ACR Appropriateness Criteria Breast Cancer Screening

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Mammography is the recommended method for breast cancer screening of women in the general population. However, mammography alone does not perform as well as mammography plus supplemental screening in high-risk women. Therefore, supplemental screening with MRI or ultrasound is recommended in selected high-risk populations. Screening breast MRI is recommended in women at high risk for breast cancer on the basis of family history or genetic predisposition. Ultrasound is an option for those high-risk women who cannot undergo MRI. Recent literature also supports the use of breast MRI in some women of intermediate risk, and ultrasound may be an option for intermediate-risk women with dense breasts. There is insufficient evidence to support the use of other imaging modalities, such as thermography, breast-specific gamma imaging, positron emission mammography, and optical imaging, for breast cancer screening.

The ACR Appropriateness Criteria are evidence-based guidelines for specific clinical conditions that are reviewed every 2 years by a multidisciplinary expert panel. The guideline development and review includes an extensive analysis of current medical literature from peer-reviewed journals and the application of a well-established consensus methodology (modified Delphi) to rate the appropriateness of imaging and treatment procedures by the panel. In those instances in which evidence is lacking or not definitive, expert opinion may be used to recommend imaging or treatment.

Key Words: Appropriateness criteria, breast cancer, screening, mammography, breast MRI, breast ultrasound

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SUMMARY OF LITERATURE REVIEW

Mammography

Mammography is the only method of screening for breast cancer shown to decrease mortality [1-4]. Annual screening mammography is recommended starting at (1) 40 years of age for the general population; (2) 25 to 30 years of age for carriers of the breast cancer 1 gene and untested relatives of carriers; (3) 25 to 30 years of age or 10 years earlier than the age of the affected relatives at diagnosis (whichever is later) for women with first-degree relatives with premenopausal breast cancer or for women with lifetime risk for breast cancer ≥20% on the basis of family history; (4) 8 years after radiation therapy but not before 25 years of age for women who received mantle radia-

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The ACR seeks and encourages collaboration with other organizations on the development of the ACR Appropriateness Criteria through society representation on expert panels. Participation by representatives from collaborating societies on the expert panel does not necessarily imply individual or society endorsement of the final document.

Dr Harvey reported that she is a shareholder in and has a research agreement with Hologic (Marlborough, Massachusetts). Dr Hayes reported that she is an international speaker for Hologic.

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Variant 1. Average-risk women: women with <15% lifetime risk of breast cancer, breasts not dense

Radiologic Procedure	Rating	Comments	RRL
Mammographic screening	9		☢☢
MRI breast without and with contrast	3		O
Ultrasound breast	2		O
MRI breast without contrast	1		O
FDG-PEM	1		☢☢☢☢
^{99m}Tc sestamibi BSGI	1		☢☢☢☢

Note: Rating scale: 1, 2, and 3 = usually not appropriate; 4, 5, and 6 = may be appropriate; 7, 8, and 9 = usually appropriate. BSGI = breast-specific gamma imaging; FDG = 2-[^{18}F]fluoro-2-deoxyglucose; PEM = positron emission mammography; RRL = relative radiation level.

tion between the ages of 10 and 30 years; and (5) any age for women with biopsy-proven lobular neoplasia, atypical ductal hyperplasia, ductal carcinoma in situ, or invasive breast cancer [5] (see Variant 1). However, mammography alone does not perform as well as mammography plus supplemental screening in certain subsets of women, particularly those with genetic predispositions to the disease and those with dense breasts [6-11]. Therefore, supplemental screening is recommended in selected high-risk populations.

MRI

Breast MRI in high-risk women has been shown to have higher sensitivity than mammography, and the combination of mammography and MRI in this population has the highest sensitivity [12-19]. In a high-risk population, MRI and mammography combined have higher sensitivity (92.7%) than ultrasound and mammography combined (52%) [6]. Therefore, in high-risk women for whom supplemental screening is indicated, MRI is recommended when possible (see Variant 2).

Screening high-risk women using breast MRI is cost-effective [20,21], and the cost-effectiveness of screening MRI rises with increasing breast cancer risk. The American Cancer Society recommends screening breast MRI in certain high-risk women [22], and the ACR and the Society of Breast Imaging endorse those recommendations [5]. Screening MRI is recommended in women with breast cancer 1 gene mutations and their untested first-degree relatives as well as women with lifetime risk for breast cancer ≥20%. Also included in this high-risk group are women who received radiation therapy to the chest between the ages of 10 and 30 years as well as women with other genetic syndromes that increase the risk for breast cancer (eg, Li-Fraumeni syndrome). For other women with intermediate risk for breast cancer, such as those with lifetime risk of 15% to 20%, personal histories of breast cancer, or histories of lobular neoplasia or atypical ductal hyperplasia, the use of screening MRI is an area of ongoing investigation [5,22].

