

Indications for Breast Imaging

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Over the past decade there have been major advances in the field of diagnostic imaging resulting in the introduction of new technology such as positron emission tomography (PET) and PET-CT, and new indications for old technology including coronary computed tomographic angiography (CCTA). In addition, techniques for old indications such as MRI of the breast have been improved. Many of these advancements have been the result of the availability of more sophisticated and user-friendly software as well as hardware with faster scan times and greater spatial resolution.

Improvements and advancements in diagnostic imaging are frequently reported in peer-reviewed literature and the lay press. Physicians and their patients cannot be expected to be current with all of these changes. In order to assist them in understanding when a test is appropriate, many national specialty societies are developing evidence-based guidelines¹⁻³ for the evaluation, treatment and follow-up or surveillance of many common medical conditions. These guidelines are usually developed by committees of specialists who search the literature and apply an established evidenced-based methodology for review of the information. The final recommendations of these committees are usually graded as appropriate, indeterminate, inappropriate, recommended, not recommended, or insufficient evidence to recommend for or against the use of the test. Often the strength of the evidence to support the recommendation will also be provided. This is often indicated as: “Category 1: Based on high level of evidence and uniform consensus; Category 2A: Based on lower-level of evidence including clinical experience and uniform consensus; Category 2B: Based on lower-level of evidence including clinical experience and nonuniform consensus (but no major disagreement); Category 3: Based on any level of evidence but reflects major disagreement.”¹

Relying on data from the National Institutes of Health Surveillance Epidemiology and End Results (SEER) program, the American Cancer Society (ACS) reported that 178,480 new cases of invasive breast cancer and 62,030 cases of in situ breast cancer would be diagnosed in American women in 2007. The Society also reported that breast cancer was the second most common cause of cancer death in American

women.⁴ It is estimated that between 1990 and 2004 the death rate from breast cancer declined by 2.2% annually with the largest decrease in younger women.⁴ Improvements in detection as well as treatment of breast cancer both contribute to the continued drop in mortality from this disease.

Screening Breast MRI

One factor for the improved early diagnosis of breast cancer, especially in younger high risk women, is the wider availability and technical improvements of breast MRI. It is considered an adjunct to mammography and should never be used as a replacement for mammography. The added value of screening breast MRI in women considered to be at high genetic risk for breast cancer is supported by several recent studies.⁵⁻⁸ In 2007, the ACS published its “Guidelines for Breast Screening with MRI as an Adjunct to Mammography.”² This paper is extremely important because it represents the first time that evidenced-based guidelines for screening breast MRI became available to physicians. It also clearly defined who is considered to be at high genetic risk for breast cancer. According to the guidelines, screening breast MRI should be offered to women who are:

1. Documented carriers of BRCA gene mutation
2. Documented first degree relative (mother, sister or daughter) of a known carrier of the BRCA gene mutation
3. Calculated to have a life-time risk for breast cancer of greater than 20% using a risk model that is dependent on family history
4. Documented to either have Li-Fraumeni syndrome or have a first degree relative (mother, father, sister, brother, daughter or son) with the syndrome
5. Documented to have either Cowden or Banayan-Riley-Rubalcaba syndrome or have a first degree relative with the syndrome
6. Known to have had radiation therapy to the chest (not breast) between the ages of 10 and 30.

Indications 1-5 define women with a high genetic risk for breast cancer^{2,6,7} and have been included in the “2009 Guidelines for Breast Cancer Screening and Diagnosis” from the National Comprehensive Cancer Network (NCCN)⁹, the American College of Radiology’s “2008 Practice Guideline

for the Performance of Contrast Enhanced Magnetic Resonance Imaging (MRI) of the Breast”¹⁰ and in the guidelines from the European Society of Breast Imaging. Indication 6 defines a group of women who are at increased risk of developing breast cancer because of a childhood cancer treated with radiation therapy to the chest. This group does not include women whose treatment for breast cancer included radiation to the breast.

