PARTE 3 – RELATO DA DRA. LUCY KERR DA CONVENÇÃO ANUAL DO AIUM DE 2012

SESSÃO DE INTERESSE ESPECIAL – SÁBADO 31 DE MARÇO DE 2012

ULTRASSOM DA MAMA E TÉCNICAS DE BIÓPSIA

1ª palestra: Breast Imaging reporting and data system categories for breast ultrasound, ministrada por Susan Ackeman, MD

Esta sessão é destinada a cobrir o sistema de categorias ultassonográficas das mamas e o laudo ultrassonográfico da mama, incluindo exemplos de cada categoria.

O sistema BIRADS foi estabelecido em 1993 para mamografia e padronizado para a US em 2003. A Dra.Ackeman explicou porque o sistema BIRADS é útil em US:

- Provê uma linguagem comum para laudos que indica claramente a conduta ao clínico.
- O sistema é muito bom em caso do médico ser processado, assim como é o BIRADS da mamografia.

O BIRADS de US usa termos similares ao BIRADS da mamografia; embora exista sobreposição de relatos quanto aos contornos e formatos .

Como optimizar a técnica?

1. Usar sonda de alta freqüência e elevada resolução;
2. Colocar o foco na região correta;
3. Ajustar a profundidade da tela;
4. Ajustar com o contraste de tal forma que a gordura realmente se apresente cinza.

ACR BIRADS E RISCO DE CÂNCER

BIRADS	TIPO	RISCO DE CÂNCER
0*	Inconclusivo	imponderável
1	Normal	0
2	Benigno	0
3	Provavelmente benigno	<2% e VPN > 99%
4A	Discretamente suspeito	>2% e < 50%
4B	Moderadamente suspeito	>50% e < 90%
4C	Muito suspeito de malignidade	Malignidade é esperada e o resultado benigno surpreende (discorda dos critérios clássicos)
5	Maligno	> 90%
6	**Câncer é conhecido	100%

***o BIRADS zero (inconclusivo ou exame insatisfatório) é uma categoria que quase inexiste no US, mas é muito utilizada na mamografia . Restringe-se aos casos aonde não foi possível realizar o exame devido haver cicatrizes abertas ou inacessibilidade da região a ser examinada devido a presença de curativos, sondas, instrumentais.**
****pacientes geralmente fazendo quimioterapia neoadjuvante (pré cirúrgica)**

As massas sólidas que requerem seguimento e entram na categoria BIRADS deverão ser observadas em intervalos curtos e isso inclui **hematomas** (diminuem de volume em pouco tempo até absorver) e **lesões que são hormônio dependentes, cistos complexos e fibroadenomas atípicos**.

Sinais ultrassonográficos a serem avaliados para classificação **BIRADS**

1. **Orientação e formato para nódulos sólidos:** largura > altura ou redondo é padrão benigno;
2. **Margens:** bem definidas com abrupta transição entre o tecido nodular e o tecido ao seu redor é padrão benigno;
3. **Macrolobulada (<que 4 lobulações):** é padrão benigno e é um termo que provém do léxico da mamografia
4. **Massa não circunscrita é padrão maligno:** microlobulada (é diferente da macrolobulada, que é comum em tumores malignos); não há limites precisos entre o tecido nodular e o tecido ao seu redor; margens anguladas;
5. **Limites:** interface abrupta é sinal benigno; halo ecogênico ou transsição espessa entre o tecido anormal e normal é sinal maligno;
6. **Ecos internos:** anecóico é sinal benigno; isoecóico mais provavelmente é benigno; hipoecóico pode ser benigno ou maligno. A maioria dos nódulos sólidos da mama são hipoecóicos e naão hipereóicos ;
7. **Sinais distais: a** sombra pode ser benigna ou maligna; o reforço acústico distal é um sinal US indeterminado que ocorre em cistos, fibroadenomas e alguns tipos de cânceres (em geral os mais agressivos);

A Dra. Ackerman cita como referência principal o artigo publicado no Radiology:

BI-RADS 3, 4, and 5 Lesions: Value of US in Management - Follow-up and Outcome

Sughra Raza, MD, Sona A. Chikarmane, AB, Sarah S. Neilsen, DO, Lisa M. Zorn, MD and Robyn L. Birdwell, MD

Abstract

Purpose: To evaluate the use, final outcome, and positive biopsy rate of American College of Radiology ultrasonographic (US) Breast Imaging Reporting and Data System (BI-RADS) categories 3, 4, and 5 recommended for breast masses.

Materials and Methods: At US, consecutive masses, palpable and nonpalpable, categorized as BI-RADS 3, 4, and 5 between January 1, 2003, and December 31, 2004, were retrospectively reviewed with institutional review board approval. Medical records provided imaging and histologic information.

Results: After patients lost to follow-up were excluded, the study population was 767 patients with 926 masses (476 palpable, 450 nonpalpable). In BI-RADS 3 masses (n = 356), imaging follow-up of 252 masses documented stability for 6–24 months. Aspiration of 24 masses revealed cysts. Biopsy in 80 masses revealed three malignancies, all of which were diagnosed within 6 months of the index examination, were smaller than 1 cm, and were node negative (negative predictive value = 99.2%). In BI-RADS 4 masses (n = 524),

aspiration results indicated 35 cysts; biopsy in 455 revealed 85 malignancies (positive predictive value [PPV] = 16.2%). Imaging follow-up only in 34 revealed no cancers 2 and more years later. Among BI-RADS 5 masses (n = 46), 43 were malignant and three benign (PPV = 93.4%).

Conclusion: Inconsistent use of BI-RADS category 3 occurred in 14.0% of cases when biopsy was recommended. Although biopsy was performed in almost equal numbers of palpable and nonpalpable masses, only 11% of palpable BI-RADS 3 and 4 masses were malignant, as compared with 22% of nonpalpable masses. Strict adherence to lexicon characteristics of probably benign lesions should improve specificity.

Diagnostic breast imaging practice consists of evaluating breast abnormalities detected clinically and with imaging. The imaging evaluation of such abnormalities most commonly includes conventional mammography, ultrasonography (US), and magnetic resonance (MR) imaging. A strategy for evaluation of some mammographic abnormalities includes periodic imaging surveillance for probably benign masses. The recommended imaging follow-up is usually at a short interval (ie, 6 months) and should be associated with a subsequent malignancy rate of less than 2% (1–4). Although initial studies regarding this issue included only nonpalpable mammographic findings, later studies have addressed palpable masses as well and have shown reliable predictive accuracy when clinical findings are combined with imaging (mammography and US) (5–11).

With heightened awareness of breast-related health concerns and larger numbers of women presenting for screening mammography, demand is increasing for evaluation of palpable and image-detected abnormalities. However, published reports cite benign biopsy results in 97%–100% of palpable lumps with no imaging findings (6–8,12) and as high as 100% benign biopsy results in palpable lumps with benign mammographic and US findings (9,10) (Table 1). The societal costs of this number of negative biopsy results are large and contribute to an already challenged health care system (13–15). One way to address this problem is to increase the specificity and reliability of imaging findings such that more women can be followed up with imaging surveillance and fewer undergo biopsy. To this end, our specific goal was to evaluate the use, final outcome, and positive biopsy rate of American College of Radiology (ACR) US Breast Imaging Reporting and Data System (BI-RADS) categories 3, 4, and 5 (16–18) recommended for breast masses.

Management—Follow-up and Outcome

Table 1.Review of Literature Regarding Management of Breast Masses at US

Study	Year	Assessment Category	Total No. of Lesions*	No. of Malignancies	NPV (%)†	Palpable vs Nonpalpable
Soo et al (6)	2001	Negative	455	1	99.8	Palpable
Dennis et al (7)	2001	Negative	600	0	100	Palpable
Moy et al (12)	2002	Negative	233	6	97.4	Palpable
Shetty and Shah (8)	2002	Negative	186	0	100	Palpable
Stavros et al (5)	1995	Benign	426	2	99.5	Both
Graf et al (9)	2004	Probably benign	157	0	100	Palpable
Mainiero et al (10)	2005	Probably benign	148	1	99.3	Both
Graf et al (11)	2007	Probably benign	448	1	99.8	Nonpalpable
Present study	2007	Probably benign	356	3	99.2	Both
Summary			3009	14	99.5	

* Includes lesions in which biopsy and/or short-interval follow-up was performed.

† NPV = negative predictive value.

MATERIALS AND METHODS

Study Design and Inclusion Criteria

This retrospective study was compliant with the Health Insurance Portability and Accountability Act and was approved by the institutional review board of Brigham & Women's Hospital. Informed consent was not required. All consecutive breast US reports obtained between January 1, 2003, and December 31, 2004, were identified in the institutional database, and we selected all breast US examinations with final recommendations of short-interval follow-up (BI-RADS category 3) or biopsy (BI-RADS categories 4 and 5) for both palpable and nonpalpable masses. Masses known to be malignant (BI-RADS category 6) were not included in the study. We then reviewed medical records to determine the pathologic examination findings and outcome of these masses. US images were not routinely re-reviewed. During the study, 835 patients' US examinations revealed 1008 masses assessed as BI-RADS categories 3, 4, or 5. Of these 835 patients, 68 with 82 masses were lost to follow-up, resulting in a study population of 767 patients with 926 masses. Patients ranged in age from 14 to 90 years (average age, 44 years). The study included 152 patients younger than 30 years, of whom 107 (70.4%) underwent only US.

Imaging and Interpretation

Breast US examinations were performed by staff radiologists (including S.R. and R.L.B.; 5-20 years of experience) with machines (HDI 5000; Philips ATL, Bothell, Wash) with which a linear 5-12-MHz or compact linear 15-5-MHz transducer was used. In the total study population of 926 lesions, 410 lesions were assessed by means of US only, and 516 were assessed by means of US and mammography.

US mass interpretation was based on shape, margins, internal echotexture, long-axis orientation, and acoustic transmission. Typical benign features included oval shape, circumscribed margins with no more than two or three gentle lobulations, long axis parallel to the skin, predominantly hypoechoic homogeneous internal echotexture, abrupt interface

with surrounding tissue, and no features suggestive of malignancy. Criteria for malignancy included irregular shape, microlobulation, indistinctness, angularity, spiculated margins, antiparallel orientation, hypoechoic appearance or heterogeneous echotexture, and posterior acoustic shadowing. The decision to recommend follow-up imaging or biopsy took into account all available data, including clinical examination and mammographic and US features, and the decision to perform biopsy was based on the finding most suggestive of possible malignancy.

Final BI-RADS assessment categories were assigned to each case by using ACR definitions (16–19). In our practice, noncystic masses without features suggestive of malignancy may be followed up with imaging only, or biopsy may be performed. At the time of US examination, the patient is advised of these management options. In cases in which short-interval imaging is recommended (BI-RADS category 3), the patient is asked to return for a 6-month follow-up. If the lesion is stable, a second 6-month follow-up (12 months after the initial examination) is typically recommended. At 12-month evaluation, assuming the mass is stable, the examiner may categorize the result as BI-RADS category 3 or 2, with recommendation for 12-month follow-up. In some cases, despite benign US features, the radiologist may recommend biopsy (BI-RADS category 4) because of clinical information such as palpability. Conversely, despite a BI-RADS category 3 recommendation, the patient or referring physician may decide on biopsy. For the purposes of this study, the latter scenario is defined as physician and/or patient preference.

