Nonpalpable Breast Lesions At Biopsy

A Detailed Analysis of Radiographic Features

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Several studies have demonstrated that mammographic screening of asymptomatic women results in a lower mortality rate where breast cancer is concerned. Often, screening mammograms reveal a nonpalpable radiographic abnormality and the diagnosis must be determined by an excisional biopsy after radiographic needle localization. The mammographic features associated with 179 nonpalpable breast abnormalities biopsied after radiographic needle localization were carefully characterized. There were 41 carcinomas (23%) in the series. The aim of this study was to determine which radiographic findings, if any, strongly portend the presence of either a malignant or benign lesion. Mammographic features that were commonly associated with malignancy include a change from a previous mammogram, a distortion of the surrounding architecture, the association of a soft tissue density and calcifications, and the presence of more than ten calcifications in the lesion. The radiographic abnormalities which were more commonly associated with benign disease include well-defined densities without calcifications, asymmetric densities without calcifications, and abnormalities consisting solely of a focus of mammographic calcifications that have fewer than ten concretions. The incidence of malignancy in lesions having these mammographic characteristics was only 5.5%. On the basis of these results alone, no firm threshold for biopsy can be recommended. The risks of deferring biopsy until there is worsening of the mammographic image remains to be determined.

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BREAST CANCER IS THE MOST COMMONLY diagnosed solid tumor among women in the United States, and ranks second in deaths due to cancer.[1] The studies performed by the Health Insurance Plan of Greater New York demonstrate that mammographic screening of asymptomatic women coupled with physical examination reduces the rate of women who die of breast cancer.[2,3] This study, initiated in 1963, reported a 23% reduction in cancer-related deaths for the screened group relative to the control population. The improved diagnostic accuracy obtained by the use of mammography was established by the Breast Cancer Detection Demonstration Project (BCDDP). Here, mammography alone was responsible for the recommendation of biopsy in 44% of the cancers, and these patients had the lowest frequency of involved axillary lymph nodes.[4] Because of the improved prognosis of breast cancer detected at an early stage, the American Cancer Society has recommended frequent screening mammograms for women over 40 years old.[5]

As a result of the widespread application of mammography, clinicians are frequently faced with an asymptomatic patient who has a suspicious finding on her mammogram but who exhibits no mass or other physical evidence of breast cancer. Increasingly, these patients undergo a mammographically placed needle-directed biopsy of the suspicious region for a histologic diagnosis. Recent studies from several institutions found cancer in these nonpalpable mammographic lesions with frequencies ranging from 14 to 29%. Thus, mammography in the absence of physical findings is a sensitive but relatively nonspecific test for the detection of breast cancer. We and others have seen a marked increase in the number of women who undergo needle-directed biopsies, and the number of procedures is likely to increase further as the practice of routine screening mammography becomes more widespread.

The aim of this study was to determine mammographic characteristics providing increased diagnostic specificity, in order that needle-directed biopsies may be applied more selectively. The study used predefined mammographic criteria in a blind retrospective review of all preoperative mammograms obtained over a 2-year pe-

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TABLE 1. *Mammographic Characteristics*

Soft Tissue Lesions
Type
Mass
Asymmetric density
Architectural distortion
Definition (mass only)
Stellate
Irregular
Well-defined
Size
Arithmetic average of two dimensions in millimeters
Calcifications
Size
Fine (<0.4 mm)
Medium (0.4–0.9 mm)
Coarse (>0.9 mm)
Number
<5
5–10
>10
Distribution
Distance of scatter in millimeters
Shape
Regular
Irregular
Pleomorphic
Linear, branched castings

Each mammogram was reviewed by a radiologist who was blind to the final diagnosis. The radiologic soft tissue lesions and calcifications were characterized by the above criteria.

riod. A separate blind review of all operative pathology was done in parallel, and mammographic characteristics were then compared to pathologic findings.

