

American College of Radiology ACR Appropriateness Criteria®

Clinical Condition: Palpable Breast Masses
Variant 1: Woman 30 years of age or older.

Radiologic Procedure	Rating	Comments	RRL*
X-ray diagnostic mammography bilateral	9	CC, MLO view of each breast. Marker on mass.	Low
X-ray supplemental mammographic views	8		Low
US breast unilateral	8		None
MRI breast	2	MRI is not indicated in the initial evaluation of a patient with a palpable breast mass.	None
Rating Scale: 1=Least appropriate, 9=Most appropriate			*Relative Radiation Level

Variant 2: Woman younger than 30 years of age.

Radiologic Procedure	Rating	Comments	RRL*
US breast unilateral	9		None
X-ray diagnostic mammography bilateral if US is suspicious or highly suggestive of malignancy	9	Bilateral diagnostic examination.	Low
X-ray diagnostic mammography bilateral if US is equivocal or negative for findings	8	Diagnostic mammogram tailored to clinical situation.	Low
X-ray diagnostic mammography bilateral if US shows benign or probably benign findings	2		Low
MRI breast	2	MRI is not indicated in the initial evaluation of a patient with a palpable breast mass.	None
Rating Scale: 1=Least appropriate, 9=Most appropriate			*Relative Radiation Level

An ACR Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those exams generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the FDA have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

PALPABLE BREAST MASSES

Expert Panel on Women's Imaging—Breast: Jay R. Parikh, MD¹; W. Phil Evans, MD²; Lawrence Bassett, MD³; Wendie A. Berg, MD, PhD⁴; Carl D'Orsi, MD⁵; Dione M. Farria, MD, MPH⁶; Cheryl R. Herman, MD⁷; Stuart S. Kaplan, MD⁸; Laura Liberman, MD⁹; Ellen Mendelson, MD¹⁰; Stephen B. Edge, MD.¹¹

Summary of Literature Review

Breast cancer is the most common female malignancy and the second leading cause of cancer deaths in the United States. The American Cancer Society estimates that 212,920 new cases of invasive breast cancer and 61,980 new cases of in situ breast cancer will be diagnosed in 2006. A breast mass will be one of the most frequent surgical indications [1]. A palpable breast mass may become evident during breast self-examination (BSE), clinical breast examination (CBE), or retrospectively following screening mammography.

Determining if a mass is present by physical examination can be difficult, as all breasts have variable combinations of glandular tissue, fibrosis, and fat. True masses are generally asymmetrical in relation to the other breast, distinct from the surrounding tissues, and three-dimensional [2]. A typical cancer may be firm, have indistinct borders, and have attachments to the skin or deep fascia with dimpling or nipple retraction. Benign lesions typically have discrete, well-defined margins and are mobile. Cysts cannot reliably be distinguished from solid breast masses by palpation. In one study, only 58% of 66 palpable cysts were correctly identified by physical examination [3]. Significant disagreement among experienced examiners may occur. In another study, four surgeons performed physical examination independently and agreed on the need for biopsy of only 73% of 15 masses subsequently proven malignant [4].

Because many breast masses may not exhibit distinctive physical findings, an imaging evaluation is necessary in almost all cases to characterize the palpable lesion and screen the remainder of each breast for additional lesions. Unfortunately not all palpable breast masses will be visualized with conventional imaging techniques. In the Breast Cancer Detection Demonstration Project (BCDDP) begun in the 1970s, 9% of the cancers were found by CBE alone [5]. With improvement in imaging methods

since the BCDDP, this percentage should be considerably less. Nevertheless a negative imaging evaluation should never overrule a strongly suspicious finding on physical examination or vice versa. Any highly suspicious breast mass detected by imaging or palpation should be biopsied unless there are exceptional clinical circumstances such as patient comorbid factors.