All lesions with low, intermediate, or high probability of malignancy were categorized as BI-RADS 4. Lesions categorized as BI-RADS 5 were those considered to be highly suggestive of malignancy.

Two authors (S.R., with 17 years of experience, and R.L.B., with 20 years of experience) selectively and retrospectively reviewed the 34 BI-RADS 4 lesions in which biopsy had not been performed but that had 2 or more years of imaging follow-up so they could assess whether, in retrospect, biopsy recommendations might have been avoided. Individual lesion morphology was reviewed, and the lesions were subcategorized by means of consensus into 4A, 4B, and 4C lesions on the basis of the physician's level of suspicion. Lesions with five of five benign US characteristics and no features suggestive of malignancy were regarded as appropriate for BI-RADS 3 categorization.

Biopsy Methods

In our practice, fine-needle aspiration is rarely performed. When aspiration yielded no fluid, it was immediately followed by core-needle biopsy ($n = 10$ in the study). Percutaneous biopsies were performed with either 14-gauge multifire needles (Bard Peripheral Vascular/Bard Biopsy Systems, Tempe, Ariz) or an 11-gauge vacuum-assisted device (Mammotome; Johnson & Johnson, Cincinnati, Ohio). After receipt of the results from pathologic examination, concordance with imaging was confirmed, and the referring physician and patient were contacted with results and recommendations. Discordant results were discussed at routine biweekly radiology-pathology conferences. In our practice, surgical excision is recommended after core biopsy results of atypical ductal hyperplasia, flat epithelial atypia, lobular neoplasia with associated calcifications, and radial scar. Excision is not recommended for papillomas without atypia.

Statistical Analysis

Statistical analysis included calculation of NPV and positive predictive value (PPV) for each lesion. Statistical significance and confidence levels were calculated by using a χ^2 test with computerized statistical software (SPSS, version 12; SPSS, Chicago, Ill). A *P* value of less than .05 was considered to indicate a statistically significant difference. Sensitivity was analyzed to evaluate potential bias from patients lost to follow-up.

RESULTS

The study included 767 patients with 926 masses (Fig 1). Indications for US examinations were based on clinical or imaging findings. Clinical indications included palpable findings (n = 408), focal breast pain (n = 25), nipple or skin changes (n = 23), mastitis (n = 5), and axillary fullness (n = 3). Indications based on imaging included findings at mammography (n = 246), MR imaging (n = 53), and computed tomography (n = 4). Of the 926 masses, 476 were palpable, of which 51 (10.7%) were malignant, and the remaining 450 were nonpalpable, of which 80 (17.8%) were malignant (P = .002). Eliminating the probable cysts and probably malignant (BI-RADS category 5) lesions from the study population, and looking only at the indeterminate lesions, we found that biopsy had not been performed in 535 noncystic BI-RADS 3 and 4 masses. Of these 535 lesions, 285 (53.3%) were palpable masses, of which 32 (11.2%) were malignant, and 250 (46.7%) were nonpalpable masses, of which 56 (22.4%) were malignant (P < .001). All core biopsy–diagnosed risk lesions were surgically excised, and none were upgraded to carcinoma.

BI-RADS 3, 4, and 5 Lesions: Value of US in Management—Follow-up and Outcome

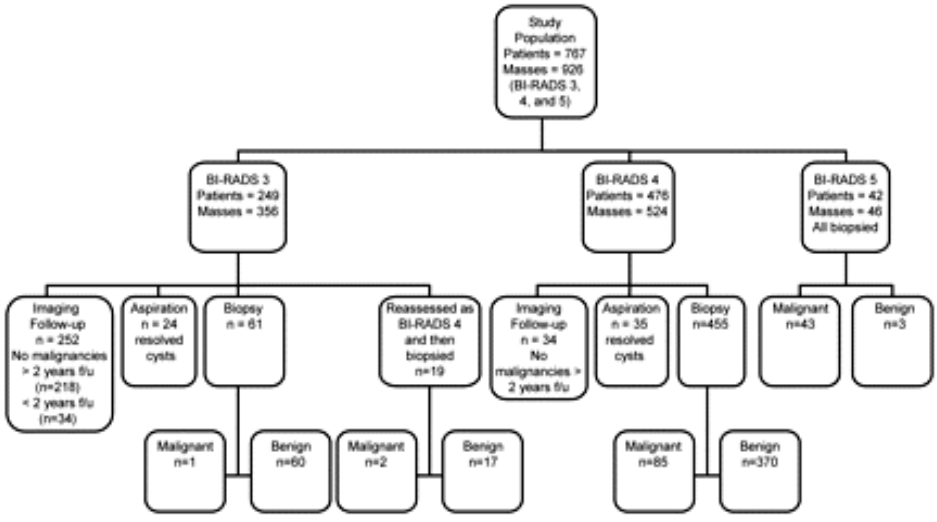

Figure 1: Flowchart of study population. *f/u* = Follow-up.

BI-RADS 3 Masses

There were 249 patients with 356 (38.4%) of 926 masses categorized as BI-RADS 3. The average patient age was 42 years (age range, 14–80 years), and the average lesion diameter

was 1.13 cm (range, 0.2–5.1 cm). Of the 356 masses, 252 (70.8%) in 178 women were followed up with short-interval imaging as recommended, of which 34 masses in 31 women were followed up for less than 2 years (6–18 months). Reasons for the shorter follow-up were as follows: mass decreased in size or resolved (n = 16), mass was assessed at follow-up with a different examiner who did not recommend continued interval imaging (n = 8), and patient was lost to follow-up (n = 7).

Aspiration or biopsy was performed in 104 (29.2%) of 356 masses, either within 3 months of initial assessment on the basis of physician and/or patient preference or after follow-up examination 6 or more months later. Aspiration revealed 24 (23.1%) cysts, and all resolved completely. Biopsy in 61 (58.7%) masses was performed because of discordant recommendation (examiner recommended biopsy while assigning BI-RADS 3 category; n = 23) or physician and/or patient preference (n = 38). Of these 61 masses in which biopsy was performed, 38 (62%) were palpable, and pathologic examination revealed one malignancy, which was excised 2.5 months after initial US (Table 2). Pathologic examination results showed a 3-mm node-negative invasive lobular carcinoma (Fig 2). Since there was no preoperative needle localization, direct correlation of the mass at US with the cancer was not possible. The remaining 23 (38%) of 61 masses in which biopsy was performed were nonpalpable, and all were benign (Table 2).

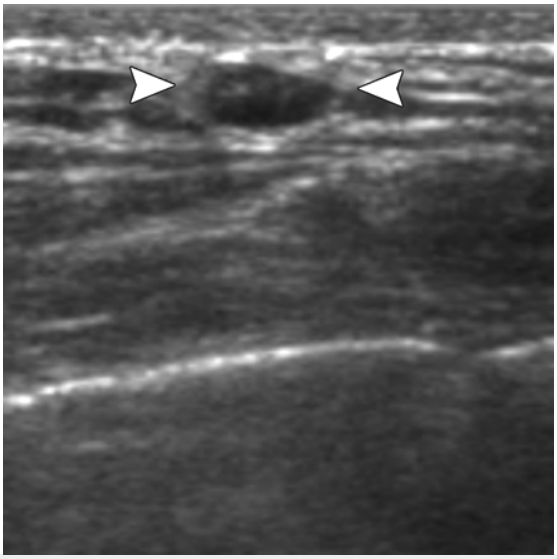

Figure 2: Palpable lump in right breast in 36-year-old woman. Initial US image shows a 2-mm, ill-defined, hypoechoic area (arrowheads) considered BI-RADS category 3 (probably benign). Two months later, on the basis of a clinical decision, the patient underwent excisional biopsy of the palpable lump, revealing a 3-mm invasive lobular carcinoma.

Table 2. Follow-up and Outcome of 356 BI-RADS 3 Lesions

Outcome or Histologic Finding*	Palpable Lesions	Nonpalpable Lesions	Total
Imaging follow-up	125	127	252 (70.8)
Aspiration (all resolved cysts)	9	15	24 (6.7)
Biopsy findings			
Malignant			3 (0.8)
Invasive	2	1	
DCIS	0	0	
Benign			77 (21.6)
ADH	1	0	
Phyllodes tumor	2	0	
Fibroadenoma	29	20	
Intraductal papilloma	1	2	
Lymph node	1	0	
Epithelial hyperplasia	3	3	
Fibrous breast tissue	2	2	
Lactational changes	2	2	
Inflammatory tissue	1	1	
Sclerosing adenosis	1	1	
Fat necrosis	1	0	
Mural fibrosis	1	1	
Total	181	175	356 (100)

Note.—Data are numbers of lesions, with percentages in parentheses.

* ADH = atypical ductal hyperplasia, DCIS = ductal carcinoma in situ.

Biopsy was performed in 19 (18.2%) of the masses originally categorized as BI-RADS 3 masses because they were recategorized as BI-RADS 4 masses at follow-up imaging owing to change in morphology or size ($n = 18$) or assessment by a different examiner ($n = 1$). Two (11%) of these 19 masses were malignant. One was palpable, was reassessed by a different examiner at 6-month follow-up, and was a 4-mm invasive ductal carcinoma (Fig 3). The other was nonpalpable, increased in size at 6 months, and was a 9-mm invasive carcinoma. Both were node negative.

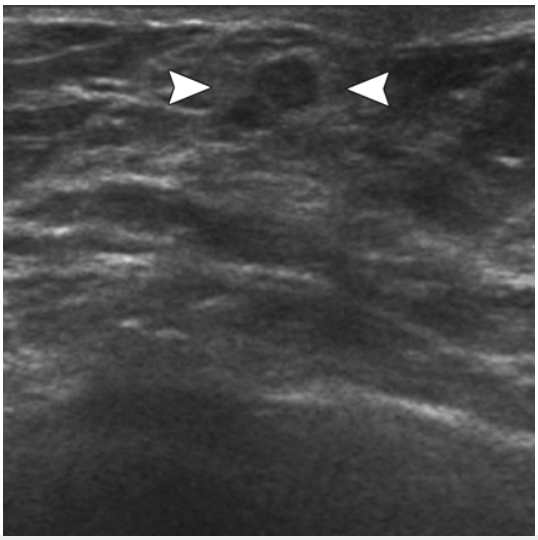

Figure 3a: Palpable lump seen as a focal asymmetry at mammography (not shown) in left breast in 72-year-old woman. **(a)** Initial US showed a 5-mm possibly intraductal mass (arrowheads), interpreted as BI-RADS category 3 (probably benign). **(b)** At 6-month follow-up, despite stable findings, a different examiner categorized the mass (arrowheads) as BI-RADS category 4 and recommended biopsy, revealing a 4-mm invasive ductal carcinoma.

