only one patient with a histologic diagnosis had tumor within 3 mm of the margins. This eliminates the need for re-excision operations and would be expected to improve cosmetic results.

These data are consistent with others' results regarding the value of a preoperative histologic diagnosis of cancer, which markedly reduces the incidence of positive margins and the need for re-excision. Cox et al.[29] showed that if patients were found to have breast cancer (both palpable and nonpalpable) by fine needle aspiration, only 12 of 233 (5%) of patients had residual cancer at the margins that would have required re-excision. This was compared with 99 of 169 (59%) cases of residual cancer found at their institution and 225 of 430 (52%) seen in patients from outside referrals. In another study, the practice of "lumpectomy," in this case, wider excision of a mam-

mographic lesion without a definitive histopathologic diagnosis with the intent to remove the lesion and enough breast tissue to provide adequate margins, was performed. Even with this practice, 27% of patients had positive or indeterminate margins, although this was much improved over the 83% seen in patients receiving "traditional" NLBx in this study.[28] It appears that a histopathologic diagnosis carries greater weight than does a mammographic diagnosis in influencing the extent of operative resection. It appears that the surgeon wants to avoid having made a large breast defect for a benign lesion even if the chance of the mass being benign is lower than approximately 20% (as for high-suspicion lesions). Furthermore, it is likely that the patient is willing to tolerate a larger breast defect if she knows the diagnosis is breast cancer.

High-suspicion mammographic lesions are usually malignant on biopsy. The SCNBx confirms the mammography and provides a definitive diagnosis to begin discussion of treatment alternatives with a patient before any surgery is performed. The surgeon then can perform definitive therapy in a single surgical procedure. Some of these high-suspicion lesions will have benign SCNBx results. Even though this is likely to be the correct diagnosis, surgical biopsy is recommended despite a benign needle biopsy finding because of the high probability of malignancy in this group. Strict adherence to the Rule of Concordance—that is, concordance of the physical examination, mammographic findings, and biopsy results—should help to avoid missed opportunities to cure cancer.

Another, less frequent, but clear indication for SCNBx is if there is more than one suspicious lesion on the mammogram of the same breast, as was seen in three patients in our study. All three patients received mastectomy, which is the usual course for patients with two separate cancers in different areas of the breast, and the cost savings was even greater because the cost savings from two biopsies were added.

Complications

There were no complications in this study, and complications in the literature have been extremely rare. In the series by Parker et al.[13] of 3765 cases with follow-up, only 6 complications (0.2%) were reported. Three were hematomas that required surgical drainage, and three were infections that required drainage or antibiotics or both.

There has been one report of malignant seeding of the needle track,[30] but in the series by Parker et al., of 3765 patients with surgical or clinical follow-up, no case of needle track seeding was reported, and there have been no other reports in the literature.[13] There was no evidence of seeding of the needle track in any of our patients. This is irrelevant for patients who receive mastectomy, and radiation therapy, which is required for breast conservation, usually includes the needle track. We also have attempted to include the SCNBx track in our breast excision for conservation therapy.

Cost

The cost of diagnosis and definitive surgical therapy in this study was substantially less for those patients diagnosed by SCNBx. We purposely did not include professional fees to accurately define hospital costs without the variability associated with such fees. However, if professional fees were included, the cost difference would be greater because NLBx would include additional anesthesia and surgical professional fees. Other studies that have included professional fees and used hospital charges (rather than costs) have projected an even greater savings.[15,31] For example, Pitre et al.[15] included hospital charges and professional fees and found a difference of $2756 (SCNBx, $834; NLBx, $3590); they did not follow costs after the diagnostic procedure. Other studies have estimated the charges of SCNBx to be one quarter to one third of NLBx.[18,31]

It seems obvious that SCNBx would cost less when a mastectomy is performed, because the clinical course is identical except for the diagnostic procedure, in which SCNBx costs less than NLBx. However, our study shows SCNBx savings also are carried through the definitive therapy when breast conservation is chosen. Even when margins are negative from NLBx and only an axillary dissection is required, SCNBx costs less when breast conservation (needle localization lumpectomy and axillary dissection) is performed as the definitive procedure, despite the additional procedure of SCNBx. This is because NLBx and axillary dissection are done in two separate surgical procedures, and the operating room, anesthesia, and recovery room costs for two separate surgical procedures far outweigh the costs of one somewhat longer surgical procedure and SCNBx. As seen in the breakdown of costs, the large cost advantage seen in operating room, anesthesia, and recovery room costs is somewhat reduced by the cost disadvantage seen in radiology and surgical pathology costs, but remains a significant cost advantage overall.

Finally, because mammographically high-suspicion lesions undergo NLBx if found to be benign on SCNBx, there is virtually no chance that SCNBx will result in a missed cancerous lesion (unless the NLBx also misses the lesion). Any controversy regarding the accuracy of SCNBx does not affect SCNBx for this group because

SCNBx is "backed up" by NLBx. A cost advantage still exists because most lesions are found to be malignant, and the NLBx is not necessary. The excess cost only occurs if the lesion is benign at NLBx because the SCNBx is superfluous in this circumstance. Based on our cost estimates, a cost advantage would be maintained for SCNBx of this group as a whole if SCNBx is able to diagnose greater than one third of the high-suspicion mammographic lesions as malignant. Because high-suspicion mammograms have approximately an 80% chance of being malignant, there is no question that SCNBx should be performed for high-suspicion mammograms from a cost perspective.