Variant 2. High-risk women: women with *BRCA* gene mutations and their untested first-degree relatives, women with histories of chest irradiation between the ages of 10 and 30 years, and women with ≥20% lifetime risk for breast cancer

Radiologic Procedure	Rating	Comments	RRL
Mammographic screening	9	Beginning at age 25-30 y or 10 y before age of first-degree relative when diagnosed with breast cancer or 8 y after radiation therapy, but not before age 25 y. Mammography and MRI are complementary examinations; both should be performed.	☢☢
MRI breast without and with contrast	9	Mammography and MRI are complementary examinations; both should be performed. See statement regarding contrast, in text under "Anticipated Exceptions."	O
Ultrasound breast	6	If patient cannot undergo MRI.	O
FDG-PEM	2		☢☢☢☢
^{99m}Tc sestamibi BSGI	2		☢☢☢☢
MRI breast without contrast	1		O

Note: Rating scale: 1, 2, and 3 = usually not appropriate; 4, 5, and 6 = may be appropriate; 7, 8, and 9 = usually appropriate. *BRCA* = breast cancer 1; BSGI = breast-specific gamma imaging; FDG = 2-[^{18}F]fluoro-2-deoxyglucose; PEM = positron emission mammography; RRL = relative radiation level.

Variant 3. Intermediate-risk women: women with personal histories of breast cancer, lobular neoplasia, atypical ductal hyperplasia, or 15% to 20% lifetime risk for breast cancer

Radiologic Procedure	Rating	Comments	RRL
Mammographic screening	9		☢☢
MRI breast without and with contrast	7	See statement regarding contrast, in text under "Anticipated Exceptions."	O
Ultrasound breast	5		O
FDG-PEM	2		☢☢☢☢
^{99m}Tc sestamibi BSGI	2		☢☢☢☢
MRI breast without contrast	1		O

Note: Rating scale: 1, 2, and 3 = usually not appropriate; 4, 5, and 6 = may be appropriate; 7, 8, and 9 = usually appropriate. BSGI = breast-specific gamma imaging; FDG = 2-[^{18}F]fluoro-2-deoxyglucose; PEM = positron emission mammography; RRL = relative radiation level.

However, recent literature supports the use of screening MRI in addition to mammography in patients with personal histories of breast cancer [23] and lobular neoplasia [24] (see Variant 3).

Ultrasound

Screening ultrasound is indicated in high-risk patients who cannot tolerate MRI. Supplemental screening with ultrasound for women with intermediate risk and dense breasts is an option to increase cancer detection. However, handheld ultrasound screening by radiologists has a high false-positive rate and is time-consuming [25]. Therefore, this may not be a cost-effective practice. The balance between cancer detection and the risk of a false positive result should be considered by women and their health care providers when considering the use of screening US or other ancillary screening examinations.

Other Imaging Modalities

There is insufficient evidence to support the use of other imaging modalities, such as thermography, breast-specific gamma imaging, positron emission mammography, and optical imaging, for breast cancer screening [5]. Radiation doses from breast-specific gamma imaging and positron emission mammography are 15 to 30 times higher than the dose from digital mammography [26,27], and they are not indicated for screening in their present form.

SUMMARY

- For high-risk women, annual screening mammography and contrast-enhanced MRI are both indicated. Ultrasound can be used for patients with contraindications to MRI.
- For intermediate-risk women, annual screening mammography is indicated. Contrast-enhanced MRI may be indicated in some patients.
- For average-risk women, annual screening mammography is indicated.

ANTICIPATED EXCEPTIONS

Nephrogenic systemic fibrosis is a disorder with a scleroderma-like presentation and a spectrum of manifestations that can range from limited clinical sequelae to fatality. It seems to be related to both underlying severe renal dysfunction and the administration of gadolinium-based contrast agents. It has occurred primarily in patients on dialysis, rarely in patients with very limited glomerular filtration rates (ie, $<$30 mL/min/1.73 m^2), and almost never in other patients. There is growing literature regarding nephrogenic systemic fibrosis. Although some controversy and lack of clarity remain, there is a consensus that it is advisable to avoid all gadolinium-based contrast agents in dialysis-dependent patients unless the possible benefits clearly outweigh the risk and to limit the type and amount in patients with estimated glomerular filtration rates $<$ 30 mL/min/1.73 m^2. For more information, please see the ACR's *Manual on Contrast Media* [28].

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 indication has been included for each imaging examination. The relative radiation levels 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. Patients in the pediatric age group are at inherently higher risk from exposure, both because of organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the relative radiation level dose estimate ranges for pediatric examinations are lower compared with those specified for adults (Table 1). Additional information regarding radia-

Table 1. Relative radiation level designations

Relative Radiation Level	Adult Effective Dose Estimate Range (mSv)	Pediatric Effective Dose Estimate Range (mSv)
O	0	0
☢	<0.1	<0.03
☢☢	0.1-1	0.03-0.3
☢☢☢	1-10	0.3-3
☢☢☢☢	10-30	3-10
☢☢☢☢☢	30-100	10-30

Note: Relative radiation level assignments for some of the examinations cannot be made because the actual patient doses in these procedures vary as a function of a number of factors (eg, region of the body exposed to ionizing radiation, the imaging guidance that is used). The relative radiation levels for these examinations are designated as "varies."

tion dose assessment for imaging examinations can be found in *ACR Appropriateness Criteria®:Radiation Dose Assessment Introduction* [29].

For additional information on ACR Appropriateness Criteria, refer to http://www.acr.org/ac.

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