Methods and Materials

Between June 1984 and July 1986, 178 women underwent needle-guided biopsy of clinically inapparent breast lesions at the Duke University Medical Center. The mammograms of seven patients were unavailable for review and the pathology slides of another three patients were likewise unavailable. This study concerns the remaining 168 patients, who underwent 179 biopsies.

Under mammographic guidance by standard methods a hook wire was placed in each patient by a radiologist.[6] The patient was then taken to the operating room where the excisional biopsy was performed either under general or local anesthesia. A specimen radiograph was obtained when the biopsy was performed for suspicious calcifications. The surgical procedure was continued until it was determined radiographically that the suspicious region was adequately excised.

The mammograms were performed by either the film-screen method (n = 55) or by xeroradiography (n = 124). Standard craniocaudal and mediolateral views were taken. Because of our referral patterns, 44 patients who arrived had had mammograms performed at other institutions. In 27 patients, the only films available for review were two views taken to confirm proper wire placement before the biopsy.

Approximately 70% of the films were examined by two radiologists who viewed the films together and agreed on the interpretation. The balance was read by each radiologist individually; in this subset, very little interobserver variability was seen. Each film was examined with a magnifying glass to ensure that no calcifications were missed. Finally, approximately 25% of the films were reinterpreted at a later time by one of the radiologists, in order to determine intraobserver variability. This was found to be minimal.

The spectrum of suspicious mammographic findings consisted of soft tissue abnormalities, suspicious patterns of calcifications, or a combination of both. Mammograms were reviewed using a check-list of predetermined characteristics, presented in Table 1. A mass was defined as a region of increased density with a distinct edge that would make it distinguishable from the surrounding breast tissue on both the craniocaudal and mediolateral views. An asymmetric density was defined as a region of increased density without a distinct edge, making it difficult to distinguish from the surrounding tissue, but which was clearly denser than the corresponding region of the contralateral breast. Finally, an architectural distortion in the absence of a discrete density was defined as a discontinuity, or a tenting, of the surrounding parenchymal features, when compared with the rest of the breast or to the contralateral breast.

The mass lesions were categorized as well-defined, irregularly defined, or stellate. A well-defined lesion was one in which at least 90% of the border of the density was clearly distinguished from the surrounding tissue on each of the mammographic views. A lesion in which less than 90% of the border was clearly distinguishable from the surrounding tissues was designated as irregularly defined. A mass lesion was considered stellate if linear structures radiated into the surrounding parenchyma.

Finally, the least and greatest dimensions of all lesions discrete enough to be measured were noted. For the purposes of this study, the size of the density was defined as the arithmetic mean of those two dimensions.

If calcifications were present in the suspicious region, their distribution, character, and number were noted (Table 1). The distribution of the calcifications refers to the area over which they were seen on the film. If any two calcifications were greater than 1 cm apart, they had a scattered pattern; if calcifications were within 1 cm of each other, a clustered pattern existed. In all cases, the actual distance over which the concretions were distributed was measured. The size of the calcifications was also characterized. Fine calcifications were those less than 0.4 mm in diameter, whereas coarse ones were greater than 0.9 mm. Medium calcifications were be-

tween 0.4 and 0.9 mm in size. If more than 20% of the calcifications were of a different texture than the rest, both categories were checked. The coarse calcifications were further characterized by their shape. Note was taken if they were either highly irregularly shaped or pleomorphic, or if they had a linear or branched appearance characteristic of intraluminal castings.[7]

Previous films, when available, were compared with current films, and any changes in the lesions were noted. In accordance with established practice, biopsies were generally recommended for any abnormality demonstrating advancing radiographic signs—that is, an increase in size, architectural distortion, or in the number of calcifications.

The microscopic slides from each biopsy specimen were reviewed blindly to determine the pathologic diagnosis. In the cases where the diagnosis was questionable, or when moderate to severe atypia or hyperplasia was present, the slides were reviewed by a second pathologist and a final diagnosis was agreed upon. In addition, one fifth of the remaining cases were reviewed by the second pathologist to ensure consistent pathologic interpretation of the specimens.

