BI-RADS 3 Category Assessment Holds Up

BY PATRICE WENDLING

CHICAGO — The majority of breast lesions assessed with magnetic resonance imaging and placed in the BI-RADS category 3 were benign on follow-up in a prospective study of 473 women.

The finding is reassuring because the category is reserved for "probably benign" findings, but doesn't resolve the confusion that exists over how to manage these lesions, according to lead researcher Dr. Michael T. O'Loughlin.

The American College of Radiology Breast Imaging Reporting and Data System (BI-RADS) breast lexicon was created in 2003 to standardize breast mammography, ultrasound, and MRI reporting. It includes assessment categories similar to those used in mammography, but doesn't tell physicians when to follow up on category 3 lesions. This had led some insurance companies to balk at providing coverage of follow-up breast MRIs in less than 1 year from the original study and some physicians to proceed directly to biopsy, he explained at the annual meeting of the Radiological Society of North America.

VITALS

Major Finding: When breast lesions were assessed with MRI and placed in the BI-RADS category 3, 162 lesions were benign and 5 were malignant on follow-up.

Data Source: A prospective study of 473 women.

Disclosures: Dr. O'Loughlin disclosed no conflicts of interest. The study was funded by an unrestricted grant from the Connecticut Breast Health Initiative.

Dr. O'Loughlin and his colleagues scanned 473 women, with 158, or 33%, given either a unilateral (104 women) or bilateral (54 women) category 3 assessment on their initial study. The lesions included 126 foci of enhancement, 65 non–mass-like regions of enhancement, and 35 benign-appearing masses, likely lymph nodes or fibroadenomas.

A total of 119 women (75%) returned for follow-up imaging at a mean of 278 days after the initial examination (range, 31-951 days). On follow-up, 162 lesions were benign and 5 were malignant, said Dr. O'Loughlin, a radiologist in a group practice in Hartford, Conn.

For the five cancers, the final diagnosis was confirmed on average 129 days after the initial MRI exam (range, 3-210 days). They consisted of one ductal carcinoma in situ and four invasive carcinomas, and ranged in size from 3 mm to 8 mm. All patients were node negative.

Session moderator Dr. Elizabeth Morris, director of breast MRI and breast imaging at Memorial Sloan-Kettering Cancer Center in New York, asked Dr. O'Loughlin how he handles follow-up in these patients, remarking that the average time for cancer change seems to be about 4 months.

"I like 6 months," he responded. "If it is cancer on follow-up, at most it is a 6-month delay. If I know the patient will not be returning for a year, I'd be calling it category 3 much less."

The mean age in the study was 50.9 years, and 91% of patients were white.

The majority of women were being scanned for diagnostic rather than screening purposes. Clinical indications included a new diagnosis of breast cancer (25%), a remote history of breast cancer (17%), an abnormal mammogram (34%), a strong family history of breast cancer (27%), prior breast surgery (26%), and an implant evaluation (0.6%). Patients could have multiple indications. ■

MRI Detected Breast Cancers Earlier in High-Risk Women

BY BRUCE JANCIN

SAN ANTONIO — Adding MRI surveillance to conventional mammography in women with BRCA1 or BRCA2 mutations results in a favorable stage shift, with breast cancers being detected at an earlier, more curable stage, according to a prospective cohort study.

This finding is consistent with the notion that MRI surveillance reduces distant recurrence rates and breast cancer mortality, although definitive proof must await another 5-10 years of study follow-up, Dr. Ellen Warner reported at the San Antonio Breast Cancer Symposium.

VITALS

Major Finding: In a sample of women with BRCA1 and -2 mutations, 13% of invasive cancers in an MRI surveillance group were node positive, compared with 40% in controls.

Data Source: The nonrandomized study involved 1,275 women with BRCA1 and -2 mutations.

Disclosures: Dr. Warner served as a consultant to Berlex and Bayer.

In the meantime, these encouraging interim results will hopefully convince very high-risk women and their physicians that surveillance with yearly MRI and mammography is a reasonable alternative to prophylactic mastectomy, added Dr. Warner of the University of Toronto.

A randomized controlled trial comparing MRI surveillance to mammography will never happen for ethical as well as practical reasons, she asserted.

The next-best study design would be a prospective cohort study, Dr. Warner said.

