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Periodic Mammographic Follow-up of Probably Benign Lesions: Results in 3,184 Consecutive Cases¹

The author prospectively evaluated the value of periodic mammographic surveillance among 3,184 consecutive cases of nonpalpable, probably benign breast lesions detected with mammography. Follow-up consisted of four mammographic examinations during a 3- or 3.5-year period. Clinical outcome was ascertained in each case after the study period, whether or not patients complied with the protocol. Probably benign lesions were subsequently found to be malignant in 17 cases (positive predictive value for cancer, 0.5%). Fifteen of the 17 cancers were identified by means of interval mammographic change prior to development of a palpable mass; all 17 were stage 0 or stage 1 tumors. All 17 women who had cancer currently show no evidence of tumor recurrence (median duration of follow-up, 5 years). These results should help establish the validity of managing mammographically detected, probably benign lesions with periodic mammographic surveillance. By decreasing the number of biopsies of benign lesions and thereby substantially reducing costs, this approach may help overcome a major barrier to widespread use of mammographic screening.

Index terms: Breast neoplasms, diagnosis, 00.31, 00.32 • Breast neoplasms, localization, 00.125 • Breast radiography, utilization, 00.11 • Cancer screening • Radiology and radiologists

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DURING routine mammography, lesions that are judged to have a very low probability of malignancy are identified frequently. Periodic follow-up examinations are recommended for patients with such lesions as an alternative to prompt excision (1-11). The basic purpose of this approach is to avert the morbidity and substantial cost of biopsies for benign lesions. It also has been suggested, although on the basis of indirect and scant evidence, that careful mammographic surveillance of probably benign lesions can likely (a) enable identification, by interval change, of those few lesions that actually are malignant and (b) do so while the tumors still have a favorable prognosis (5). In the single published study limited to consecutive cases for which periodic follow-up was recommended instead of biopsy, Helvie et al (11) found only one cancer (1%) among 90 "low-suspicion" lesions that were either sampled with biopsy or followed up for at least 20 months with mammographic surveillance.

The study reported in this article involves a considerably larger number of prospectively identified, consecutive cases, for which follow-up data collection is more complete and of longer duration. I believe that this experience provides much more meaningful insight into the validity of managing probably benign lesions with periodic mammographic surveillance.

MATERIALS AND METHODS

The study population was derived from all 34,282 women with or without symptoms who underwent mammography at the University of California, San Francisco (UCSF) during the 8.5-year period from September 1, 1978, to February 28, 1987. The single criterion for eligibility was identification with mammography of nonpalpable lesions interpreted as probably benign, for which periodic mammo-

graphic surveillance was recommended. This interpretation was made with full knowledge of a woman's breast cancer risk factors, pertinent past medical history, and current breast physical examination, and included comparison with prior mammograms, if available. Excluded from the study were women with normal mammograms who had previously undergone lumpectomy and radiation therapy for breast cancer; in such women I routinely image the treated breast at 6-month intervals for several years after a diagnosis of cancer.

Otherwise eligible cases were excluded from study in several specific situations: (a) Two women died of causes other than breast cancer without having undergone biopsy of the probably benign lesion and before at least 3.5 years of mammographic follow-up was completed. (b) Lesions ultimately identified with confidence, by means of ultrasound (US), as simple benign cysts also were excluded, because all such lesions are diagnosed now as unequivocally benign at the time of initial mammography, with follow-up recommendation limited to routine mammography at age-appropriate screening intervals. US of the breast became available at my institution in December 1980, and all noncalcified lesions already undergoing periodic mammographic surveillance were evaluated with US at that time. (c) Lesions demonstrating the classic mammographic features of sedimented calcium within tiny benign cysts also were excluded. During the course of the study, many of these lesions had been interpreted as probably benign and were subject to periodic mammographic follow-up. Because experience at my institution now shows the lesion to be invariably benign (12), however, inclusion of such lesions would inappropriately skew study results. (d) Finally, lesions were excluded if the initial mammographic interpretation was made by a radiologist other than myself. This was done to maximize the likelihood that uniform interpretive criteria were used to select lesions for mammographic surveillance. To avoid potential confusion in comparing the re-

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Abbreviation: UCSF = University of California, San Francisco.