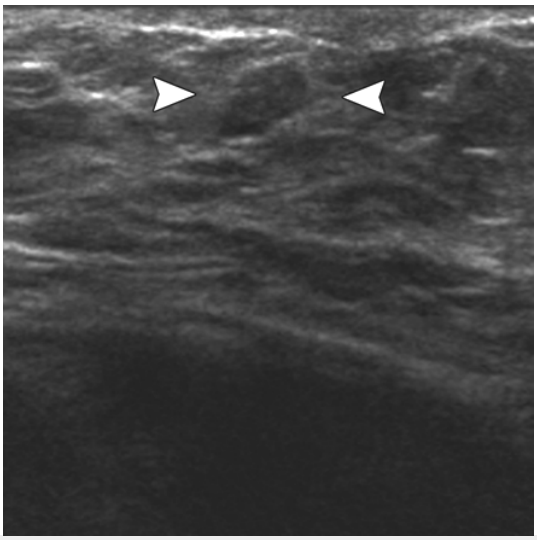

Figure 3b: Palpable lump seen as a focal asymmetry at mammography (not shown) in left breast in 72-year-old woman. **(a)** Initial US showed a 5-mm possibly intraductal mass (arrowheads), interpreted as BI-RADS category 3 (probably benign). **(b)** At 6-month follow-up, despite stable findings, a different examiner categorized the mass (arrowheads) as BI-RADS category 4 and recommended biopsy, revealing a 4-mm invasive ductal carcinoma.

In summary, three (0.8%) of 356 BI-RADS 3 masses were malignant. One was palpable, and biopsy was performed within 3 months of initial US examination on the basis of referring physician preference, and two (one palpable, one nonpalpable) were reassessed as BI-RADS category 4 at 6-month follow-up. All three were smaller than 1 cm and node negative. Aspiration or biopsy was performed in another 101 lesions, and all were benign. Most (70.8%) of the 356 BI-RADS 3 masses remained stable at subsequent imaging follow-up after 2 or more years (n = 218; 61.2%) or 6–18 months (n = 34; 9.6%).

BI-RADS 4 Masses

A total of 476 patients were identified as having 524 BI-RADS 4 masses. These patients had an average age of 43 years (age range, 17–90 years) and an average lesion size of 1.5 cm (range, 0.6–2.7 cm). Of these masses, 34 (6.5%) were followed up with short-interval imaging rather than the recommended biopsy for the following reasons: changed to BI-RADS category 3 by a subsequent examiner at the time of scheduled biopsy (n = 16), physician and/or patient preference (n = 15), or changed on the basis of MR imaging findings within 2 months of the US examination (n = 3). All of these masses remained stable, without malignancy detected for 2 or more years.

Aspiration, core-needle biopsy, or surgery was performed in the remaining 490 (93.5%) of 524 BI-RADS 4 masses (Table 3). Aspiration resolved 35 (6.7%) cysts. Another 238 (48.6%) of the 490 masses were palpable; 30 (12.6%) of 238 were malignant (26 invasive, one lymphoma, and three DCIS), and 208 (87.4%) were benign (Table 3). The remaining 217 (44.3%) of 490 BI-RADS 4 masses were nonpalpable. Of these, 55 (25.3%) were malignant (41 invasive, 14 DCIS), and 162 (74.7%) were benign (Table 3).

Table 3.

Follow-up and Outcome of 524 BI-RADS 4 Lesions

Outcome or Histologic Finding*	Palpable Lesions	Nonpalpable Lesions	Total
Imaging follow-up	23	11	34 (6.5)
Aspiration (all resolved cysts)	15	20	35 (6.7)
Biopsy findings			
Malignant	26	41	85 (16.2)
Invasive carcinoma			
Non-Hodgkin lymphoma	1	0	
DCIS	3	14	
Benign			370 (70.6)
ADH	1	4	
LCIS	0	2	
ALH	0	3	
Radial scar	0	1	
Phyllodes tumor	7	1	
Sclerosing adenosis	7	8	
Papilloma	8	3	
Epithelial and columnar hyperplasia	12	15	
Fibroadenoma	119	86	
Lactating adenoma and change	11	1	
PASH	3	5	
Myofibroblastoma	0	1	
Ductal ectasia and hyperplasia	2	1	
Hemangioma	0	1	
Tubular adenoma	3	0	
Apocrine metaplasia or cyst	5	8	
Fat necrosis	2	2	
Fibrous breast tissue	10	7	
Epidermal inclusion cyst	2	1	
Postradiation changes	0	1	
Spindle tumor (benign)	1	0	
Ruptured cyst	1	0	
SMOLD	1	0	
Lymphoctyic mastopathy	1	0	
Chronic abscess	1	0	
Lymph nodes	2	2	
Normal or fibroadipose tissue	9	9	
Total	276	248	524 (100)

Note.—Data are numbers of lesions, with percentages in parentheses.

* ADH = atypical ductal hyperplasia, ALH = atypical lobular hyperplasia, LCIS = lobular carcinoma in situ, PASH = pseudoangiomatous stromal hyperplasia, SMOLD = squamous metaplasia of lactiferous ducts.

In summary, of the 524 BI-RADS 4 masses, 85 (16.2%) were malignant (68 invasive, 17 DCIS), 11 (2.1%) were risk lesions, and 394 (75.2%) were benign.

The 34 (76.5%) masses in which biopsy was not performed remained stable for 2 or more years (Table 3). The retrospective review of the US characteristics of these lesions led to the following reassignments: 12 (35%) BI-RADS category 3, 15 (44%) category 4A, and seven (21%) category 4B lesions (Figs 4–6).

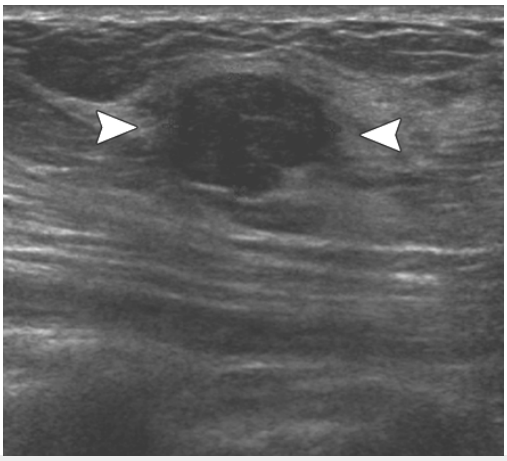

Figure 4: Palpable mass in right breast in 30-year-old woman. US showed a corresponding 14-mm, oval, smoothly marginated, parallel, homogeneously hypoechoic solid mass (arrowheads), interpreted as BI-RADS category 4. Core-needle biopsy revealed fragments of a fibroadenoma. The US features suggest a potential categorization into BI-RADS category 4A.

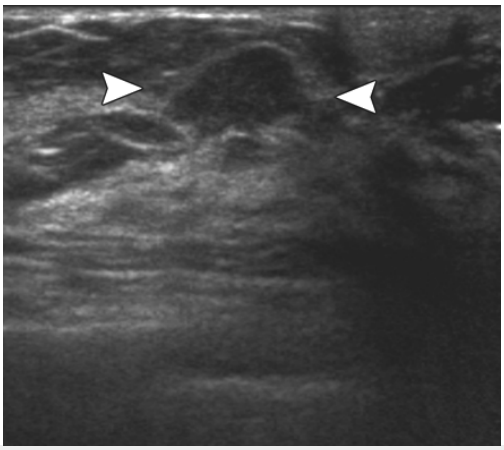

Figure 5: Palpable mass in right breast in 50-year-old woman. US showed a corresponding 11-mm solid hypoechoic mass (arrowheads) with irregular posterior margins, interpreted as BI-RADS category 4. Excision showed 1.0-cm invasive ductal carcinoma with associated DCIS. This lesion would also be appropriately classified as BI-RADS category 4B (intermediate suspicion).

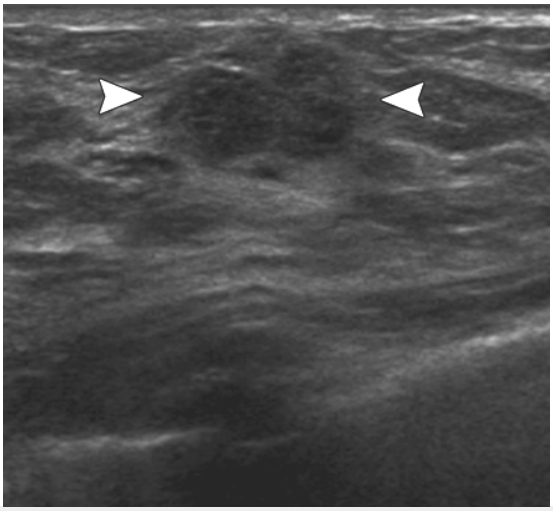

Figure 6a: Questionable mass seen at US performed at another institution was believed to correlate with an enhancing mass at MR imaging (not shown) in right breast in 47-year-old woman. **(a, b)** Correlative US showed a heterogeneous 14-mm solid mass (arrowheads) with indistinct margins in **(a)** sagittal and **(b)**

transverse planes, interpreted as BI-RADS category 4. Core-needle biopsy results revealed DCIS. Although these US characteristics are not classic for malignancy, the indistinct margins and heterogeneous echotexture are compatible with category 4B classification.

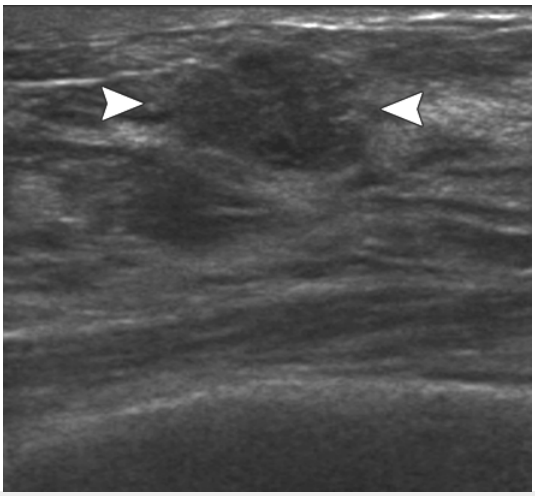

Figure 6b: Questionable mass seen at US performed at another institution was believed to correlate with an enhancing mass at MR imaging (not shown) in right breast in 47-year-old woman. **(a, b)** Correlative US showed a heterogeneous 14-mm solid mass (arrowheads) with indistinct margins in **(a)** sagittal and **(b)** transverse planes, interpreted as BI-RADS category 4. Core-needle biopsy results revealed DCIS. Although these US characteristics are not classic for malignancy, the indistinct margins and heterogeneous echotexture are compatible with category 4B classification.

BI-RADS 5 Masses

Forty-two patients had 46 masses categorized as BI-RADS 5. These patients had an average age of 56 years (age range, 28–83 years) and an average lesion size of 2.5 cm (range, 0.5–10 cm). Of these 46 masses, 19 (41%) were palpable, and all were malignant (18 invasive, one DCIS). The 27 (59%) nonpalpable masses included 24 (89%) of 27 malignancies (22 invasive, two DCIS), two risk lesions, and one benign lymph node. These results represent a PPV of 93.4% (Table 4).