Such a study is underway in Toronto. It involves 1,275 women with BRCA1 or -2 mutations who to date have been followed for a mean of 3.2 years for incident breast cancer.

The nonrandomized study involves 445 women in a Toronto surveillance program involving annual MRI and mammography along with twice-yearly clinical breast examination and a control group comprising 830 women who were screened by annual mammography and twice-yearly clinical breast examinations.

There have been 41 cases of invasive breast cancer detected in the MRI group and 77 in the controls.

The incidence in the two groups was nearly identical.

However, there was a marked difference in cancer stage. Only 13% of invasive cancers in the MRI group were node positive, compared with 40% in the controls ($P = .009$).

The mean 9-mm tumor size in the MRI group was one-half that in the controls.

Only 3% of invasive tumors in the MRI group exceeded 20 mm, compared with 29% in the controls.

Ductal carcinoma in situ (DCIS) was detected in 2.2% of the MRI group and 1.1% of the controls.

After baseline differences in menopausal status, tamoxifen therapy, and other potential confounders were controlled for, the MRI cohort was 5.7-fold more likely than the controls to be diagnosed with DCIS, threefold more likely to be diagnosed with stage I breast cancer, and one-quarter as likely to have stage II or higher breast cancer. ■

Distant Metastasis More Likely in Obese Breast Cancer Patients

BY BETSY BATES

SAN ANTONIO — Obese women are substantially more likely than women of normal weight to die of breast cancer, a large Danish registry study concluded.

Researchers from the Danish Breast Cancer Cooperative Group examined extensive health information from nearly 19,000 women with breast cancer, with follow-up data available for up to 30 years post diagnosis.

VITALS

Major Finding: Women with BMIs of 25-30 and greater than 30 were 26%-38% more likely than normal weight women to die of breast cancer 10 or more years after diagnosis.

Data Source: An analysis of a registry involving nearly 19,000 women with breast cancer.

Disclosures: Dr. Ewertz received a research grant from Novartis Pharmaceuticals Corp., and GlaxoSmithKline sponsored her trip to the meeting. The study, however, was conducted and analyzed without support from pharmaceutical companies.

Breast cancer patients with body mass indexes (kg/m^2) greater than 25 faced a 42%-46% increased risk of developing distant metastasis, even after investigators adjusted for numerous other prognostic factors such as age, tumor size, histologic characteristics, estrogen receptor status, and lymph node involvement.

The disparity showed up early in the course of their disease, Dr. Marianne Ewertz said at the annual meeting of the San Antonio Breast Cancer Symposium.

"For distant metastasis, the curves begin to separate after 3 years," said Dr. Ewertz, professor of oncology at Odense (Denmark) University Hospital.

By 5 years, women with a BMI of 25-30 had an increased adjusted hazard ratio of developing distant metastasis of 1.42 (95% confidence interval, 1.17-1.73; $P = .0005$). For those with a BMI greater than 30, the adjusted odds of distant metastasis beginning at 5 years were 1.46 (95% confidence interval, 1.11-1.92; $P = .007$).

Women with BMIs of 25-30 and greater than 30, respectively, were 26%-38% ($P = .002$ and .003) more likely than normal-weight women to die of their disease 10 or more years after diagnosis, and more likely to die of other causes as well.

Heavier women in the study were older, were more likely to be postmenopausal, had larger tumors, had more positive lymph nodes, and had more tumor invasion into deep fascia than did those with a BMI less than 25 (all P values less than .0001). They also had more grade 3 tumors ($P = 0.04$).

However, all of these factors were statistically accounted for in the multivariate analyses of distant metastasis and overall survival.

Poorer outcomes over time may indicate that adjuvant therapy is less effective in obese women than in normal-weight women, Dr. Ewertz suggested.

Inadequate dosing or biological factors could account for the study's findings, said Dr. Michelle D. Holmes of the Dana-Farber/Harvard Cancer Center in Boston, who was the formal discussant of the presentation.

The impact of lifestyle factors on cancer can be "confounding" because they cannot be studied in prospective, randomized trials.

Therefore, prospective observational evidence is gathered from huge, well-controlled population databases such as the Danish health registries. "This is kind of as good as it gets, and it's pretty good," Dr. Holmes said. ■