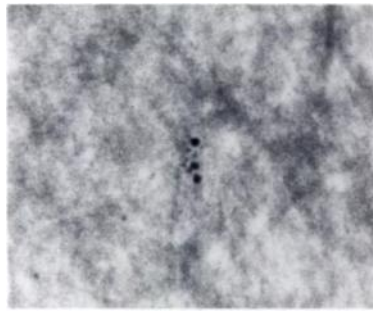


Figure 1. Solitary cluster of tiny calcifications, considered probably benign. Note that the shape of each calcific particle is round or oval. These calcifications may vary somewhat in size, therefore varying in apparent density as well.

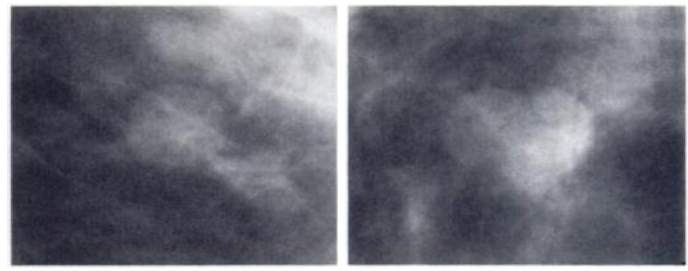


Figure 2. Noncalcified solid nodules, considered probably benign. (a) Note the smooth contour and ovoid shape of this nodule. Its margins are almost entirely well defined. (b) This nodule demonstrates a slightly lobulated contour, and portions of its otherwise well-defined margins are obscured by adjacent isodense, benign-appearing fibroglandular tissue.

sults of this study with those of others, I do not recommend periodic mammographic follow-up for these clearly benign findings: dermal calcifications (even if clustered), characteristically calcified fibroadenomas, arterial calcification, dystrophic and/or sutural postoperative calcification, intraductal or periductal calcifications of benign ductal ectasia, discrete masses entirely or partially fatty in content, and masses that demonstrate the typical size, shape, and location of intramammary lymph nodes (13,14).

Mammographic findings interpreted as probably benign with a recommendation for mammographic surveillance consisted of two major categories, localized and generalized. Localized lesions were characterized by a focal distribution occurring in one segment of one breast. This included the following: (a) clusters of tiny calcifications (five or more calcific particles per cubic centimeter) if fine-detail images demonstrated that all of the particles were round or oval (Fig 1); (b) noncalcified solid nodules (no size limitation, but nonpalpable) with round, ovoid, or gently lobulated contours and well-defined margins not obscured by adjacent fibroglandular tissue (Fig 2); (c) selected focal asymmetric areas of fibroglandular density (no size limitation, but nonpalpable), defined as discrete opacities readily visible on two orthogonal projection mammograms, with concave-outward margins and/or interspersed with fat (Fig 3); and (d) several miscellaneous focal findings, including single dilated ducts (especially if not associated with spontaneous nipple discharge) and subtle areas of architectural distortion without central increased fibroglandular density (when occurring at known biopsy sites). Whenever two separate clusters of calcifications or two noncalcified solid nodules were identified at the same examination, they were reported as one case. In all such cases the subsequent treatment of both component lesions was identical.