Table 4. Biopsy Results in 46 BI-RADS 5 Lesions

Histologic Finding*	Palpable Lesions	Nonpalpable Lesions	Total
Malignant			
IDC with DCIS	3	5	8
IDC	12	13	25
Invasive, mixed	0	1	1
ILC with LCIS	0	1	1
ILC	2	0	2
Papillary carcinoma	1	0	1
Poorly differentiated carcinoma	0	1	1
Adenocarcinoma	0	1	1
DCIS	1	2	3
Benign			
Mucocele-like lesion with ADH	0	1	1
Radial scar	0	1	1
Reactive node	0	1	1
Total	19	27	46

* ADH = atypical ductal hyperplasia, IDC = invasive ductal carcinoma, ILC = invasive lobular carcinoma, LCIS = lobular carcinoma in situ.

Statistical Analysis

In our study, 49 patients (54 masses) with BI-RADS category 3 masses and 19 patients (28 masses) with BI-RADS category 4 masses were lost to follow-up. The average age of these 68 patients was 38.4 years (age range, 17–71 years), significantly younger than those in the study group, with an average age of 44 years (age range, 14–90 years; $P = .002$). Applying hypothetical rates ranging from 0.5% to 5.0% for BI-RADS 3 lesions and 2.0% to 90.0% for BI-RADS 4 lesions, we recalculated NPV and PPV. For BI-RADS 3 lesions, the adjusted NPV ranged from 99.2% to 98.6%, and for BI-RADS 4 lesions, the adjusted PPV ranged from 15.5% to 20.0%.

DISCUSSION

Clinical application of the mammography BI-RADS lexicon (16), now in its fourth edition, has spanned more than a decade. Breast US lesion characterization, BI-RADS categorization, and management recommendations have a shorter history, with the US lexicon (17) only in its first edition, and guidelines for management of US-detected lesions are less widely validated.

Possibly because of the operator-dependent nature of US, interpretation and use of BI-RADS category 3 recommendations vary, perhaps more than those reported for mammography (19). In our study, assignment of the BI-RADS 3 category was correctly used for 306 (86.0%) of 356 cases. In the remaining 50 cases (14.0%), the stated recommendations that biopsy could or should be considered were contradictory, ultimately leading to an interventional procedure.

Another issue specific to interval imaging is that a different examiner may evaluate the finding at follow-up. In some cases, this second examiner may recognize, with greater confidence, benign characteristics of a mass initially interpreted as probably benign and may choose to reassign it as BI-RADS category 2 or even 1. Similarly, the examiner at follow-up imaging may interpret as suspicious a lesion initially considered probably benign, as illustrated by one of our false-negative BI-RADS 3 cases. In 2006, Berg et al (20), reporting on 11 experienced examiners' performance in an experimental setting, found very good agreement ($\kappa > 0.7$) for lesion location and size and lower κ values for margin assessment (0.67), echogenicity (0.25), and final assessment (0.52). Such variation is also reported in the clinical setting (21), where κ for margin assessment (0.40) was lower than in the Berg et al study, whereas that for mass echogenicity (0.29) was similar. Possible causes of such variation include level of training, experience, technical parameters, and patient-specific issues such as breast size and lesion accessibility. In recognition of this variation among examiners, the ACR lexicon guidance chapter (16) suggests that "with a properly worded report the assessment category may be then changed to one that the current reader feels is appropriate."

Finally, an issue pertinent to follow-up is identification of the original lesion at subsequent examinations. This may be particularly challenging in larger breasts and highlights two other important issues related to standards for breast US: patient positioning (arm up and target area parallel to skin) and image annotation.

In cases in which US is used, the decision to perform biopsy in a solid mass is often swayed by whether it is palpable, regardless of recognized benign imaging features, which leads to false-positive biopsy results and incurs both financial and psychological costs (13–15). It is desirable to improve imaging specificity without losing the opportunity for early detection or increasing potential legal liability for any perceived delay in breast cancer diagnosis. Identification of masses detected at US, whether they are palpable or nonpalpable, that could be followed up with imaging alone is a laudable but difficult goal.

Conventional teaching and practice have maintained that biopsy should be performed in solid palpable masses, often despite recognized benign imaging characteristics. In our study population, there was an almost even distribution of palpable (51.4%) and nonpalpable (48.6%) masses. If we eliminate the almost definitely benign lesions (cysts) and the almost definitely malignant lesions (BI-RADS category 5), and look only at the indeterminate lesions, we find 32 (11.2%) of the 285 palpable masses and 56 (22.4%) of the 250 nonpalpable masses in this study to be malignant. This finding suggests that even when a lesion is palpable, if the characteristics at US are benign, the likelihood is that it is benign and may be managed without biopsy. This conclusion is supported by the results of Graf et al (9), who report that palpable, noncalcified solid breast masses with benign imaging characteristics "can be managed similarly to nonpalpable BI-RADS category 3 lesions, with short-term follow-up (6-month intervals for 2 years)."

Patient compliance should be considered in any study regarding recommendation outcomes. In our study, of 178 patients who initiated the recommendation for interval US, we have 2 or more years of documented follow-up in 147 (82.6%). This number is considerably higher than the 54% compliance with imaging follow-up after benign stereotactic biopsy reported by Goodman et al (22). We speculate that this discrepancy in compliance may be based on the fact that with biopsy, an answer has been provided to the patient, whereas with imaging follow-up, there is continued uncertainty, motivating the patient to return for the recommended interval imaging.

In our group of 356 BI-RADS 3 masses, there were three (<1%) cancers, all diagnosed at or before the first 6-month follow-up examination, all smaller than 1 cm, and all node negative. One of the corollaries to BI-RADS 3 categorization (<2% risk of malignancy) (1) is that delay in diagnosis of those few malignancies that are followed up should not cause undue harm to the patient. All of our false-negative cases are within this standard and support appropriate use of the BI-RADS 3 category.

The probability of malignancy in BI-RADS 4 lesions ranges from 2% to 95% (16). Lesions in this category include oval, circumscribed, hypoechoic, solid masses, as well as irregular masses with posterior acoustic shadowing. To improve internal audits, communication with clinicians and pathologists, and image-directed research, many facilities now subdivide category 4 into 4A, 4B, and 4C. During this prospective study (2003–2004), BI-RADS category 4 lesions were not subdivided. Of 34 lesions prospectively deemed to be BI-RADS category 4 in which biopsy was not performed and that remained stable at imaging follow-up, retrospective review suggested that 12 (35%) demonstrated all five US characteristics associated with benignity and could have been followed up with imaging. Conversely, 21% (seven of 34) were judged as moderately suggestive of malignancy, warranting biopsy.

We recognize that our retrospective study had some weaknesses. In particular, the examinations were performed by a number of different breast examiners, with individual variations in use of lexicon characterization and classification. In addition, patient

expectations and fears likely influence our decision making, limiting our autonomy in categorizing lesions solely on the basis of imaging characteristics. In our re-review of the category 4 lesions in which biopsy had not been performed, the retrospective subcategorization into 4A, 4B, and 4C lesions was performed with the knowledge of the benign histologic findings and therefore was somewhat artificial. Finally, in a tertiary care center, optimal follow-up is often challenging because some patients continue care at their local facilities. Sensitivity analysis revealed, however, that follow-up bias did not affect our findings with respect to the NPV and PPV of BI-RADS 3 and BI-RADS 4 lesions, respectively.

Interobserver variation in lesion recognition, classification, and recommendation is a reality, and the expectation of complete standardization of any practice with multiple practitioners is unlikely to be met. However, even should such standardization dominate a practice, the issue of whether to biopsy benign-appearing breast masses simply because they are palpable needs to be addressed. Our results corroborate those of other studies reporting an NPV of more than 99% in masses at US with recognized benign characteristics, which allows greater confidence in the use of the BI-RADS 3 category for US-determined probably benign masses, whether palpable or not, in a manner akin to the established mammographic paradigm.

ADVANCES IN KNOWLEDGE

- Probably benign Breast Imaging Reporting and Data System (BI-RADS) category 3 masses at US have a consistently low likelihood of subsequent malignancy (negative predictive value = 99.2%).
- Palpable masses that appear benign according to strict US criteria do not necessarily have a higher likelihood of malignancy.

IMPLICATION FOR PATIENT CARE

- Adherence to the BI-RADS US lexicon with correct classification of breast masses will potentially lead to fewer unnecessary breast biopsies.

Abbreviations:ACR = American College of Radiology; BI-RADS = Breast Imaging Reporting and Data System; DCIS = ductal carcinoma in situ; NPV = negative predictive value; PPV = positive predictive value

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Abstract/FREE Full Text

A Dra Ackerman também mencionou o artigo publicado em 2004 pelo Dr. Graf:

Follow-up of Palpable Circumscribed Noncalcified Solid Breast Masses at Mammography and US: Can Biopsy Be Averted?

Oswald Graf, MD, Thomas H. Helbich, MD, Michael H. Fuchsjaeger, MD, Gottfried Hopf, MD, Margarita Morgun, MD, Claudia Graf, PhD, Reinhold Mallek, MD and Edward A. Sickles, MD

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Abstract

PURPOSE: To determine whether palpable noncalcified solid breast masses with benign morphology at mammography and ultrasonography (US) can be managed similarly to nonpalpable probably benign lesions (Breast Imaging Reporting and Data System [BI-RADS] category 3)—that is, with periodic imaging surveillance—and to determine whether biopsy can be averted in these lesions.

MATERIALS AND METHODS: No institutional review board approval or patient consent was required. This retrospective analysis, based on final imaging reports, included 152 patients (age range, 28–77 years; mean age, 48.3 years) with 157 palpable noncalcified solid masses that were classified as probably benign at initial mammography and US. Of 152 patients, 108 underwent follow-up with mammography and US (6-month intervals for 2 years, then 12-month intervals). The remaining 44 patients underwent surgical or needle biopsy after initial imaging. Lesions were analyzed at initial and follow-up examinations. Statistical analysis included Student *t* test and corresponding exact 95% confidence intervals.

RESULTS: In 108 patients who underwent follow-up only, 112 lesions were palpable. In 102 (94.4%) of 108 patients, masses remained stable during follow-up. Lesions were followed for at least 2 years (mean, 4.1 years; range, 2–7 years). In six (5.6%) patients, palpable lesions increased in size during follow-up; these lesions were benign at subsequent open biopsy. No breast carcinoma was diagnosed in the 44 patients with 45 palpable lesions who underwent biopsy after initial imaging. Of 157 lesions, no malignant tumors were observed (exact one-sided 95% confidence interval: 0%, 1.95%).

CONCLUSION: The data strongly suggest that palpable noncalcified solid breast masses with benign morphology at mammography and US can be managed similarly to nonpalpable BI-RADS category 3 lesions, with short-term follow-up (6-month intervals for 2 years). More data, based on a larger series, are required to determine whether this conclusion is correct.; RSNA, 2004

The use of less-invasive needle biopsy techniques for breast abnormalities has substantially decreased morbidity and cost compared with those for open surgical biopsy (1–5). However, up to 80% of women in whom biopsy is performed do not have cancer (6–10). Thus, efforts are under way to safely reduce the number of biopsies performed that ultimately yield a benign result.