The ACS guidelines also state that screening breast MRI is not recommended for women with a life-time risk for breast cancer of less than 15% calculated with a risk model that is largely dependent on family history. The Society further indicated that they found very little information on the value of breast MRI in screening women whose sole risk was a personal history of breast cancer. The paper stated that:

“While women with a previous diagnosis of breast cancer are at increased risk of a second diagnosis, the ACS panel concluded that the estimated absolute life-time risk of 10% does not justify a recommendation for MRI screening at the present time.”²

Other indications for which the ACS panel determined that there was insufficient evidence to recommend for or against the use of screening breast MRI include:

1. Life-time risk for breast cancer of 15-20% using a risk model that is dependant on family history
2. Personal history of lobular carcinoma in situ (LCIS) or atypical lobular hyperplasia (ALH)
3. Atypical ductal hyperplasia (ADH)
4. Heterogeneously dense or extremely dense breast on mammography

Surveillance of Breast Cancer Patients

It is often assumed by patients and some physicians that more testing, especially tests that are considered to be non-invasive and safe (such as blood tests and MRI, nuclear and CT scans), improve health care outcomes for all cancer patients. The question of whether or not a particular test, especially an imaging test, improves survival or quality of life is often not known before it is widely accepted and used by physicians and requested by patients. Cancer survivors, especially breast cancer survivors, and their families are reassured when follow up or surveillance testing is negative.¹¹⁻¹⁴ But all tests, even those with little or no intrinsic risk, can have false positive results leading to additional unnecessary tests or interventions which have the potential to do more harm than good.¹⁰ In addition, negative test results can provide a false sense of security by suggesting that there is no active disease present. Practice guidelines directed at asymptomatic patients not in active treatment and with no evidence of

disease are designed to provide physicians with the tools to choose the most appropriate tests for their patients, which are most likely to improve the results of ongoing treatment or surveillance programs.

In 2006 the American Society of Clinical Oncology (ASCO) published an updated paper entitled “American Society of Clinical Oncology 2006 Update of the Breast Cancer Follow-Up and Management Guidelines in the Adjuvant Setting.”³ This guideline addresses the management and follow-up recommendations for asymptomatic women who have completed primary, curative treatment for breast cancer. The final recommendations are based on whether or not a test, including an imaging study, was shown to: improve overall or disease free survival; improve quality of life; decrease toxicity; and improve cost effectiveness. Based on the panel’s review of the literature, the recommended follow-up for asymptomatic women treated for cure was: history and physical examination every 3-6 months for three years, and then every 6-12 months for the next two years, and annually after five years; breast self examination; mammography; pelvic examination; and referral for genetic counseling if appropriate. The panel recommended against routine blood tests such as liver function, tumor markers and blood counts. Chest x-rays, liver ultrasound, and CT, PET, bone and breast MRI scans were also listed as not recommended.³

The NCCN’s “Practice Guideline in Oncology-v.1.2009 Breast Cancer”⁹ includes detailed, evidence-based recommendations for the initial work-up and treatment of women diagnosed with different types and stages of breast cancer. The guideline also includes evidence-based recommendations regarding surveillance testing of asymptomatic women with no clinical evidence of disease. The findings are essentially the same as those published by ASCO. Routine blood tests, tumor markers, bone scans, CT or MRI scans of the brain, chest, abdomen and pelvis, and breast MRI are not listed as recommended for surveillance.

Diagnostic Breast MRI

For many breast surgeons and oncologists diagnostic breast MRI has become routine in the evaluation of women with a new diagnosis of either invasive or in situ breast cancer.^{15,16} Although this indication is still somewhat controversial it has been adopted by the American College of Radiology¹⁰ and is considered optional in NCCN guidelines for the work up of a woman with a new diagnosis of breast cancer.⁹ Recent studies have demonstrated that preoperative breast MRI may change surgical management because it better defines the extent of the cancer than mammography or ultrasound.^{10,17,18} This is especially true if the diagnosis is invasive lobular carcinoma. In addition, MRI can detect multicentric or multifocal disease in

the ipsilateral breast.¹⁹ An occult cancer in the contralateral breast has been reported in up to 3% of patients.¹⁵

Other indications²⁰ for diagnostic breast MRI for women with a diagnosis of cancer include: the evaluation of women with positive margins on a lumpectomy specimen¹⁸ and women with documented adenocarcinoma in enlarged axillary lymph nodes who have negative mammography and ultrasound in an attempt to find the primary lesion. It is also indicated if change in a lumpectomy or mastectomy scar is noted in a woman with prior history of breast cancer. Other important uses of diagnostic breast MRI are in the pretreatment assessment of a woman scheduled for neoadjuvant chemotherapy prior to surgery and in the post chemotherapy assessment of the same woman after completion of chemotherapy and prior to surgery. It also may be helpful in the evaluation of women with a personal history of breast cancer in whom there is suspicion of recurrence and clinical and standard imaging are inconclusive.¹⁰

Breast MRI may also be a good diagnostic problem-solving tool in women with equivocal findings on mammography and or ultrasound.¹⁰ For example, it is very helpful to confirm the presence or absence of an abnormality suspected on only one view of a mammogram. However, it should not be used to determine whether or not a biopsy of a lesion demonstrated on two views of a mammogram or on a sonogram or found on physical examination should be performed.¹⁰ It is also a very valuable tool for the evaluation of a woman with nipple discharge when mammography, sonography and galactography are not diagnostic.^{21,22}

Breast MRI is also indicated for the evaluation of silicon breast implants for rupture. In fact the FDA currently recommends routine breast MRI three years after placement and every two years thereafter.