The second major category of probably benign findings was characterized by a generalized distribution, demonstrating multiple (three or more) similar lesions,



Figure 3. Focal asymmetric area of fibroglandular density, considered probably benign. This lesion is distinguished from a mass because portions of its central region appear relatively less white, suggesting that it is interspersed with fat. It also lacks the convex-outward contour typically displayed by a mass.

either tiny calcifications or nodules, randomly distributed in both breasts. Here the most important radiologic feature prompting a "probably benign" interpretation was the similarity of the component parts of such scattered lesions. A distinction was made between two clearly different subtypes of widely distributed tiny calcifications: multiple discrete clusters of calcifications (similar in appearance to those shown in Figure 1) and numerous bilateral scattered and randomly clustered calcifications (Fig 4).

All initial mammographic examinations were done at my institution with dedicated mammographic equipment, which at that time had state-of-the-art imaging capabilities. Approximately 60% of study cases were imaged with screen-film mammography alone, the remaining 40% either partially or entirely with xeroradiography. In all cases additional magnification mammograms, with or without spot compression technique, were obtained prior to initial radiographic interpretation to more clearly portray the lesion in question (15-17).

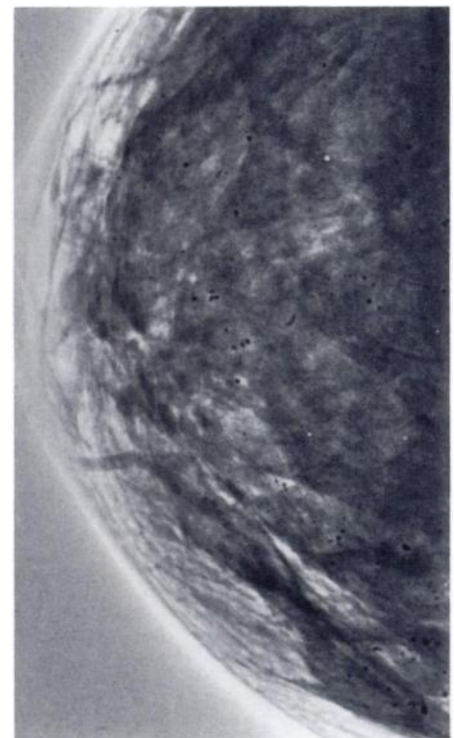


Figure 4. Scattered tiny calcifications, considered probably benign primarily because of the widespread distribution of calcific particles throughout both breasts (contralateral breast not shown) and the observation that no particular area of calcifications looks different from all other areas. Note that some calcifications appear to be clustered. This should not raise suspicion of malignancy, because random scattering of calcifications inherently distributes some particles in proximity to others. The frequency of random clustering is directly proportional to the number of calcifications seen per unit volume.

A protocol of periodic mammographic surveillance for probably benign lesions had become widely accepted at my institution prior to September 1978. As a result, study patients and their referring physicians were fully informed about the rationale for and timing of recommended mammographic follow-up, specifically of

its use as an alternative to biopsy. It also was understood in advance that any change in the probably benign lesion that raised even a slight suspicion of malignancy would prompt the suggestion of immediate biopsy. The protocol called for repeat mammography of the ipsilateral breast in 6 months, with orthogonal projection radiographs obtained with whatever technique most effectively portrayed the lesion at initial workup. Subsequent-

ly, bilateral mammography was required 6–12 months later, with specific timing determined on the basis of age-appropriate screening intervals for examination of the contralateral breast. Finally, the follow-up protocol called for two additional annual bilateral mammographic examinations. Thus, mammographic surveillance involved a total of four follow-up examinations spanning a 3- or 3.5-year period.

Results of all mammographic surveil-

lance examinations and breast biopsies done at my institution were readily available for data analysis. Similar results were obtained, occasionally with great difficulty, for all women who chose to undergo follow-up elsewhere.

RESULTS

During the 8.5-year accrual period, 5,824 of the 34,282 mammograms obtained at my institution were interpreted by radiologists other than myself. Of the 28,458 mammograms that I read personally, 3,184 mammograms (11.2%) showed lesions that were interpreted as probably benign with recommendation for periodic mammographic surveillance, also fulfilling the other requirements for entry into the study. Ages of study patients ranged from 28 to 96 years (mean, 52.6 years; median, 51 years). As an indication of the biopsy yield attributed to cases I interpreted as suspicious for malignancy, 38% of the needle localizations prompted by my readings during the 8.5-year accrual period of the study resulted in a diagnosis of invasive carcinoma or ductal carcinoma in situ.