Several imaging techniques are commonly used in evaluating palpable breast masses. Screening mammography is most useful for early detection of nonpalpable breast lesions. The examination is performed on women thought to be asymptomatic and usually consists of craniocaudal and mediolateral oblique views of each breast. A mass found with screening mammography may become perceptible by palpation after its location has been identified radiographically. Following detection of a clinical or mammographic mass, diagnostic mammography may be performed. A small metal marker is placed on the skin over the mass to identify its location. Supplemental mammographic views may be needed to clarify the features, location, or reality of a mammographic lesion. These views have been discussed extensively [6] and include spot compression, spot compression/magnification, magnification, exaggerated craniocaudal to the medial or lateral side, tangential, change of angle, cleavage, cleopatra, and 90-degree lateral views. Any creative nonstandard view may be used to image a lesion or move it closer to the film. These supplemental views improve visualization of palpable and nonpalpable masses and are predictive of whether they are benign or malignant.

Ultrasound (US) was initially used only to differentiate cystic from solid lesions. Many palpable masses not visualized mammographically are cysts and can be diagnosed sonographically [7]. With the development of 7.5-10 MHz linear array transducers with excellent near-field resolution, the role of US has expanded to include characterization of the shape, margins, and internal matrix of masses and guidance for needle localization, aspiration, and biopsy. US is also highly accurate in identifying palpable malignant breast masses, although no one exam alone should be used to exclude malignancy [8].

Fine-needle aspiration/biopsy (FNAB) is used to remove fluid from a cyst and cellular material from a solid mass. Some physicians suggest FNAB as the first means of evaluation following physical examination [2], and patients with a palpable mass referred for imaging evaluation may have already undergone FNAB.

Stereotactic (x-ray) or US guidance may be used for FNAB or core biopsy if the mass is vaguely palpable, small, deep, mobile, or multiple, or attempts using palpation to biopsy the mass have been unsuccessful [9].

¹Co-Author, Swedish Cancer Institute, Seattle, Wash; ²Co-Author and Panel Vice-Chair, UT Southwestern Medical Center, Dallas, Tex; ³Panel Chair, UCLA School of Medicine, Los Angeles, Calif; ⁴Johns Hopkins at Green Spring, Lutherville, Md; ⁵Emory University Hospital, Atlanta, Ga; ⁶Washington University, Saint Louis, Mo; ⁷Vanderbilt University Breast Center, Nashville, Tenn; ⁸Strax Institute, Lauderhill, Fla; ⁹Memorial-Sloan Kettering Cancer Center, New York, NY; ¹⁰Northwestern Memorial Hospital, Chicago, Ill; ¹¹Roswell Park Cancer Institute, Buffalo, NY, American College of Surgeons.

Reprint requests to: Department of Quality & Safety, American College of Radiology, 1891 Preston White Drive, Reston, VA 20191-4397.

An ACR Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those exams generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the FDA have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

The use of multiple modalities in diagnosing palpable masses has been advocated as a measure to increase the true positive rate. In one study comparing physical examinations, mammography, and US, the authors concluded that for palpable masses, physical examination, and US formed the optimal preoperative test combination [8]. Mammography was also necessary to detect occult cancer in the contralateral or ipsilateral breast. Diagnostic breast US can improve the specificity of clinically detected abnormalities.

The most common uses of US are characterization of palpable and mammographically-depicted masses and guidance for biopsy procedures. Using strict criteria for benign and malignant features for solid masses seen on US, a high negative predictive value (99.5%) is possible to achieve [10]. When both mammography and US are negative or benign in the evaluation of a palpable breast mass, the negative predictive value is also very high, over 97% [11-13].

Together, these imaging modalities can be reassuring when the physical examination is not highly suspicious and follow-up is planned. However, a highly suspicious physical examination should prompt biopsy regardless of the imaging findings.

With respect to a palpable breast mass, other imaging techniques remain investigational. Magnetic resonance imaging (MRI) has emerged as a promising modality for detecting occult breast cancer in high-risk women and for evaluating disease extent in women diagnosed with breast cancer. The sensitivity of the exam is high, but specificity continues to be problematic due to false positives [14]. Although palpable masses can be imaged with MRI, it is generally more cost effective to use mammography and US as the initial imaging examinations. In patients with palpable biopsy-proven breast malignancy in nonfatty tissue, MRI appears to be more sensitive than US or mammography for staging [15], and MRI appears to be superior to clinical examination, mammography, and US for monitoring response to neoadjuvant therapy [16].