When a nonpalpable mass with benign morphology is detected at screening mammography, the standard practice in many institutions is to follow the lesion if, after a full diagnostic imaging evaluation, it is judged to have a 2% or lower probability of cancer (called a probably benign lesion) (11–14). Follow-up of nonpalpable probably benign lesions (Breast Imaging Reporting and Data System [BI-RADS] category 3) has been reported in several studies (15–21). Furthermore, study results have shown that women with palpable abnormalities but negative results at mammography and ultrasonography (US) (BI-RADS category 1) are at very low risk for cancer but should be followed up at short-term intervals with clinical examination and imaging if biopsy is not performed (22–26).

However, if a circumscribed noncalcified solid mass is palpable, the recommended management is usually to obtain a tissue diagnosis, even when, according to morphologic criteria, the mass is probably benign (27–29). The rationale behind this recommendation is the absence of published data on the safety and efficacy of periodic imaging surveillance for palpable circumscribed noncalcified solid breast masses. In women who refuse to undergo surgical biopsy, the consensus is that diagnosis of a benign lesion requires the

combination of a clinical examination, imaging, and nonsurgical tissue biopsy (the triple test) (30,31). However, some women refuse even needle biopsy if the clinical and morphologic criteria suggest that the palpable lesion is probably benign (22). Thus, the purpose of our study was to determine whether palpable noncalcified solid breast masses with benign morphology at both mammography and US can be managed safely in a way similar to nonpalpable probably benign lesions (BI-RADS category 3)—that is, with periodic imaging surveillance—and to determine whether biopsy can be averted for most of these lesions.

MATERIALS AND METHODS

Case Selection

The study cases were retrospectively identified by searching the computer database at the Ambulatory Care Center Steyr for cases of palpable noncalcified solid breast masses that were classified as probably benign at imaging between January 1996 and July 2003. The identification and analysis of cases was based on final reports and not on image review. Women with clearly benign findings at mammography or US (BI-RADS category 2; ie, calcified fibroadenomas, intramammary lymph nodes, fat-containing lesions, raised skin lesions, simple cysts) or with findings suspicious for malignancy (BI-RADS category 4 or 5), as well as those with palpable abnormalities but in whom no abnormality could be detected at mammography or US (BI-RADS category 1), were not included in this study.

For this type of retrospective analysis, approval by the institutional review board was not required at our institution; informed consent was not required, because patient anonymity was maintained.

There were 235 patients in whom the palpable abnormality met the morphologic criteria reported for probably benign masses, as assessed by the original interpreting radiologists. On the basis of the reports, 83 of 235 patients were subsequently excluded from analysis. Fourteen of these 83 were women younger than 25 years of age and were excluded because only US was performed in these cases, since 25 years of age was our lower limit for diagnostic mammography, and breast cancer is exceedingly rare in women this young. In 42 of 83 patients, the palpable mass was obscured by dense breast tissue on the mammogram and was characterized only on US images; these women were excluded because lesion characteristics could not be defined at mammography in these patients. Twenty-seven of the 83 patients did not undergo at least 2 years of follow-up and did not undergo biopsy; they were also excluded from study. Thus, the study included 152 women (age range, 28–77 years; mean, 48.3 years ± 9.7 [standard deviation]; median, 47 years). Twenty-five (16.4%) of the 152 women were younger than 40 years.

Imaging and Image Evaluation

In each patient, full clinical examination of both breasts was performed by the referring physicians. At clinical breast examination, 157 palpable lesions were detected in 152 patients by those physicians. The women were subsequently referred to our institution to undergo diagnostic mammography and US. Patient history (eg, breast cancer, previous biopsy) was recorded. At the time of imaging, the area of interest was determined from the written imaging request, the patient was asked to identify the lump for which she was referred, and we performed a brief physical examination of the area of concern.

Mammographic examinations were performed with a dedicated mammography unit (Senographe 800T; GE Medical Systems, Milwaukee, Wis). Film processing optimized for the mammographic unit was used (Kodak, Rochester, NY). Standard-view mammograms were obtained in the craniocaudal and mediolateral oblique projections. Five radiologists, each with 5–20 years of experience in mammography and US, were involved in interpreting the images. After viewing the standard images, additional views (mediolateral view, spot compression, magnification) were ordered by a radiologist in 124 (81.6%) of 152 patients. US was performed by the same radiologist, immediately after viewing the mammograms, by using 10–14-MHz linear array transducers (Ultramark 9 HDI, Advanced Technology Laboratories, Bothell, Wash; Powervision 6000, Toshiba, Tokyo, Japan). At US, the area of the palpable abnormality was examined. Subsequently, all mammograms and US images were evaluated by at least two experienced breast radiologists (O.G., T.H.H., G.H., R.M.) in consensus at the time of the initial examination, as well as at each follow-up examination.

The following mammographic and US criteria were used to define a probably benign lesion (15–22,32–34): On the mammogram, lesions were characterized as circumscribed noncalcified masses with a round, an oval, or a slightly lobular contour. Circumscribed masses with partially obscured (<25%) margins caused by adjacent isodense normal tissue were included as probably benign findings, but none of the margins of a given mass were judged to be either indistinct or spiculated (Fig 1a, 1b). Probably benign masses may have the same density as or may have higher or lower density than benign fibroglandular breast tissue, but these masses do not contain fat.

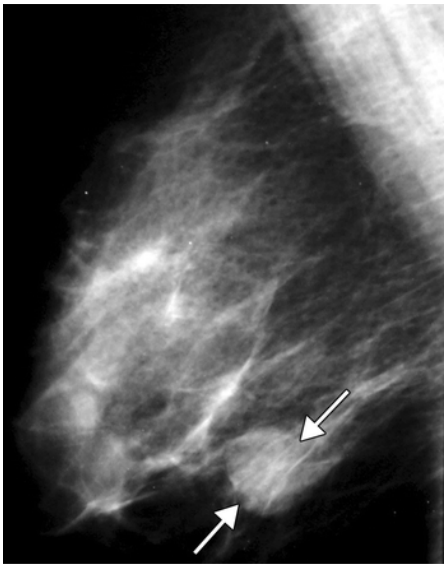

Figure 1a. Images obtained in a 48-year-old woman with a palpable solitary mass at clinical examination. **(a)** Mediolateral oblique and **(b)** craniocaudal projection (detail) mammograms of the right breast show an oval circumscribed noncalcified mass (arrows) with a contour partially obscured by superimposition of normal breast tissue. **(c)** US image shows an oval circumscribed solid mass (arrows) classified as probably benign. Fibroadenoma was histologically diagnosed after surgical biopsy.

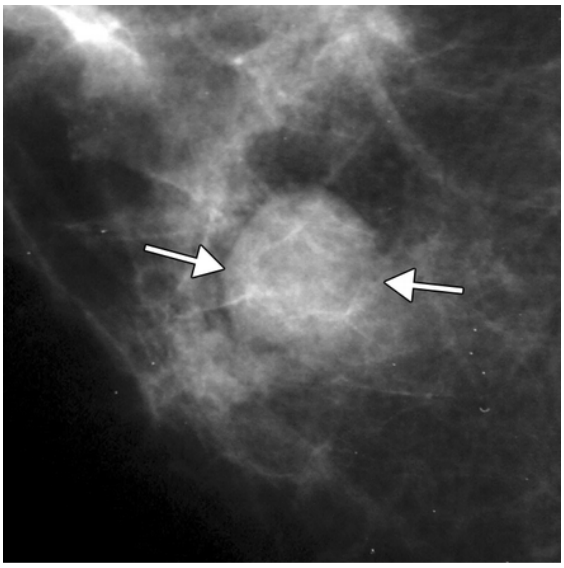

Figure 1b. Images obtained in a 48-year-old woman with a palpable solitary mass at clinical examination. **(a)** Mediolateral oblique and **(b)** craniocaudal projection (detail) mammograms of the right breast show an oval circumscribed noncalcified mass (arrows) with a contour partially obscured by superimposition of normal breast tissue. **(c)** US image shows an oval circumscribed solid mass (arrows) classified as probably benign. Fibroadenoma was histologically diagnosed after surgical biopsy.

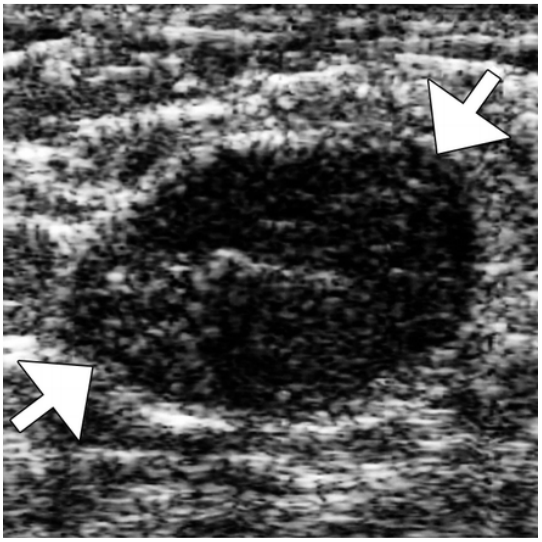

Figure 1c. Images obtained in a 48-year-old woman with a palpable solitary mass at clinical examination. **(a)** Mediolateral oblique and **(b)** craniocaudal projection (detail) mammograms of the right breast show an oval circumscribed noncalcified mass (arrows) with a contour partially obscured by superimposition of normal breast tissue. **(c)** US image shows an oval circumscribed solid mass (arrows) classified as probably benign. Fibroadenoma was histologically diagnosed after surgical biopsy.

US criteria used to define a probably benign solid breast mass were shape (round, oval, or macrolobulated), margins (circumscribed), and width (width greater than height, ie, long axis parallel to the skin surface). All of these criteria were required for an assessment of a probably benign mass at US (Fig 1c).

The number, location, side, and size (greatest diameter at mammography and US) of the lesions detected at clinical breast examination, mammography, and US were recorded. A lesion-to-lesion correlation was performed at follow-up examinations.

Management of Palpable Probably Benign Lesions

The patient and the referring physician were informed that the palpable abnormality corresponded to a solid mass with morphologic characteristics that suggested that the lesion was probably benign. Patients were told that, on the basis of morphologic criteria alone, the probability of a carcinoma is less than 2% when such lesions are nonpalpable and that, at our institution, periodic imaging surveillance is standard practice for these lesions (11–21). Patients were told that the recommended management for a palpable mass with similar morphology is still to obtain a tissue diagnosis, since there are no published data that establish the safety and efficacy of periodic imaging surveillance. The decision to undergo biopsy (surgical or needle) or periodic imaging surveillance was made by the patient and the referring physician on the basis of their preferences and the analysis of all criteria, which included patient history and findings at clinical breast examination. Periodic imaging surveillance was offered as an alternative for patients who refused to undergo immediate biopsy.

Of the 152 patients, 108 (71%; age range, 28–77 years; mean age, 48.0 years ± 9.8) chose to undergo periodic imaging surveillance. Forty-four (29%; age range, 31–69 years; mean age, 48.7 years ± 9.7) of 152 patients chose to undergo surgical or needle biopsy after initial imaging. The age difference between these groups of patients was not statistically significant ($P = .75$).

In the 108 patients who chose to undergo imaging surveillance, a short-term follow-up study with US was scheduled for 3 months after the initial examination, and further follow-up studies with mammography and US were scheduled at 6-month intervals for the first 2 years. After the first 2 years, we performed follow-up at our regular recommended screening interval, which is 1 year. The duration of follow-up from the initial examination to the last follow-up examination was recorded for every patient. After each follow-up study with mammography and US, the patient underwent a follow-up clinical breast examination performed by the referring physician.