Table 1 lists the frequency distribution of specific mammographic findings interpreted in the study as probably benign. Tiny calcifications were encountered most commonly, in 58.2% of cases ($n = 1,853$). Well-defined nodules accounted for 26.4% of probably benign interpretations ($n = 842$), followed by focal asymmetric areas of fibroglandular density in 14.1% of cases. Almost three-fourths of probably benign lesions were localized to one segment of one breast; the remainder were generalized in distribution.

Biopsy was done shortly after the initial mammographic examination in 12 of the 3,184 women in the study (0.4%), despite the radiologic recommendation for follow-up mammogra-

Table 1

Specific Mammographic Findings in 3,184 Probably Benign Lesions and in the 17 Breast Cancers Detected among Them

Finding	No. of Cases ($n = 3,184$)	No. of Cancers ($n = 17$)
Localized		
Cluster of tiny round or oval calcifications	1,234 (38.8)	1 (0.1)
Noncalcified, well-defined solid nodule	589 (18.5)	12 (2.0)
Focal asymmetric area of fibroglandular density	448 (14.1)	2 (0.4)
Miscellaneous	41 (1.3)	0 (0)
Generalized*		
Discrete clusters of tiny calcifications	97 (3.0)	0 (0)
Scattered or randomly clustered tiny calcifications	522 (16.4)	1 (0.2)
Noncalcified, well-defined solid nodules	253 (7.9)	1 (0.4)

Note.—Numbers in parentheses are percentages.

* These lesions were multiple (three or more) and randomly distributed in both breasts or widely scattered throughout both breasts. At no one site did a lesion appear to be substantially different from its appearance at other sites.

Table 2

Mammographic Surveillance of Probably Benign Lesions

Follow-up Examination*	Follow-up at UCSF	Follow-up Elsewhere	Follow-up Not Done	Total No. of Patients [†]
1 [‡]	2,193 (69.1)	724 (22.8)	255 (8.0)	3,172
2 [§]	2,050 (65.3)	739 (23.5)	352 (11.2)	3,141
3	1,741 (57.0)	777 (25.4)	541 (17.7)	3,059
4 [#]	1,505 (50.0)	461 (15.3)	1,049 (34.8)	3,015

Note.—Numbers are number of patients; numbers in parentheses are percentages.

* Follow-up mammography was considered done if it was performed within 3 months of the date appropriate for a 6-month follow-up examination or within 6 months of the date appropriate for a 1-year follow-up examination.

[†] The decrease with time in total number of patients who underwent mammographic follow-up is due to biopsy between examinations. No patients were lost to follow-up.

[‡] Six months after initial mammography.

[§] Six or 12 months after examination 1 (see text for explanation).

[#] One year after examination 2.

One year after examination 3.

Table 3

Biopsy of Probably Benign Lesions during the Course of Mammographic Surveillance

Follow-up Examination	Follow-up at UCSF		Follow-up Elsewhere		Biopsy Done without Follow-up Mammography
	Biopsy due to Mammographic Change	Biopsy without Mammographic Change	Biopsy due to Mammographic Change	Biopsy without Mammographic Change	
1	15 (0.7)	2 (0.1)	6 (0.8)	6 (0.8)	2 (0.8)
2	51 (2.5)	3 (0.1)	19 (2.6)	3 (0.4)	6 (1.7)
3	26 (1.5)	2 (0.1)	11 (1.4)	2 (0.3)	3 (0.6)
4	2 (0.1)	0 (0)	1 (0.2)	0 (0)	1 (0.1)

Note.—Biopsies were tabulated only if done at the site of the lesion considered probably benign at initial mammography. Biopsies were considered associated with follow-up examinations only if the date of mammography preceded the date of surgery by 3 months or less. Numbers in parentheses are percentages, calculated by dividing the number of biopsies by the total number of follow-up mammographic examinations done (columns two and three in Table 2) or not done (column 4 in Table 2).

phy as an alternative to surgery. All of these patients had localized lesions: six had calcifications; four, nodules; and two, focal architectural distortion. The resultant histopathologic diagnosis was benign in each case.