The Yates-corrected chi-squared test or Fisher's exact test was used to determine the statistical significance of categorical data. In cases where the mean values of two populations were compared, the two-tailed T test was used to determine significance. Statistical significance was defined at the $p = 0.05$ level.

Results

Pathology

Data from 179 needle-directed breast biopsies performed in 168 women for suspicious mammographic abnormalities were reviewed. In this series, 138 lesions were benign and 41 cancers (23%) were identified (Table 2). Invasive carcinoma was found in 32 of the 41 positive needle-directed biopsies (78%). These were infiltrating ductal carcinoma (30 biopsies), infiltrating lobular carcinoma (1 biopsy) or tubular carcinoma (1 biopsy). The remaining 9 biopsies (24%) contained noninvasive carcinoma. These were all intraductal carcinoma. There were 30 patients who underwent an axillary dissection for lymph node evaluation subsequent to the needle-directed biopsy. Twenty-three patients (77%) had no axillary metastases. In six patients (20%), there were 1–4 positive nodes, and one patient (3%) had more than four positive nodes. The average age of the patients having a malignant lesion was 59 years; the average age of the women who had a benign lesion was 54 years. These were not significantly different; there was also no difference in the average ages of the patients having invasive *versus* noninvasive malignancies.

TABLE 2. *Pathology and Stage at the Time of Diagnosis*

Clinical and Pathologic Characteristics	Needle-Directed Biopsies (n = 179*)	
	Number	Percentage
Malignant biopsies	41	23
Invasive carcinoma	32	18
Noninvasive carcinoma	9	5
Axillary dissections	30	
0 Lymph nodes positive	23	77†
1–4 Lymph nodes positive	6	20
>4 Lymph nodes positive	1	3
Total having positive nodes	7	23
Distant metastatic disease	0	0
Total metastatic disease	7	17‡

* Total number of biopsies in series.
† Expressed as a percentage of total axillary dissections.
‡ Expressed as a percentage of positive biopsies.

Mammographic Features

The indications for needle-directed biopsy (tabulated in Table 3), were suspicious mammographic calcifications alone in 60 cases (34%), suspicious mass lesion or soft tissue density only in 86 procedures (48%), and the presence of both calcifications and soft tissue density lesion in 33 cases (18%). The isolated presence of mammographic calcifications was poorly correlated with the presence of carcinoma; biopsies for this indication were positive in only 13% of the cases. Biopsies for soft tissue lesions in the absence of calcification were positive 22% of the time, whereas lesions with both calcifications and a soft tissue abnormality were indicative of cancer in 42% of the cases. The presence of both findings was significantly more likely to be associated with cancer than either calcifications ($p = 0.04$) or soft tissue lesion ($p = 0.05$) alone.

The soft tissue lesions seen on the mammograms were placed in one of three descriptive categories: a mass, an asymmetric density, or an architectural distortion. Although the first two categories are mutually exclusive, as defined in "Methods," either may exist with an architec-

TABLE 3. *Mammographic Indications and Results of Biopsy*

Indication	Biopsies		Malignancies	
	Number	Percentage	Number	Percentage
Calcifications only ($p = 0.04$)	60	34	8	13
Calcifications and soft tissue lesion	33	18	14	42
Soft tissue lesion only ($p = 0.05$)	86	48	19	22

The radiologic indications for the needle-directed biopsy of mammographic abnormalities that were clinically inevident and the percentage of positive biopsies in each group. The presence of a soft tissue lesion with calcifications was significantly more likely to portend the presence of breast carcinoma than either finding alone.