Lesion progression at follow-up studies (enlargement or changes from initial border characteristics) was considered an indication for surgical or needle biopsy (2).

In 32 of the 44 patients who chose to undergo biopsy after initial imaging, surgical biopsy was performed. In the remaining 12 patients, 14-gauge core needle biopsy was performed. Given the nonzero false-negative rate for needle biopsies, periodic imaging surveillance was continued after needle biopsy in those patients.

Statistical Analysis

Statistical analysis of lesion size was performed by using the Statview program (Abacus Concepts, Berkeley, Calif). In those patients who had more than one palpable mass, the size of each lesion was measured. Results are expressed as mean ± 1 standard deviation. *P* values were determined by using the unpaired Student *t* test, and $P < .05$ was considered to indicate statistical significance.

To demonstrate that the number of retrospectively included cases was sufficient to prove the study assumption (<2% of the masses were malignant), frequencies were described by using percentages, and corresponding exact 95% confidence intervals were calculated (Clopper-Pearson method). The clustering dependency of data for patients with more than one palpable lesion was taken into account, and the corresponding 95% confidence intervals were calculated from the total number of patients rather than from the total number of palpable lesions.

RESULTS

Follow-up

Of 108 patients who chose to undergo periodic imaging surveillance, 14 had a history that included surgical biopsy for a solitary palpable lesion, each of which was found to be a fibroadenoma. One patient had previously undergone two surgical biopsies at two different times. In this patient, a fibroadenoma was diagnosed at histologic work-up in each case. None of these patients had a history of breast cancer.

At clinical breast examination, 112 lumps were palpable in the 108 patients who chose periodic imaging surveillance. These lumps corresponded to the lesions for which the patients were referred. In 105 of 108 patients, a solitary lesion was palpable. Two patients each had two palpable lumps (one in each breast), and one patient had three palpable lumps (two in the left breast and one in the right breast) at clinical breast examination.

The mean size of the lesions at initial imaging was 18.0 mm ± 6.1 (range, 7–38 mm).

In 102 (94.4%) of 108 patients, the palpable lesion did not increase in size, and the margins remained stable during the follow-up period (Fig 2). In six patients (5.6%), an increase in the diameter of the palpable mass and/or a change in the initial border characteristics was observed at follow-up, and surgical biopsy was subsequently performed. At histologic work-up, fibroadenoma was diagnosed in each of these cases. An increase in size and a change in the initial shape of the lesion was observed between the 6-month and 12-month follow-up examinations in one patient (Fig 3), and, in the remaining five patients, an increase in the lesion size was observed over a 12-month period. At the 3-month follow-up examination, which included only US, no substantial changes in lesion size or border characteristics were observed in any of the 108 patients.

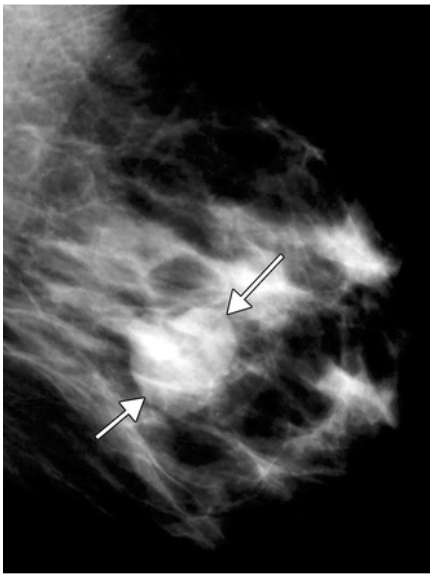

Figure 2a. Images obtained in a 37-year-old woman who underwent surgical biopsy of a solitary palpable lump in the right breast at 22 years of age; fibroadenoma was histologically diagnosed at that time. At 34 years of age, a new palpable lump occurred in the left breast. Initial **(a)** mediolateral oblique projection mammogram and **(b)** US image of the left breast show a well-circumscribed mass (arrows) corresponding to the palpable lump. Lesion was classified as probably benign and remained stable during 3 years of follow-up. **(c)** Mediolateral oblique projection mammogram and **(d)** US image at follow-up 3 years after the initial examination again show the mass (arrows).

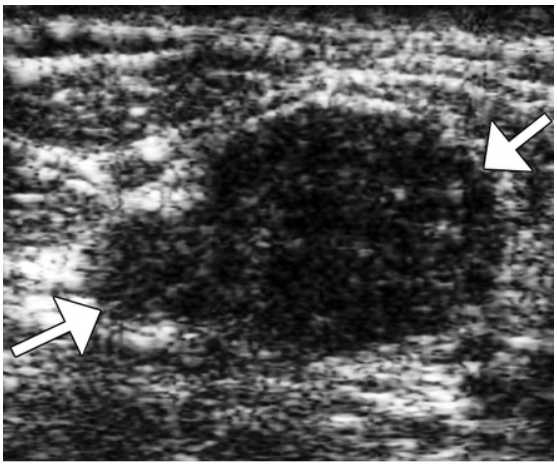

Figure 2b. Images obtained in a 37-year-old woman who underwent surgical biopsy of a solitary palpable lump in the right breast at 22 years of age; fibroadenoma was histologically diagnosed at that time. At 34 years of age, a new palpable lump occurred in the left breast. Initial **(a)** mediolateral oblique projection mammogram and **(b)** US image of the left breast show a well-circumscribed mass (arrows) corresponding to the palpable lump. Lesion was classified as probably benign and remained stable during 3 years of follow-up. **(c)** Mediolateral oblique projection mammogram and **(d)** US image at follow-up 3 years after the initial examination again show the mass (arrows).

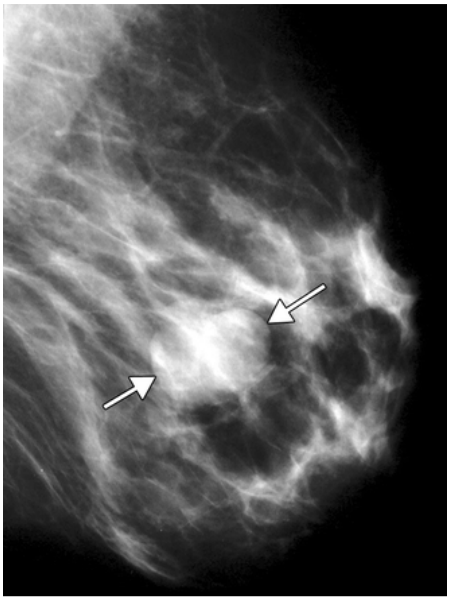

Figure 2c. Images obtained in a 37-year-old woman who underwent surgical biopsy of a solitary palpable lump in the right breast at 22 years of age; fibroadenoma was histologically diagnosed at that time. At 34 years of age, a new palpable lump occurred in the left breast. Initial **(a)** mediolateral oblique projection mammogram and **(b)** US image of the left breast show a well-circumscribed mass (arrows) corresponding to the palpable lump. Lesion was classified as probably benign and remained stable during 3 years of follow-up. **(c)** Mediolateral oblique projection mammogram and **(d)** US image at follow-up 3 years after the initial examination again show the mass (arrows).

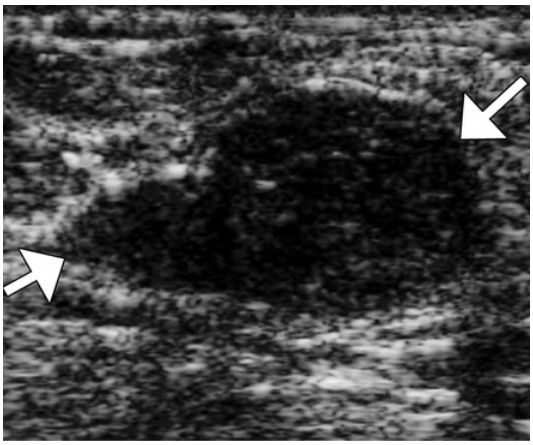

Figure 2d. Images obtained in a 37-year-old woman who underwent surgical biopsy of a solitary palpable lump in the right breast at 22 years of age; fibroadenoma was histologically diagnosed at that time. At 34 years of age, a new palpable lump occurred in the left breast. Initial **(a)** mediolateral oblique projection mammogram and **(b)** US image of the left breast show a well-circumscribed mass (arrows) corresponding to the palpable lump. Lesion was classified as probably benign and remained stable during 3 years of follow-up. **(c)** Mediolateral oblique projection mammogram and **(d)** US image at follow-up 3 years after the initial examination again show the mass (arrows).

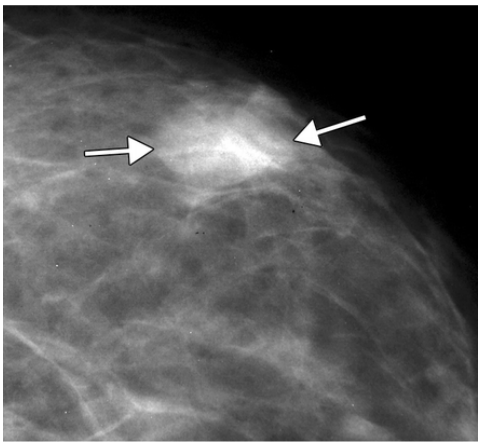

Figure 3a. Images obtained in a 43-year-old woman with a superficially located solitary palpable lump in the right breast. **(a)** Craniocaudal mammogram (detail) and **(b)** US image obtained 6 months after initial study. Images show a well-circumscribed mass (arrows) classified as probably benign. The lesion showed no changes compared with that on the initial examination images. On **(c)** mammogram and **(d)** US image at 12-month follow-up, lesion is slightly larger and shows lobulations (arrows). Surgical biopsy was performed, and fibroadenoma was diagnosed at histologic analysis.

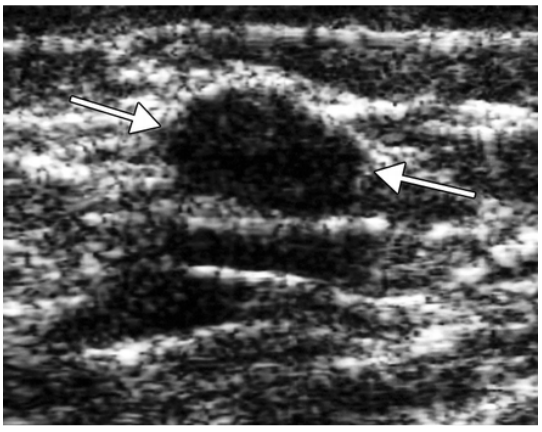

Figure 3b. Images obtained in a 43-year-old woman with a superficially located solitary palpable lump in the right breast. **(a)** Craniocaudal mammogram (detail) and **(b)** US image obtained 6 months after initial study.

Images show a well-circumscribed mass (arrows) classified as probably benign. The lesion showed no changes compared with that on the initial examination images. On **(c)** mammogram and **(d)** US image at 12-month follow-up, lesion is slightly larger and shows lobulations (arrows). Surgical biopsy was performed, and fibroadenoma was diagnosed at histologic analysis.