The other 3,172 women constitute the subset of the study group subject to mammographic follow-up. Compliance with the follow-up protocol declined progressively with each subsequent examination (Table 2) but fell off most strikingly at the final follow-up examination, scheduled for 3 or 3.5 years after initial mammography. Slightly less than two-thirds of women underwent this last follow-up examination; 1,438 patients (45.2%) completed all four follow-up examinations according to protocol, within the time ranges defined in Table 2. A portion of the decreasing compliance occurred because of failure of non-UCSF radiologists to recommend strict adherence to the protocol, just as a portion of the shift of follow-up examinations away from my institution occurred because women moved away from the Bay Area.

Table 3 catalogs the 161 biopsies of probably benign lesions done during the course of mammographic surveillance. More than 80% of these biopsies were prompted by mammographic demonstration of interval change of the probably benign lesion. Biopsies done for this purpose were performed with similar frequency independent of whether follow-up was carried out at my institution or elsewhere, probably because recognition of mammographic change requires little subjective interpretation and because radiologists generally agree that such interval change should result in immediate biopsy.

Biopsies were done in only seven women (0.1%) after follow-up at my institution showed no interval change. In each case biopsy was performed because the patient stated a preference for the definitive diagnosis produced by biopsy to overcome anxiety and uncertainty induced by continued mammographic follow-up. However, when follow-up at sites other than my institution showed no interval change, three to eight times more biopsies were done. Almost all of these biopsies were prompted by the suggestion of the non-UCSF radiologist, and this always occurred the first time that that radiologist made an interpretation of the case. In these situations, it is likely that the non-

UCSF radiologist was unwilling to accept the probably benign diagnosis that had been made in interpreting the initial mammogram, even allowing for demonstrated radiologic stability. It also is possible that women who had become disenchanted with the uncertainty of periodic follow-up were more likely to go to a site other than my institution for their biopsy and prebiopsy mammography.

Biopsy at the site of the probably benign lesion also was done for 12 women who had not undergone recent mammographic follow-up. In each case the reason for biopsy was interval development of a palpable mass or otherwise clinically suspect finding at physical examination. These palpable lesions were removed without the aid of mammographic needle localization, unlike the previously described lesions, all of which remained nonpalpable at the time of excision.

Seventeen cancers were found among the study population of 3,184 probably benign lesions, indicating an overall positive predictive value for malignancy of 0.5%. No differences in cancer detection were observed in women who underwent mammographic follow-up at my institution or elsewhere. Fifteen of the cancers were detected among the 131 biopsies performed because of mammographic demonstration of interval change. These cancers were found at the four follow-up examinations as follows: two at the 6-month follow-up and then eight, four, and one at the subsequent examinations. The other two cancers were identified among the 12 palpable lesions sampled by means of biopsy without benefit of mammographic surveillance, 7 and 10 months, respectively, after 12-month follow-up examinations. No cancers were found among the biopsy samples obtained despite lack of interval change at follow-up mammography.

Table 1 lists the mammographic findings at initial examination of the 17 cancers that were detected during the course of mammographic surveillance. At initial examination, 12 of these cancers were solitary, noncalcified, well-defined solid nodules, indicating a positive predictive value of 2.0% for this mammographic finding. Both of the palpable masses were solitary nodules at initial examination. The other probably benign findings each had a positive predictive value of less than 0.5%.