TABLE 4. *Biopsy Results for Various Mammographic Features*

Mammographic Feature*	Malignant	Benign	% Positive	
Asymmetric density†	6	25	19	
Architectural distortion	7	10	41	
Mass†	20	51	28	
Mass subtotals				
Stellate	6	2	75	
Irregularly-defined	12	22	35	
Well-defined	2	27	6	
Number of calcifications				
>10	14	27	34	
≤10	8	44	15	p = 0.07
Size of calcifications				
≥0.4 mm	13	41	24	
<0.4 mm	9	30	23	p > 0.25
Distribution of calcifications‡				
Clustered	9	37	20	
Scattered	9	15	38	p = 0.15

* The radiographic features are considered independently (i.e., lesions having both a soft tissue lesion and calcifications are included twice).

† Lesions not associated with an architectural distortion.

‡ Lesions having more than five calcifications.

tural distortion. Indeed, it was more common to see an architectural distortion with either a mass or an asymmetric density than by itself. A mass was further characterized by whether it was well-defined, irregularly defined, or stellate. The majority of well-defined masses were benign, and most of the stellate masses were malignant. Neither mammographic finding was absolutely predictive, however; two of 29 well-defined masses were malignant, and two of eight stellate masses were benign (Table 4).

Soft tissue abnormalities classified as asymmetric densities were malignant in 19% of the cases. This was not significantly different than the 28% incidence of malignancy in the lesions classified as masses. The addition of architectural distortion tended to increase the likelihood of an underlying malignancy in these lesions. Seven of 17 abnormalities (41%) containing an architectural distortion, excluding frankly stellate masses, contained cancer. However, the difference did not attain statistical significance in this study (p = 0.06).

Finally, the size of the lesion was determined to be the arithmetic average of the longest and shortest dimensions measured from the film. There was no difference in size between the benign and malignant lesions, both averaging 14 mm. In addition, the invasive and noninvasive carcinomas did not differ with regard to their size on the mammogram.

Mammographic calcifications are considered a hallmark of malignancy.[8-10] In the current study, calcifications were present in 93 mammograms, either with or without an associated soft tissue lesion. Overall, 22 (24%) were positive for malignancy, which represents just over half (54%) of all positive biopsies. Calcifications were further characterized by their texture, number, and area of distribution, as described in "Methods." As shown in Table 4, neither the texture nor shape of the calcifications could improve the prediction of cancer. Definition of calcifications as being fine, medium, or coarse failed to uncover a subgroup more significantly associated with any particular pathologic diagnosis. However, lesions having large, solitary concretions are generally recognized as benign, and were not usually biopsied. Furthermore, there was no improvement in the ability to predict the presence of cancer when the analysis was limited to calcifications that were clustered. A malignancy was found in 20% of the lesions associated with the mammographic finding of five or more concretions located within a distance of 1 cm. This did not differ significantly from the frequency of finding cancer in association with other patterns of mammographic calcifications (p = 0.15), and the predictive ability was not improved if analysis was limited to clusters less than 5 mm in size.

Most of the particles large enough to suggest a shape were irregular or pleomorphic. There were only three cases where many calcifications were seen that were small, linear, and branching, suggestive of intraluminal castings. It has been previously reported that such a finding may be indicative of intraductal necrosis from carcinoma.[11] We found cancer in two of three biopsies performed for this mammographic finding.

Using the actual number of calcifications seen on the mammogram was of more assistance. For this analysis, the biopsied lesions were placed in one of three groups, according to whether there were fewer than five, between five and ten (inclusively), and more than ten calcifications visible on the mammogram. Although malignant lesions tended to have more than ten calcifications more frequently than benign lesions, this fell short of achieving statistical significance (p = 0.07). When mammographic calcifications were present, there were fewer than five calcifications noted in four of the cancerous lesions (10%), which was not significantly different from the frequency of finding as few calcifications in benign lesions (14%). In each of the four positive biopsies, however, the mammographic calcifications were associated with either an irregular or stellate mass. The mammographic finding of a cluster of calcifications with fewer than five particles has previously been shown to be malignant only rarely if there was no associated soft tissue lesion.[8,12] Such lesions are rarely biopsied.