Exciting new prospects for breast cancer detection using nuclear medicine are now being actively investigated. A study comparing positron emission tomography (PET) using an isotope of glucose and single-photon-emission computed tomography (SPECT) indicate that both techniques are comparable in diagnosing breast cancer, with a sensitivity of 79% for PET and 76% for MIBI SPECT [17]. In another study [18] MIBI SPECT modified patient management in 49% of patients after a doubtful or discordant triple test with mammography, US, and FNAB. More work must be done to establish criteria for the use of nuclear medicine for breast cancer diagnosis.

Because of the theoretical increased radiation risk and the low incidence of breast cancer (less than 1%) in women

younger than 30 years of age [19], the imaging evaluation for patients over 30 years of age differs from that performed for younger patients, according to most investigators [20-24]. As with all age-related guidelines, pertinent clinical factors such as family history should be used to determine appropriate patient care.

In determining the utility of mammography in women younger than 30 years of age, most researchers have retrospectively either studied patients referred for mammography or reviewed the mammographic findings of patients in whom cancer was found. In the first group of studies, as one would expect, there was a predominance of benign masses and nonspecific benign findings [23-27], although a few carcinomas were found. Most of the benign lesions were not visualized mammographically, and US was suggested as the initial imaging modality [6,7,24]. If US demonstrates a suspicious finding, then bilateral mammography is recommended to evaluate for additional ipsilateral and contralateral lesions. If US is negative, then mammography is still recommended as a prebiopsy assessment in cases where cancer is strongly suspected clinically [21,24]. As with women 30 years of age and older, most investigators agree that if physical examination is highly suspicious and mammography is negative, tissue sampling with FNAB, core biopsy, or surgical biopsy is warranted. In symptomatic young women subsequently proven to have breast cancer, mammography was abnormal preoperatively in 86%-90% of them, [28-30], suggesting that it is of substantial value in the diagnosis of malignancy.

Relative Radiation Level Information

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level (RRL) indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Additional information regarding radiation dose assessment for imaging examinations can be found in the ACR Appropriateness Criteria® [Radiation Dose Assessment Introduction](#) document.

Relative Radiation Level Designations	
Relative Radiation Level	Effective Dose Estimate Range
None	0
Minimal	< 0.1 mSv
Low	0.1-1 mSv
Medium	1-10 mSv
High	10-100 mSv

An ACR Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those exams generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the FDA have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