The histopathologic diagnosis was ductal carcinoma in situ in two of the

17 cancer cases, invasive ductal carcinoma in 14, and invasive lobular carcinoma in one of the cancers. No cases of lobular carcinoma in situ were identified. The two in situ ductal cancers were 8 and 14 mm, respectively, in greatest diameter, and the diameters of the invasive cancers were 5–18 mm (median, 13 mm). Only two of the cancers (12%) (one noncalcified, well-defined solid nodule and one focal asymmetric density) demonstrated axillary lymph node metastasis, each to only one node, and none were found to have systemic metastasis at time of initial cancer staging. Indeed, all of the 17 cancers were either stage 0 or stage 1 tumors; six cancers (35%) fulfilled Breast Cancer Detection Demonstration Project criteria for minimal cancer (18), and three cancers (18%) were considered minimal cancer according to the criteria of Martin and Gallager (19). Finally, all 17 women with cancer continue to show no evidence of tumor recurrence (median duration of follow-up, 60 months; range of follow-up, 33–119 months). The two women with metastasis to a single axillary node have been followed up for 78 and 91 months, respectively.

All 1,049 women who did not undergo their last scheduled mammographic follow-up examination were contacted soon thereafter to establish breast health status. None had developed breast cancer at the site of the probably benign lesion identified at initial mammography. Although formal data collection procedures for the study ended with these exit interviews or after 3- or 3.5-year follow-up was completed, many women actually have been followed up for longer periods, some for up to 11 years. Among those women who have undergone continued routine mammographic screening at my institution, none of the probably benign lesions have subsequently proved malignant.

DISCUSSION

Many radiologists advocate mammographic surveillance as an alternative to biopsy in the treatment of probably benign lesions detected at mammographic screening. However, few published reports assess the clinical validity of this alternative, and all of these are deficient in one way or another. Hall et al retrospectively reviewed 400 nonpalpable lesions sampled by means of biopsy in an attempt to define "minimally or slightly suspicious" findings that might

have been treated more effectively with periodic follow-up (5). Their study was limited principally by its retrospective design, which did not permit actual clinical circumstances to determine the ultimate outcomes of mammographic surveillance. Wolfe et al reported on 1,356 prospectively identified, probably benign lesions as part of a series of 21,057 consecutive mammographic examinations (4). However, that study, too, is of limited value in assessing the efficacy of mammographic surveillance because the duration of follow-up was only 6–12 months. Finally, Helvie et al described a prospective series of 144 probably benign lesions, 90 of which were followed up for at least 20 months (11). Their study, although more completely documented than the other two, also provides insufficient data to define proper treatment of probably benign lesions, because of its very small number of cases, relatively short observation period, and high percentage of patients lost to follow-up.

This study overcomes the limitations of prior investigations because it is a very large prospective study of consecutive cases, fully documents its methods, and provides 100% complete follow-up data on all study patients for a minimum of 3–3.5 years after initial mammography.

Several differences exist between the results of this study and those published previously. My report indicates an 11.2% frequency of probably benign interpretations, higher than the 5.4% of Helvie et al (11) and the 6.4% of Wolfe et al (4). This could be due in part to subjective variation in the use of similar selection criteria for identifying probably benign lesions, use of completely different selection criteria, or the possibility that more patients at my institution had symptoms of breast disease than did patients in the other studies. Furthermore, it is noteworthy that others have reported frequencies of probably benign lesions considerably higher than mine—as high as 20% in one instance (3).

In this study the rate of compliance with the mammographic follow-up protocol was substantially higher than that of Helvie et al. Some of this disparity may be due to the slightly different definitions of compliance in the two studies, the use of slightly different follow-up intervals, and the inability of Helvie et al to monitor follow-up examinations performed at sites other than the site of their own

practice. It is also possible that the system at my institution more effectively educates physicians and patients about the desirability of strict adherence to follow-up protocol.