Radiographic abnormalities that exhibit a change from a previous mammogram cause more suspicion of malignancy. There were 38 biopsies performed in patients who had had previous Duke mammograms performed at least several months before the abnormal mammograms for which the biopsy was recommended.

On review of these films, 25 were noted to have changed since the previous study. Ten of these biopsies (40%) were positive for malignancy. Only one of the 13 biopsies was positive in the group of patients for whom the mammograms were known to be unchanged since the previous exam. Since a biopsy was less likely to be performed if the mammogram was known to be unchanged, no firm conclusions can be drawn from these data. If there was a known change, however, there was a higher likelihood of carcinoma.

Soft Tissue Lesions Alone, Calcifications Alone, and Soft Tissue Lesions With Calcifications Considered Separately

The specific radiologic features that are associated with malignancy are best evaluated by considering the three mammographic groups separately. Analysis of the lesions that consisted of mammographic calcifications without a concomitant soft tissue lesion reveals that the only feature which varies significantly between the benign and malignant groups is the number of calcifications seen. There were 60 biopsies in the group, 31 of which had ten or fewer calcifications on the mammogram. Only one of these 31 biopsies was positive for malignancy. By contrast, seven of 29 biopsies uncovered malignancy in the group having more than ten mammographic calcifications ($p = 0.02$). When the benign and malignant groups were compared, there was no significant difference with regard to the size or clustering of the calcifications.

Biopsies performed for soft tissue lesions without the presence of calcifications were positive for cancer in 22% of the cases. However, only one of 23 (4.3%) masses judged to be well-defined were malignant. This is significantly lower than the cancer rate for the balance of this group, which includes the irregularly defined masses, stellate masses, asymmetric densities and architectural distortions ($p = 0.04$). Similarly, only two of 20 solitary asymmetric densities were malignant, but this difference failed to reach statistical significance when compared to the rest of the group.

The mammographic features associated with the group of biopsies that had both calcifications and a soft tissue lesion were also analyzed. In this group, the overall incidence of malignancy was high (42%), and none of the particular mammographic descriptors of soft tissue lesions or calcifications significantly increased predictive power.

Discussion

Our aim in this study was to ascertain which mammographic findings are either rarely or frequently associated with breast cancer. We have evaluated a large series of mammographically placed needle-directed biopsies. All of the mammograms and pathology slides were reviewed in a blind fashion, with the radiologic images carefully characterized. A number of radiologic features have been identified which are helpful in estimating the risk of cancer in nonpalpable breast abnormalities.

The radiographic indications for breast biopsy include a soft tissue lesion without calcifications, a soft tissue lesion with calcifications, and a focus of calcifications without an associated soft tissue lesion. When these three groups were considered together, there were no radiographic features which were significantly predictive of either cancer or benign disease (Table 4). However, if the three groups are considered separately, some important findings become evident.

The greatest diagnostic accuracy of the mammographic examination of nonpalpable breast lesions is in those lesions that have no calcifications; the radiographic images in this group may be most easily classed as either benign or malignant. The characteristic causing the most suspicion and which portends the presence of malignancy is the presence of an architectural distortion. This may occur either as a frankly stellate mass or as a more subtle tethering of adjacent breast structures and in association with less well-defined mass lesions. In addition, irregularly defined masses are more likely to be associated with malignancy than well-circumscribed masses. The vast majority of well-defined masses not having mammographic calcifications are benign. In our series, there was only one malignant diagnosis out of 23 such lesions. Finally, if the mammographic density causing suspicion was not clearly seen on all of the views, there was a low likelihood of cancer's being present. In this study, such lesions were called asymmetric densities, and only two of 19 biopsies were positive.