References

1. American Cancer Society. *Cancer Facts and Figures 2006*: Atlanta: American Cancer Society; 2006.
2. Donegan WL. Evaluation of a palpable breast mass. *N Engl J Med* 1992; 327(13):937-942.
3. Rosner D, Blair D. What ultrasonography can tell in breast masses that mammography and physical examination cannot. *J Surg Oncol* 1985; 28(4):308-313.
4. Boyd NF, Sutherland HJ, Fish EB, Hiraki GY, Lickley HL, Maurer VE. Prospective evaluation of physical examination of the breast. *Am J Surg* 1981; 142(3):331-334.
5. Baker LH. Breast Cancer Detection Demonstration Project: five-year summary report. *CA Cancer J Clin* 1982; 32(4):194-225.
6. Eklund GW, Cardenosa G. The art of mammographic positioning. *Radiol Clin North Am* 1992; 30(1):21-53.
7. Dershaw DD, Eddins G, Liberman L, et al. Sonographic and clinical findings in women with palpable breast disease and negative mammography. *Breast Dis* 1995; 8:13-17.
8. Georgian-Smith D, Taylor KJ, Madjar H, et al. Sonography of palpable breast cancer. *J Clin Ultrasound* 2000; 28(5):211-216.
9. Liberman L, Ernberg LA, Heerd A, et al. Palpable breast masses: is there a role for percutaneous imaging-guided core biopsy? *AJR* 2000; 175(3):779-787.
10. Stavros AT, Thickman D, Rapp CL, Dennis MA, Parker SH, Sisney GA. Solid breast nodules: use of sonography to distinguish between benign and malignant lesions. *Radiology* 1995; 196(1):123-134.
11. Soo MS, Rosen EL, Baker JA, Vo TT, Boyd BA. Negative predictive value of sonography with mammography in patients with palpable breast lesions. *AJR* 2001; 177(5):1167-1170.
12. Shetty MK, Shah YP. Prospective evaluation of the value of negative sonographic and mammographic findings in patients with palpable abnormalities of the breast. *J Ultrasound Med* 2002; 21(11):1211-1216; quiz 1217-1219.
13. Moy L, Slanetz PJ, Moore R, et al. Specificity of mammography and US in the evaluation of a palpable abnormality: retrospective review. *Radiology* 2002; 225(1):176-181.
14. Orel SG, Schnall MD. MR imaging of the breast for the detection, diagnosis, and staging of breast cancer. *Radiology* 2001; 220(1):13-30.
15. Berg WA, Gutierrez L, NessAiver MS, et al. Diagnostic accuracy of mammography, clinical examination, US, and MR imaging in preoperative assessment of breast cancer. *Radiology* 2004; 233(3):830-849.
16. Yeh E, Slanetz P, Kopans DB, et al. Prospective comparison of mammography, sonography, and MRI in patients undergoing neoadjuvant chemotherapy for palpable breast cancer. *AJR* 2005; 184(3):868-877.
17. Yutani K, Shiba E, Kusuoka H, et al. Comparison of FDG-PET with MIBI-SPECT in the detection of breast cancer and axillary lymph node metastasis. *J Comput Assist Tomogr* 2000; 24(2):274-280.
18. Mathieu I, Mazy S, Willemart B, Destine M, Mazy G, Lonneux M. Inconclusive triple diagnosis in breast cancer imaging: is there a place for scintimammography? *J Nucl Med* 2005; 46(10):1574-1581.
19. Feig SA, Ehrlich SM. Estimation of radiation risk from screening mammography: recent trends and comparison with expected benefits. *Radiology* 1990; 174(3 Pt 1):638-647.
20. Bennett IC, Freitas R, Jr., Fentiman IS. Diagnosis of breast cancer in young women. *Aust N Z J Surg* 1991; 61(4):284-289.
21. Ciatto S, Bravetti P, Bonardi R, Rosselli del Turco M. The role of mammography in women under 30. *Radiol Med (Torino)* 1990; 80(5):676-678.
22. Feig SA. Breast masses. Mammographic and sonographic evaluation. *Radiol Clin North Am* 1992; 30(1):67-92.
23. Harris VJ, Jackson VP. Indications for breast imaging in women under age 35 years. *Radiology* 1989; 172(2):445-448.
24. Williams SM, Kaplan PA, Petersen JC, Lieberman RP. Mammography in women under age 30: is there clinical benefit? *Radiology* 1986; 161(1):49-51.
25. Bassett LW, Ysrael M, Gold RH, Ysrael C. Usefulness of mammography and sonography in women less than 35 years of age. *Radiology* 1991; 180(3):831-835.
26. Kronemer KA, Rhee K, Siegel MJ, Sievert L, Hildebolt CF. Gray scale sonography of breast masses in adolescent girls. *J Ultrasound Med* 2001; 20(5):491-496; quiz 498.
27. Palmer ML, Tsangaris TN. Breast biopsy in women 30 years old or less. *Am J Surg* 1993; 165(6):708-712.
28. Jeffries DO, Adler DD. Mammographic detection of breast cancer in women under the age of 35. *Invest Radiol* 1990; 25(1):67-71.
29. Meyer JE, Kopans DB, Oot R. Breast cancer visualized by mammography in patients under 35. *Radiology* 1983; 147(1):93-94.
30. Shaw de Paredes E, Marsteller LP, Eden BV. Breast cancers in women 35 years of age and younger: mammographic findings. *Radiology* 1990; 177(1):117-119.

An ACR Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those exams generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the FDA have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.