Only minor interstudy differences exist in the calculation of the positive predictive value of a “probably benign” interpretation (ie, the frequency with which cancer is found among lesions initially classified as probably benign). At my institution this value is 0.5%, similar to the 0.6% reported by Wolfe et al (4). These two findings are likely more reliable than the 1.1% finding obtained by Helvie et al (11), which is based on a much smaller sample. Subjective or objective differences in selection criteria for identifying probably benign lesions may also partially explain these differences. Nevertheless, the striking similarity of all positive predictive values strongly suggests that it is possible for radiologists to identify selected abnormal mammographic lesions for which the likelihood of malignancy is 1% or less. Because the pejorative nature of terms such as “low-suspicion” (11) and “minimally suspicious” (5) may be sufficient to prompt unintended biopsy, I recommend that in describing these lesions the term “probably benign” should be used.

The findings in this study support the hypothesis of Hall et al that mammographic surveillance of probably benign lesions enables correct identification of the few lesions that are malignant and is likely to do so while most of the tumors remain curable (5). Indeed, 15 of the 17 cancers in this study were sampled by means of biopsy because mammography showed interval progression prior to the development of palpable findings. In addition, prognostic factors are very favorable among all 17 of the malignancies detected during mammographic surveillance and are similar to those of cancers found in the UCSF Mammography Screening Program, the results of which have been reported previously (20). For example, median tumor size, axillary lymph node status, and frequency of systemic metastasis are virtually identical in the two studies. Furthermore, although the overall screening data at my institution show a higher percentage of so-called minimal cancers, all the tumors in this study are stage 0 or stage 1 whereas 20% of cancers detected with screening at my institution are stage 2 or higher.

Hall et al (5) also suggest, on the basis of retrospective case review,

that the use of less aggressive interpretive criteria for mammography would increase the biopsy yield of cancer from the current national average of 15%–30% to approximately 40% without a substantial reduction in the detection of small cancers. The results of this prospective study support these estimates. During the 8.5-year period of case accrual, the biopsy yield of cancer was 38% for lesions that I initially considered suspicious for malignancy. This result was obtained during the same period in which only 0.5% of my “probably benign” lesions eventually proved to be cancers.

Conservative treatment of probably benign lesions detected at mammographic screening has several important advantages. Substituting mammographic follow-up for excisional biopsy substantially reduces morbidity and induced monetary costs, thereby benefiting both patients and third-party payers. Another, perhaps more significant effect of nationwide adoption of the follow-up approach for such lesions is to make mammographic screening more cost-effective, thereby helping to remove a major remaining barrier to the widespread use of screening, especially among women under age 50 years (21).

An interesting sidelight of this study relates to the usefulness of interval change as a mammographic indicator of malignancy. In 131 study cases, such change was considered sufficiently suspicious for malignancy to prompt immediate biopsy instead of continued mammographic surveillance. Fifteen of these lesions proved cancerous, a biopsy yield of only 11%. However, because these 15 cancers remained nonpalpable despite evidence of progression, and because the prognoses were still favorable after the cancers were excised, the mammographic demonstration of interval change appears to be an important, albeit nonspecific, sign of occult malignancy.

In summary, this large series of prospectively identified, consecutive cases should help establish the validity of treating probably benign lesions with periodic mammographic surveillance rather than immediate biopsy. However, the results of this study apply only to the specific conditions under which it operated, the most important of which were the following: (a) cases restricted to nonpalpable lesions; (b) preinterpretation comparison with prior mammograms, if available; (c) acquisition

and evaluation of supplementary magnification mammograms in orthogonal projections before one interprets findings as probably benign; and (d) use of the specific interpretive criteria described and illustrated previously. Even more convincing evidence in the management of probably benign lesions may soon become available as uniform standards of terminology for mammographic interpretation are developed, accepted, and used in pooled computer data bases (22). This will produce a truly large-scale multi-institution experience that should be applicable to all radiologists. ■

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