Breast MRI Scans Need Standards, Experts Say

By Karyn Hede

Two years ago the Institute of Medicine’s National Cancer Policy Board recommended uniform standards for all forms of breast imaging—not just mammography. That advice seems all the more important now that the American Cancer Society is recommending yearly magnetic resonance imaging (MRI) screening for women at high risk of breast cancer. Yet uniform standards for performing breast MRI scans have yet to be developed.

“I would say right now that breast MRI is in the situation that mammography was in the late 1980s,” said Edward Hendrick, Ph.D., director of breast imaging research at the Northwestern University School of Medicine in Chicago. “There are places that do very good breast MRI and there are places that do not-so-good breast MRI.”

That lack of standardization, along with a dearth of studies demonstrating whether breast MRI actually saves lives, has many experts questioning whether the American Cancer Society recommendations are perhaps premature.

Hendrick is a member of the American College of Radiology (ACR) committee to set standards for breast MRI. He is concerned that physicians and patients may move too quickly to get MRI scans before standards can be set.

“Only about half [of facilities performing breast MRI] know what they are doing,” he said.

Studies Fuel Popularity

Yet the popularity of breast MRI has been growing steadily as a screening tool for women at high risk of developing breast cancer, particularly women with known mutations in BRCA1 or BRCA2 genes. Such women face a 2%–4% risk of developing breast cancer over any 3-year period, according to Mark Robson, M.D., a medical oncologist at Memorial Sloan-Kettering Cancer Center in New York.

Several studies have now confirmed that breast MRI is more sensitive than standard mammography in detecting breast cancer in this population of women, said Robson, who specializes in treating women with genetic risk factors for breast cancer.

Also, a study published in March in the New England Journal of Medicine concluded that women who have been newly diagnosed with breast cancer benefit from using a breast MRI to screen for cancer in the opposite breast. Twenty-five sites, ranging from large academic medical centers to small community hospitals, participated in what is the largest study of the screening value of breast MRI in newly diagnosed patients.

All 969 participants had previously received mammograms and clinical evaluation of the opposite breast, with no abnormalities found. After an MRI, 121 (12.5%) of the 969 women received biopsies on suspicious findings. Thirty (25%) of the 121 specimens were positive for cancer and more than half (18 of 30) were invasive cancer. The mean diameter of the invasive tumors was 10.9 mm. Mammograms miss breast cancer in the opposite breast in up to 10% of women who have received treatment for cancer in one breast.

“When we compare breast MRI to all other modalities, MRI comes out by far the most sensitive,” Hendrick said. But, at this point, it also generates a substantial number of false positives, which can lead to unnecessary invasive biopsies, he added. For example, in the latest study, 75% of the women biopsied did not have cancer.

The new American Cancer Society recommendation states that only women whose lifetime risk of breast cancer is more than 20% should have a yearly breast MRI. That recommendation includes not just women with a known genetic mutation but also women with a strong family history of breast or ovarian cancer and women who received chest radiation to treat Hodgkin lymphoma. Recent studies indicate that about 2%–3% of women are BRCA1 or BRCA2 carriers. The number of women whose overall lifetime risk is greater than 20% is unknown and depends on the risk model used. The recommendations leave unresolved whether women in other categories of increased risk should receive yearly MRI screening, including women who have had ductal carcinoma in situ, atypical hyperplasia, or extremely dense breasts on mammography.

“Defining who is at risk is a bit of a challenge,” Robson said. “Which risk model do you use? How reliable are those models when you start extrapolating out to the general population? These are all questions that need to be addressed.”

Constance Lehman, M.D., Ph.D., director of breast imaging at the Seattle Cancer Care Alliance and lead investigator of the New England Journal of Medicine study, agrees that the recent results with newly diagnosed patients are just the beginning of understanding who will best benefit from breast MRI screening.

“We have a lot of work to do in the scientific community to understand better how to assess a woman’s individual
risk,” said Lehman, who is also an associate professor of radiology at the University of Washington Medical Center in Seattle.