A recent study using a theoretical model suggested that the use of SCNBx instead of surgical biopsy in a mammographic screening program could lower the marginal cost per year of life saved by a maximum of 23%.[32] With 500,000 breast biopsies of mammographic lesions performed annually in the United States, the use of SCNBx could result in yearly savings of $500 million to $1 billion.[18,31]

CONCLUSION

This study has shown that making the diagnosis of breast cancer by SCNBx rather than by NLBx has advantages to the patient by decreasing the need for trips to the operating room, decreasing the incidence of positive margins at breast tumor excision, decreasing the need for breast parenchyma re-excision for breast conservation, and decreasing the cost of patient management by approximately $1000 per patient. The SCNBx should be used as the initial diagnostic procedure for women with indeterminate or high-suspicion lesions on mammogram. Careful attention must be paid to the technical aspects of SCNBx and the interpretation of some specific histopathologic results to ensure optimal patient management. Use of this strategy should decrease the number of NLBx necessary, improve the care, and decrease the cost of care for those patients who do have breast cancer.

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Discussion

DR. EDWARD M. COPELAND (Gainesville, Florida): Thank you, Dr. Haller. I was pleased to see this paper accepted for presentation, Dr. Yim and Dr. Norton, because I suspected it would stimulate a lot of discussion and, quite frankly, it has, by number of people listed to discuss it.

The issue is going to be how accurate the stereotactic biopsy will be when those lesions that are deemed initially negative are followed longitudinally by clinical methods rather than by immediate pathologic confirmation. Also, the accuracy of stereotactic biopsy as well as needle localization breast biopsy are, as all of you know, very operator dependent. As a rule, the initial reports of the efficacy of a new procedure come from institutions where the physicians have the most expertise and, consequently, the best results. We are currently in the initial phases of reporting about stereotactic biopsy. The next wave of reports may well be a plea to limit the procedure.

Across the country, a battle is being waged by surgeons and radiologists as to which specialists should do the procedure. Expensive courses for surgeons to take to learn the technique are sprouting up nationwide. Some of these courses are in the same locations as prior courses in laparoscopic surgery. Thus, the use of the technique will soon mushroom, and the threshold for stereotactic biopsy may be lowered. Already I have seen a patient in my office with three different areas of the same breast biopsied stereotactically, all benign.

The cost may be less at Washington University, but what about institutions where the patient gets the stereotactic biopsy followed by needle localization biopsy to find the nonpalpable cancer and then has a definitive oncologic procedure? In fact, Dr. Norton and Dr. Yim, how does your group handle this same situation: a nonpalpable lesion visible on mammogram which is biopsy-positive by stereotactic technique and then the patient is a candidate for segmental mastectomy? Do you not sometimes require needle localization to ensure that your segmental mastectomy in fact removes the lesion?

Why not do the needle localization initially for a highly suspicious lesion, obtain frozen section and proceed to a definitive oncologic procedure at the same time if indicated?

For palpable, highly suspicious lesions, I often do a core biopsy myself once the patient is on the operating table, obtain frozen section while the patient is being prepared and proceed with the indicated procedure, based on the frozen-section diagnosis, therefore, eliminating any cost whatsoever for a biopsy. Fine-needle aspiration in the office for palpable lesions still has a place in the treatment armamentarium because segmental mastectomy will confirm the diagnosis before axillary dissection at the same operation.

In our institution, a surgeon participates in the decision for all stereotactic biopsies which are then done by the radiologist. The technique is superb when used appropriately, as I am sure is the case at Washington University. I use it often for the indeterminate lesion, less frequently for the highly suspicious lesion and almost never for benign appearing lesions except in a circumstance where an older woman has her initial mammogram and has a lesion which appears to be an old, atrophic nonpalpable fibroadenoma. In that case, stereotactic biopsy confirms the diagnosis.

Thank you very much.

DR. R. PHILLIP BURNS (Chattanooga, Tennessee): Dr. Haller, Dr. Copeland, Ladies, and Gentlemen. I, too, wish to compliment Dr. Norton and his group on this presentation and look forward to publication of these data in the surgical literature. I also am proud of the program committee of the Southern Surgical for including this important topic on our program, because it is a very important issue to surgeons.

In fact, last night at the presidential reception, one of our colleagues who is very active in American College activities and other surgical association activities told me that in his state, the number one issue among general surgeons is stereotactic core-needle biopsy. The number two issue is ultrasound-directed breast evaluation and biopsy. He felt there was no third issue.

Earlier this year, our surgical faculty group purchased a stereotactic core-needle biopsy unit to add to an ultrasound unit that we already had been utilizing in our surgical clinic or office. Both units are installed in our surgical clinic and are utilized daily by our surgical faculty as an extension of their practice. Beginning with consecutive patients, April through September 1995, we have done 118 of these stereotactic core-needle biopsies, with a positivity rate of 17.8%. This compares almost identically with a 16.8% positivity rate at our institution previously published for needle localization breast biopsy. I believe that the utilization activity is reasonable, based on this comparison.

In keeping with Dr. Copeland's admonishment this morning regarding the closer we get to being history, the more we might appreciate it, we have pauseed to look back at the time frame of attitudes that have prevailed since I, and several of our faculty, started medical school regarding new technology and changes in surgery. As young students, the macho image of the surgeon impressed us. The disease processes and dynamics of treatment utilized by surgeons impressed us. But some of the remarks that we recall hearing from colleagues during the early 1970s and 1980s regarding new technology included, "I don't have time for that" (*i.e.*, angiography); "ultrasound is not of much use"; and "I don't have time for endoscopy." By the 1980s, many of us regretted having not been more intimately involved in the