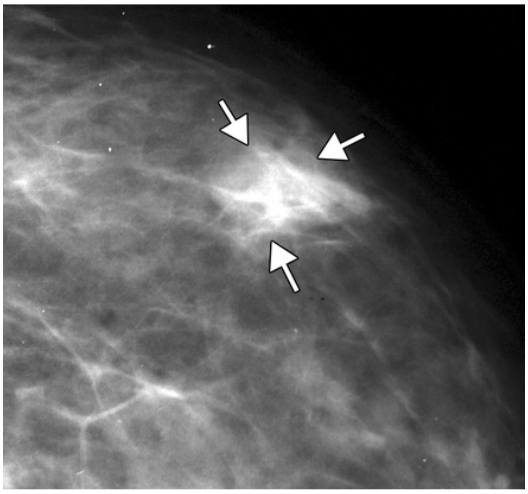

Figure 3c. Images obtained in a 43-year-old woman with a superficially located solitary palpable lump in the right breast. **(a)** Craniocaudal mammogram (detail) and **(b)** US image obtained 6 months after initial study. Images show a well-circumscribed mass (arrows) classified as probably benign. The lesion showed no changes compared with that on the initial examination images. On **(c)** mammogram and **(d)** US image at 12-month follow-up, lesion is slightly larger and shows lobulations (arrows). Surgical biopsy was performed, and fibroadenoma was diagnosed at histologic analysis.

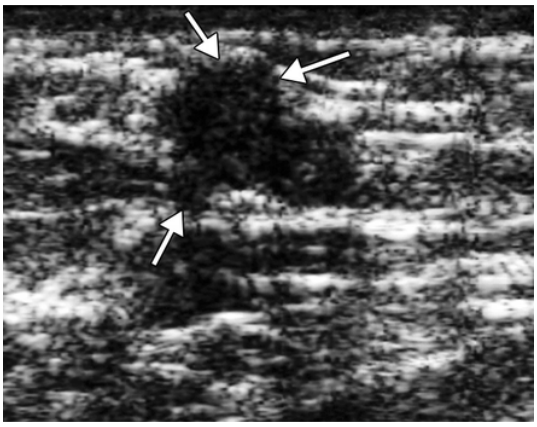

Figure 3d. Images obtained in a 43-year-old woman with a superficially located solitary palpable lump in the right breast. **(a)** Craniocaudal mammogram (detail) and **(b)** US image obtained 6 months after initial study. Images show a well-circumscribed mass (arrows) classified as probably benign. The lesion showed no changes compared with that on the initial examination images. On **(c)** mammogram and **(d)** US image at 12-month follow-up, lesion is slightly larger and shows lobulations (arrows). Surgical biopsy was performed, and fibroadenoma was diagnosed at histologic analysis.

In one patient, suspicious bilateral microcalcifications that were unrelated to a solitary palpable mass (17 mm in maximum diameter) developed over the course of 1 year. In this patient, a fibroadenoma was diagnosed at histologic work-up when the palpable lesion was excised at surgery. In the remaining patients, no breast carcinomas developed during the follow-up period.

By combining the six patients in whom lesion size increased at follow-up and the patient with suspicious microcalcifications that were unrelated to the palpable mass, a benign histologic diagnosis after surgical biopsy was available in seven of the 108 patients in whom follow-up was initially performed.

In 101 of 108 patients, no histologic diagnosis is available, and the palpable lesions are still under surveillance. In all of these patients, follow-up was performed for at least 2 years (range, 2–7 years; mean, 4.1 years). At the time this report is being published, of 101 patients, 23 have been under surveillance for more than 2 years, 26 have been under surveillance for more than 3 years, and 52 have been under surveillance for 4 years or longer.

Of the patients in whom the palpable mass remained stable at imaging, none underwent biopsy because of findings at clinical follow-up breast examinations performed by the referring physician.

Biopsy

Of the 44 patients who chose to undergo biopsy, five had a history of breast carcinoma in the contralateral breast. One patient had a history of surgical biopsy with a diagnosis of fibroadenoma. Of 44 patients, 43 (97.7%) had a solitary lump at clinical breast examination. In one patient (2.3%), two lesions were palpable in the left breast. Thus, 45 lesions were palpable in 44 patients. These lumps corresponded to the lesions for which the patients were referred to our institution.

The mean size of the lesions in these patients was 17.7 mm ± 6.0 (range, 7–30 mm). The difference between the size of palpable lesions in this group and the size of palpable lesions in patients in whom follow-up was performed was not statistically significant ($P = .16$).

No malignancy was diagnosed at excisional biopsy or core needle biopsy in any of these 44 patients. Forty-three of 45 palpable lesions were fibroadenomas at histologic work-up. The other two histologic diagnoses were adenomyoepithelioma and benign fibrocystic changes.

In 12 of 44 patients in whom 14-gauge core needle biopsy was performed, fibroadenoma was diagnosed at histologic work-up. Imaging surveillance after biopsy did not show any enlargement or other suspicious changes in these lesions for at least 2 years.

When we combine the patients in whom follow-up was performed and those in whom biopsy was performed, we have observed no malignant tumors in 152 patients with 157 palpable lesions. The exact one-sided 95% confidence interval for this number of patients (0%, 1.95%) indicates that the likelihood of malignancy for these lesions is less than 2%.

DISCUSSION

The BI-RADS final assessment category 3 (probably benign) is meant to be used for findings with imaging characteristics that suggest a more than 0% but less than 2% likelihood of malignancy. The benign nature of such lesions can be presumed by demonstrating stability on surveillance mammograms over a total interval of 2–3 years. Malignant breast lesions that are initially diagnosed as probably benign are reliably and promptly identified with periodic mammographic follow-up. Characterization of these probably benign lesions is an important and frequently used tool for the breast radiologist to avert low-yield biopsies, which increase both the morbidity and the cost associated with breast cancer screening (11–21).

However, BI-RADS category 3 has traditionally been used only for nonpalpable lesions. This is because, to date, only nonpalpable lesions have been shown to have such a low likelihood of malignancy that periodic imaging surveillance is a safe and effective

alternative to immediate tissue diagnosis. The results of this study strongly suggest that the palpable, circumscribed, noncalcified, solid breast mass also can be placed in BI-RADS category 3 when findings at mammography and US suggest that the mass is probably benign and that biopsy will be averted if the lesion remains stable at mammographic follow-up. Our results show that the probability of cancer is as low in palpable lesions as it is in nonpalpable BI-RADS category 3 lesions.

The rather small number of included patients should be considered a limitation of this study. However, the exact one-sided 95% confidence interval (0%, 1.95%) confirmed the adequacy of the number of patients to prove our study hypothesis, which is that palpable probably benign lesions have a less than 2% likelihood of malignancy. All surveillance studies, if large and of sufficiently long duration, will demonstrate a finite number of cancers from a population of circumscribed solid masses. More data from a larger series will provide the greater statistical power needed to establish the clinical acceptability of managing palpable noncalcified solid breast masses with periodic mammographic surveillance; this management would be similar to what has already been established for nonpalpable probably benign lesions.

Every benign or malignant lesion is nonpalpable at inception and for some subsequent time; it becomes palpable only when a specific size is reached. Whether a mass is palpable is determined by the size of the lesion, its location in the breast, and the size of the breast itself. We relied on morphologic characteristics at imaging when lesions were evaluated for the first time. Temporal stability at follow-up corroborated our assessment of a probably benign lesion. In our study, none of the noncalcified solid masses that were deemed probably benign proved to be malignant. In those patients in whom no tissue diagnosis was available, the chance that one of the palpable noncalcified solid masses would be malignant is extremely low, since all such lesions remained stable in size and border characteristics for a period of at least 2 years (range, 2–7 years; mean, 4.1 years). Excisional biopsy did not reveal a malignant lesion in those six patients in whom the lesion had increased in size at follow-up, in the patient in whom the lesion was excised at the time of surgery for newly developed microcalcifications that were unrelated to the palpable mass, or in those 44 patients in whom biopsy was performed instead of mammographic surveillance.

As with nonpalpable probably benign lesions, if follow-up of a palpable mass is considered as an alternative to immediate biopsy, it is essential that lesions strictly meet the reported and established criteria for benignity (35–37). We did not encounter a single palpable cancer that showed benign morphology at imaging in our patients. Our data support the hypothesis that cancers that have progressed to a palpable size and still show benign morphology at imaging are rare.

However, follow-up of a palpable mass with benign morphology may be more risky than follow-up of a nonpalpable lesion. On the chance that the lesion is malignant, the risk for metastasis is higher, since palpable masses are usually larger than nonpalpable lesions (38). We performed the first follow-up study with US 3 months after the initial examination. We believed that monitoring of palpable probably benign lesions very closely in the beginning of follow-up might help to demonstrate suspicious changes early. However, no significant changes were found at 3-month follow-up US.

While a minimum of 2 years of follow-up has been widely accepted as an indicator of benignity for nonpalpable masses, no standards have been established for palpable probably benign lesions. We chose surveillance intervals similar to those recommended for

nonpalpable lesions. After following a lesion at 6-month intervals for the first 2 years, we lengthened our interval to 12 months. We believed that a lesion that has progressed to a palpable size and has remained stable for at least 2 years is very likely benign. Although, to our knowledge, there were no published data on this issue prior to our study, we assumed that if a benign-appearing palpable mass (usually larger than a nonpalpable mass) is actually malignant, it should demonstrate malignant changes at imaging no later in its course than would a nonpalpable mass.

Since a palpable benign lesion could conceivably obscure an adjacent developing cancer at clinical breast examination, we believed that, in addition to demonstrating stability at mammography, surveillance of internal features of the lesion and observation of its surroundings with US might help to reduce the risk of a false-negative assessment. After initial characterization of a mass at mammography and US, and given the established validity of mammographic surveillance, follow-up with mammography alone would be sufficient to demonstrate stability. However, additional surveillance with US bolstered our level of confidence in the management of the probably benign mass.

As in nonpalpable BI-RADS category 3 lesions, it is essential that the patient and the referring physician are aware of the fact that the lesion may be malignant despite the benign morphology. We told our patients that less than 2% of nonpalpable circumscribed masses prove to be malignant at biopsy and that standard practice is usually to follow the lesion (11–14). However, for palpable lesions with similar morphology, the effectiveness and safety of periodic imaging surveillance had not, to our knowledge, been documented prior to our study. The refusal to undergo biopsy and decision to undergo imaging surveillance should be made only if the potential shortcomings of imaging are completely understood. We recommend biopsy in those women for whom the perceived level of risk is unacceptable. On the condition that findings of a full clinical breast examination performed by the referring physician do not require immediate tissue diagnosis, we now perform imaging surveillance for those women who reject surgical or needle biopsy.

The final decision for follow-up or biopsy was made by the patient and the referring physician and was based on analysis of the imaging report, the full clinical breast examination performed by the referring physician, and the patient history (also assessed by the referring physician). Although we did not consider patient history when making our imaging assessments, it is interesting to note that a history of surgical biopsy that yielded a benign result or a history of breast cancer could influence the patient's decision for biopsy versus follow-up. Fifteen (13.9%) of the 108 patients who chose follow-up had undergone a previous surgical biopsy with benign results, whereas only one (2.3%) of the 44 patients who chose biopsy had undergone a previous surgical biopsy with benign results. On the other hand, five (11.4%) of the 44 patients in the biopsy group had a history of breast cancer, but no patient in the follow-up group had such a history.