In 2007, Basset et al²³ published the results of a survey of the members of the Society of Breast Imaging regarding their current practices with respect to breast MRI. The results of the survey indicate that the use of breast MRI is increasing. The most common indications reported for diagnostic breast MRI were either the evaluation of the extent of disease or an indeterminate or equivocal diagnostic imaging evaluation. Screening breast MRI was most commonly used for the evaluation of women who were known carriers of a BRCA gene mutation or who had a mother or sister with premenopausal breast cancer.

Another interesting finding was the indication by the respondents that requests from referring physicians were frequently appropriate 72.6% of the time, always appropriate 10.6% of the time and sometimes appropriate 15.5% of the time. The survey also indicated that 11.8% of physicians frequently gave in to patients who requested breast MRI when it was not appropriate and that 44.7% did so some of the time. Approximately 86% of the participants indicated that referring physicians followed radiologists' recommendations for breast MRI.

The following chart compares CareCore National's criteria for breast imaging with national guidelines.

<i>Comparison of CareCore National Criteria for Breast MRI and National Guidelines</i>	
American Cancer Society Screening	CareCore National Screening
Known carrier of BRCA gene mutation	Known carrier of BRCA gene mutation
First degree relative of a known carrier of BRCA gene mutation	First degree relative of a known carrier of BRCA gene mutation
Life-time risk of greater than 20-25% as defined by risk calculator that is dependant on family history	Life-time risk of greater than 20-25% as defined by risk calculator that is dependant on family history
Radiation to the chest between ages 10 and 30	Radiation to the chest between ages 10 and 30
Li-Fraumeni syndrome or known first degree relative with this syndrome	Li-Fraumeni syndrome or known first degree relative with this syndrome
Cowden syndrome or any first degree relative with this syndrome	Cowden syndrome or any first degree relative with this syndrome
Bannayan-Riley-Ruvalcaba syndrome or any first degree relative with this syndrome	Bannayan-Riley-Ruvalcaba syndrome or any first degree relative with this syndrome
	Male relative with breast cancer
	Personal history of lobular carcinoma in situ (LCIS)
	One or more relatives with two breast cancers or both breast and ovarian cancer
	History of breast cancer in two or more relatives before the age of 50
	Breast or ovarian cancer and Ashkenazi Jewish background
	Evaluation of silicon implants three years after placement and every two years thereafter

Comparison of CareCore National Criteria for Breast MRI and National Guidelines

American College of Radiology Diagnostic	CareCore National Diagnostic
New diagnosis of breast cancer	New diagnosis of breast cancer
Detect extent of residual cancer in the recently post operative breast with positive pathological margins after incomplete lumpectomy	Detect extent of residual cancer in the recently post operative breast with positive pathological margins after incomplete lumpectomy
Staging of invasive lobular carcinoma	Staging of invasive lobular carcinoma
Detect primary lesion in woman with axillary nodes demonstrated to have metastatic adenocarcinoma without focal findings on physical examination, mammography or ultrasonography	Detect primary lesion in woman with axillary nodes demonstrated to have metastatic adenocarcinoma without focal findings on physical examination, mammography or ultrasonography
	Bloody or clear nipple discharge not explained on mammography or ultrasonography
	New nipple retraction not explained by mammography or Ultrasonography
Evaluation of suspected silicon implant rupture	Evaluation of suspected silicon implant rupture
Evaluation before and after neoadjuvant chemotherapy prior to surgery	Evaluation before and after neoadjuvant chemotherapy prior to surgery
Suspicion of breast cancer recurrence in a woman with uninterpretable mammogram and ultrasound	Suspicion of breast cancer recurrence in a woman with uninterpretable mammogram and ultrasound
Evaluation of mastectomy and reconstruction with an implant for suspected recurrence	Evaluation of mastectomy and reconstruction with an implant for suspected recurrence

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