Our subjective estimations of the likelihood that the biopsies would be positive were least accurate in the group of patients having calcifications without an associated mass. We were unable to discern a particular shape or pattern of mammographic calcifications which would reliably place lesions in either the benign or malignant category. We did, however, find that malignant lesions tended to have more radiographic calcifications than benign lesions. In the 31 lesions in which fewer than ten calcifications were seen, there was only one malignancy. This is consistent with the previous reports in which it has been stated that lesions having fewer than five clustered calcifications are virtually always benign.[8,12] However, when a soft tissue lesion was associated with calcifications, their actual number was less important. The incidence of carcinoma in cases of soft tissue lesions with calcifications becomes 42%, and half of the 14 malignancies in this group had fewer than ten mammographic calcifications.

TABLE 5. *The Mammographic Features of Clinically Occult Breast Abnormalities that are Associated with an Increased Likelihood of Malignancy*

1. Curvilinear and branched calcifications.
2. Change from previous mammogram.
3. Soft tissue lesion with calcifications.
4. Focus with greater than ten calcifications.
5. Architectural distortion.

In this study of the mammographic features of clinically inapparent breast abnormalities, several findings that are particularly associated with cancer were found. First, it has been reported that the presence of small, curvilinear and branched calcifications reminiscent of intraductal castings is an important clue in indicating cancer.[11] In this series, this finding was rare, but was positive in two of three cases. In addition, lesions that are known to exhibit a change in their radiographic appearance from a previous mammogram have a high likelihood of being malignant. We believe that lesions demonstrating these findings should be biopsied. Also, since mammographic abnormalities having both calcifications and a soft tissue lesion were positive for cancer in 42% of the cases, they should be biopsied, as should lesions that are associated with a distortion of the surrounding architecture. Table 5 presents a list of radiographic findings, that are particularly associated with malignancy, discovered in this study or by others.

Another aspect of this study was to define, when possible, a subset of mammographic abnormalities that have a low likelihood of being malignant. It is widely acknowledged that mammographic-directed biopsy is a time consuming, difficult, and expensive procedure. The point at which risk of cancer for certain mammographic patterns is sufficiently low to recommend deferral of biopsy has not been established in this study and should be a goal for future work. However, there are several mammographic characteristics which are significantly more likely to be benign than malignant. These features include well-defined masses and asymmetric densities, if there are no calcifications present, and where there is no associated soft tissue lesion, lesions having fewer than ten calcifications.

In the present series, although there were 73 biopsies performed for mammographic abnormalities having these characteristics, only four (5.5%) were positive for cancer. The most conservative method of analyzing these data was to calculate the number of positive biopsies for an acceptable confidence interval. Analysis of the binomial probabilities of this group reveals that the 95% confidence interval for the number of malignancies ranged from 0 to 7. The upper limit of this interval corresponds to a positive biopsy rate of 10% (seven of 73 cases), which means that there is a 95% probability that fewer than one tenth of the biopsies for these radiographic indications would be positive. This may be an unacceptable rate for many surgeons, and it is difficult to make definite recommendations for biopsy based on these data.

Rather, we believe our results indicate that the risk of delaying biopsy of a suspicious radiographic finding needs to be determined. Although the metastatic potential of a noninvasive or "minimal" breast cancer is small, the pivotal issue is whether these lesions can be safely followed when they present as equivocal mammographic findings only. Furthermore, there are strong medical and legal considerations that influence clinical decision-making. Perhaps prospective studies of patients presenting with low risk radiographic findings can be designed to determine the safety of following certain mammographic findings.

Although not addressed in the current study, simple techniques are available that may increase the sensitivity and specificity of conventional mammograms. These include the liberal use of compression views to resolve density lesions, magnification to enumerate calcifications and examine density effects, and directed breast ultrasonography to exclude simple cysts from biopsy. Experience with the use of these simple adjuncts may increase the specificity of the mammogram without decreasing its sensitivity and may result in a more precise use of the biopsy.

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