In conclusion, the use of periodic mammographic surveillance for nonpalpable probably benign masses is now widely accepted. Our data suggest that palpable masses that display the same probably benign features at mammography and US can be managed in a similar way and that biopsy will be averted if such lesions remain stable at follow-up. More data, based on a larger series, will help to establish the clinical acceptability of periodic surveillance for palpable probably benign masses.

Acknowledgments

We acknowledge the work of Erich Walter, MD, dedicated breast radiologist and teacher at the Ambulatory Care Center Steyr, who unfortunately died 4 years ago.

Footnotes

Abbreviation: BI-RADS = Breast Imaging Reporting and Data System

Index terms:Breast, biopsy, 00.1261; Breast neoplasms, diagnosis, 00.31; Breast neoplasms, radiography, 00.11; Breast neoplasms, US, 00.1298

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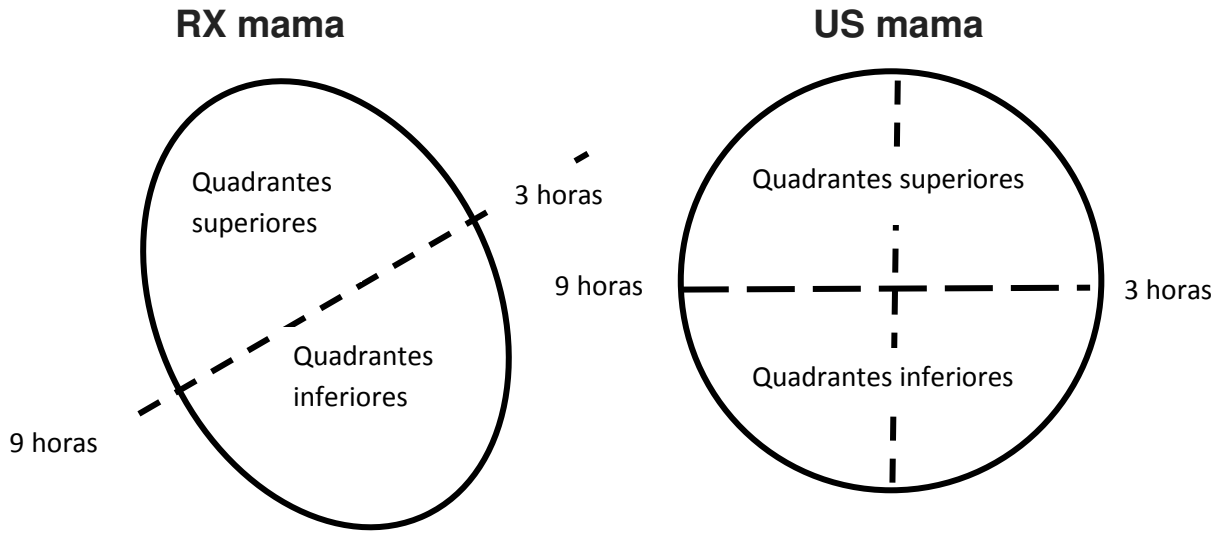
CONCLUSÃO

1. E a lesão mais suspeita que deve servir para conduzir o paciente.
2. A correlação dos achados US com a classificação BIRADS permite direcionar a conduta de acordo com a avaliação da mama, integrando à US com outras categorias de diagnóstico por imagem

PEARLS AND PITFALLS IN BREAST ULTRASOUND AND INTERVATION,

ministrada por Abid Irshad,MBBS, Medical University of South Caroline Charleston

O ultrassom de mama tem um papel importante no diagnóstico e conduta das lesões mamárias. A aula apresentada foi baseada em casos específicos que mostram o aspecto da eficiência diagnóstica que se quer enfatizar, bem como as principais limitações do US em mama. O autor mostrou casos em que a US mama ofereceu informações adicionais a cerca do comportamento biológico do tumor, demonstrando sua agressividade. Reviu as técnicas mais valiosas da biopsia da mama com especial atenção a modificações que podem auxiliar em algumas situações difíceis.
Mostra uma imagem de uma mamografia de mama densa e pergunta :
Há alguma lesão na mama ou é apenas tecido mamário ?
se a mama é densa não é possível responder negativamente quanto a ausência de neoplasia
A contra partida US seria a maior dificuldade que apresenta no rastreamento do tumor mamário em mama hipodensa. Recomendou como técnicas de exame para facilitar o diagnostico desses casos o uso de sonda de maior freqüência, com pressão modulada para aumentar a ecogenicidade do tecido adiposo.
É a sombra de massa real ou de uma estrutura normal?
Quando você comprime a mama e a sobra vem do ligamento de Cooper ela desaparece à medida que você o torna mais paralelo a pele e aumenta a ecogenicidade do tecido mamário. Se isso não resolveu você tem que ajustar sua sonda para uma freqüência menor para poder penetrar posteriormente a sombra. Também realizar a compreensão adequada ajuda diminuir a sombra.
É fácil correlacionar a posição da lesão ma mamografia e US ?
Nem sempre. Mas para isso é necessário saber a posição do nódulo em relação à hora, profundidade e distância do mamilo. Se você for observar a mama na mamografia lateral não existe uma correlação absoluta das horas no US e RX mama, pois há uma distorção dos planos mamários no RX. Vejam este esquema, onde se mostra a posição das 3 e 9horas no RX e US :



A posição da hora em RX e US da mama:

- 6 e 12 horas não alteram
- 3 e 9 horas é muito diferente a posição do US e RX de mama
  A profundidade ajuda a correlacionar a US com a mamografia. Exemplos:
- Se a lesão e profunda no RX de mama, quase acolado ao tórax, certamente não pode ser a lesão que se vê acolada à pele no US mama
- Se uma lesão é profunda no US mama não se verá superficialmente no RX de mama
- Se a lesão for central na mamografia mas próximo à margem, funciona melhor a correlação US e RX mama.

A posição do mamilo em RX e US da mama:

- Ela tem várias falhas potenciais e muita variação de posição durante exame US, pois as estruturas mamárias se espalham quando o exame é realizado em posição supina. Entretanto, elas correlacionam com as estruturas ao seu redor. Tem que verificar se o nódulo está dentro do tecido fibroglandular ou adiposo mamário.
- Tem que checar cada um dos aspectos topográficos: posição inlda hora, distância do mamilo e se está rodeado por tecido fibroglandular ou adiposo mamário

O que fazer quando uma massa que parece muito suspeita de malignidade vem com um anatomopatológico de lesão benigna?

- Verificar qual é o tipo histológico da lesão pois existem vários diagnósticos que simulam malignidade ao US, sendo os principais:
  - Fibrose
  - Mastite
  - Tumor de células granulares
  - Inflamação granulomatosa

As lesões ecogênicas das mamas raramente são malignas é as mais frequentes são:

- Tecido estromal
- Lipoma
- Amartoma
- Extravasamento extra capsular do silicone
- Esteatonecrose (se tem sonotransparência no RX não precisa biopsiar)

O tumor maligno ecogênico ocorre de 0.4 a 2% dos tumores malignos da mama.

Quais são os tipos mais comuns de lesão da pele?

- Abscesso folicular
- Cisto de inclusão epidermóide
- Cisto sebáceo

As lesões primárias da pele empurram o subcutâneo para baixo. Se existe tumor na mama que invade a pele ele empurra anteriormente a pele adjacente, abaulando-a.

ELASTOGRAFIA MAMÁRIA, ministrada por Dra G Sharat Lin , PHD
Advanced Imaging Associates – Fremont CA

Uma vez que é detectada uma massa sólida na mama, o principal do US é diferenciar a massa benigna da maligna. Uma variedade de critérios morfológicos permitem a classificação das massas mamárias em um sistema de categorias (Birads) com graus de risco de malignidade variáveis, que permitem estabelecer a conduta com relação a indicação de biópsia. A elastografia pretende oferecer um critério adicional na diferenciação da massa benigna ou maligna da mama baseada em sua dureza e em critérios morfológicos. As técnicas elastográficas asssociadas ao aparelho de US englobam as imagens de compressão manual e virtual para mensurar as propriedades viscoelasticas dos tecidos. A maioria das lesões sólida e císticas podem ser facilmente distinguidas dos tecidos adjacentes pelo US.
Métodos elastográficos em uso:

- Elastografia de compressão mecânica
- Elastografia de compressão manual
- Imagens do Doppler vibracional
- Imagem induzida pela vibração virtual das ondas de cisalhamento
- Imagem induzida pela vibração das ondas de cisalhamento pela técnica ARFI.

A **elastografia manual** é método não quantitativo devido ao grau de compressão que é empregado para gerar a imagem não é conhecido, mas ela oferece uma elastograma que é útil para distinguir os diferentes graus dos tecidos. A principal vantagem da elastografia manual é que a imagem obtida é uma imagem verdadeira do grau de estiramento (tensão, compressão) tecidual.
As imagens do Doppler vibracional (VDI) são obtidas pela aplicação de uma áudio freqüência vibracional através de um transdutor externo para gerar as ondas de cisalhamento nos tecidos e medir a resposta da movimentação tecidual com a imagem de Power Doppler. A imagem é facilmente obtida com US convencional, mas produz uma imagem que combina as propriedades viscoelásticas dominantes por sua dureza. As imagens mostradas pela palestrante do Doppler vibracional parecem muito com as imagens obtidas com o frêmito vocal na mama, sem a utilização de equipamentos elastográficos específicos.
Outro método para gerar as vibrações teciduais internamente utilizam a força de radiação acústica (ARFI) que quantifica a elasticidade pela estimativa da velocidade de propagação das ondas de cisalhamento em cada ponto utilizando equipamento especial.
Os tumores malignos são tipicamente mais duros do que os benignos e a elastografia e talvez o critério morfológico mais promissor seja as variáveis de densidade entre as várias patologias mamárias:

Papiloma	= 6.5 kPa
Gordura	= 9.2 kPa
Fibroglandular	= 11.3 kPa
Lesões benignas	= 46.1 kPa
Adenose	= 149.5 kPa

A palestrante menciona o resultado da US mais elastografia na avaliação de 44 nódulos sólidos das mamas.

Sens.	= 94%
Esp.	= 92%
VPP	= 94%
VPN	= 92%

A elastografia nunca é usada isoladamente e sempre concomitante com outro método de imagem.

Conclusão

1. Grandes melhoras das imagens elastográficas ocorreram desde que surgiram os primeiros aparelhos de elastografia
2. Ainda existem muitas interferências nas imagens dos elastogramas
3. Existe muita variabilidade na capacidade de diferenciar o tecido normal do anormal, o nódulo benigno do maligno o que torna a acuidade diagnóstica muito diferente entre os vários equipamentos de elastografia
4. A decisão de usar ou não a elastografia pode depender do fluxo do trabalho não do beneficio real do método
5. Existem imagens muito variáveis entre os diferentes métodos que utilizam a elastografia, o que esta dificulta a interpretação correta dos resultados