For example, the American Cancer Society guidelines at this time do not say whether a woman with a personal history of breast cancer should be screened with MRI from that point on. The committee that made the recommendations, of which Lehman is a member, could not find enough scientific evidence that MRI screening in these women is cost-effective, absent other confounding risk factors. However, Lehman said, physicians should take other extenuating circumstances into account.

“In our patients if they never had a preoperative breast MRI at the time of diagnosis, we do recommend MRI baseline [in the conserved breast],” she said. “After that, whether they should continue to be screened or not usually depends on the patient’s age [and] how dense their breast tissue is. For some of our patients, if their original cancer was not diagnosed by mammography then we are more inclined to want to add MRI to mammography as a complementary tool. These are all just guidelines because we don’t have a hard-and-fast rule of when women should or should not be screened with MRI.”

**Standardization Solution?**

Lehman acknowledges that women may want breast MRI because of its heightened sensitivity, but that sensitivity and specificity depend on the experience of the person reading the MRI and performing the MRI to recommended technical standards.

Even within the ACR study, Lehman said several facilities that wanted to be part of the study had to be turned down because they did not meet its minimum requirements, which included participating radiologists who had interpreted at least 50 breast MRI scans and had performed at least five magnetic resonance–guided breast biopsies. Facilities also had to have a 1.5-T or larger magnet and a dedicated breast-surface coil capable of imaging both breasts within one administration of contrast material.

“MRI is not as standardized across the country as mammography is, and until that standardization and accreditation process is established, I don’t think everyone can expect the get the same benefits from MRI that you saw in the [recent] studies,” Robson said.

The ACR is creating an accreditation process for breast MRI, as well as practice guidelines and new technical standards for the procedure. ACR spokesman Shawn Farley estimates that accreditation will be available beginning in 2008. As a first step in the process, the ACR recently surveyed members of the Society of Breast Imaging to find out how many offered breast MRI and to whom.

Lawrence Bassett, M.D., professor of breast imaging at the University of California, Los Angeles, School of Medicine, led the survey, which has been completed but not yet published. Bassett surveyed 1,305 members of the Society of Breast Imaging and received 629 electronic responses; another 100–200 responded to a follow-up print survey. Bassett has analyzed the electronic responses and says they offer an early glimpse into the current state of breast MRI.

Most society members, 75%, offer breast MRI, but most are doing fewer than 10 per week, with only a few doing more than 35 per week. And while 64% offer screening MRI, nearly all MRIs, 93%, are done to determine extent of disease in newly diagnosed breast cancer patients. Most reported that a Mammography Quality Standards Act–certified breast imaging specialist interprets the results, but 4% reported never having a certified screener examine results. Also, respondents were mixed in their use of computer-aided diagnosis, with about half using computer-aided detection and half reading screens manually.

Bassett says the results will help inform the ACR joint committee as it develops practice guidelines and in the accreditation process.

But perhaps the most glaring unresolved issue in the use of screening breast MRI is whether identifying breast cancers through MRI will result in better outcomes and reduced mortality for patients. Such results can come only from a randomized, controlled clinical trial involving thousands of patients monitored over 10–15 years. But despite calls for such a study from organizations such as the National Breast Cancer Coalition, few researchers think that such a study will ever be done. Several physician–scientists said that a long-term survival study is impractical because of the pace of change in the technology and demand for what patients believe is the best available technology.

“There are patients coming in of their own accord, or from referring physicians, who are misinterpreting what ‘high-risk’ is,” Bassett said. “But we’re not going to say, ‘No, we won’t do you, because you haven’t been to the high-risk clinic.’ They can just go down the street and go to our competitors and we’re going to lose them totally as patients.”

However, they will add that information to the patients’ history sheet and develop a risk score, making it possible to go back retrospectively and ask whether breast MRI screening was valuable for certain subgroups of patients, Bassett said.

“I think there will be an uptick on that kind of screening,” Robson agreed. “But whether or not that’s going to be helpful and change outcomes, I don’t know.”