Guidelines Address Use of MRI in Breast Cancer

BY DAMIAN McNAMARA

HOLLYWOOD, FLA. — A cautious footnote about the use of magnetic resonance imaging to stage breast cancer or to gauge response to breast cancer therapy was added to guidelines from an alliance of 21 leading cancer centers.

"The value of MRI is uncertain, practice varies, and the potential downsides are real," Dr. Stephen B. Edge said at the annual conference of the National Comprehensive Cancer Network.

"This is a rapidly evolving area in practice. This is an area where there is no consensus," he said.

To guide clinicians on the utility of MRI in breast cancer, NCCN added six new recommendations to the Principles of Dedicated Breast MRI Testing section of the guidelines. (Unless noted, all are grade 2A recommendations, reflecting uniform consensus from NCCN panel members.)

This section said that MRI may be useful to stage the extent of cancer or to detect multifocal or multicentric disease in the ipsilateral breast, or to screen the contralateral breast at time of diagnosis (a category 2B recommendation, which has the same level of evidence as a 2A recommendation, but with nonuniform NCCN consensus).

"The impact of identification of contralateral cancers is unclear," Dr. Edge said. MRI leads to frequent biopsies, 75%-80% of which are benign, he added. For example, in an MRI screening study of 969 women with a normal mammogram, 121 had a biopsy-based on MRI lesion detection, and 30 (3%) of the 969 women had a diagnosis of contralateral cancer (N. Engl. J. Med. 2007;356:1295-303).

MRI may be useful before and after neoadjuvant therapy to define the extent of disease or response to therapy. In addition, 'MRI can help assess candidacy for surgery after adjuvant therapy.'

MRI may also be useful before and after neoadjuvant therapy to define the extent of disease or response to therapy. In addition, "MRI can help assess candidacy for surgery after adjuvant therapy," said Dr. Edge, chair of the department of breast surgery and medical director of the Breast Center at Roswell Park Cancer Institute in Buffalo, N.Y.

However, MRI findings may underestimate residual disease, he said. In one study, "unfortunately, half of women cleared by MRI still had residual tumor at time of surgery" (Br. J. Cancer 2004;90:1349-60). "So, complete clearance on MRI does not mean complete clinical clearance. There is clearly a need for prospective data in this field."

In addition, MRI may be useful to identify primary cancer in women with axillary node adenocarcinoma or with Paget's disease of the nipple when primary breast disease is not identified on mammography, ultrasound, or physical exam.

Also, because of a high rate of false-positive findings, the panel concluded that surgical decisions should not be based solely on MRI findings.

For example, a multicenter study of 426 women with a suspicious mammogram and proven cancer revealed a 24% incidental lesion false-positive rate with MRI, compared with 10% false-positive rate with mammography (J. Surg. Oncol. 2005;92:32-8)."But MRI also detected some additional lesions," Dr. Edge said.

An unanswered question is whether MRI affects long-term breast cancer outcome and survival, Dr. Edge said. "The only available evidence—retrospective data—shows no impact of MRI on local recurrence or survival."

Another updated NCCN guideline, this one on breast cancer screening and diagnosis, states that physicians can consider MRI as an adjunct to screening high-risk women in addition to annual mammography and breast exam. New definitions of high-risk patients include women aged 25 years and older with a history of thoracic radiotherapy, and those with a lifetime risk of breast cancer exceeding 20%. MRI is not recommended for screening average-risk women.

The NCCN guidelines panel also included MRI expertise recommendations. For example, an expert breast-imaging team should perform and interpret breast MRI examinations, working in concert with a multidisciplinary treatment team.

In addition, breast MRI should be done by a radiologist with expertise in breast imaging using a dedicated coil. Also, an imaging center should have the ability to perform MRI-guided needle sampling and/or wire localization of relevant findings. ■

Silicone or Saline? Expert Takes a Long-Term View

BY BRUCE JANCIN

SCOTTSDALE, ARIZ. — Silicone or saline?

With 550,000 breast augmentations performed each year in the United States, it's a question physicians and surgeons get asked a lot.

Today, most women choose silicone. Indeed, silicone gel breast implants have dominated the marketplace since November 2006, when the Food and Drug Administration lifted its moratorium on their primary cosmetic use. Silicone gel now accounts for 56% of all breast implants; saline implants, for 44%. But many women who opt for silicone gel implants don't fully appreciate the higher long-term complication rate, one expert said at the annual meeting of the American Academy of Cosmetic Surgery.

"It's really important for these young ladies to understand what they're getting in for 10-20 years from now, because often the complications are not reversible," explained Dr. Erik J. Nuveen, an Oklahoma City cosmetic surgeon who has performed more than 4,000 breast augmentations.

Dr. Nuveen uses both silicone and saline implants. In presurgical counseling, he has witnessed how the tactile experience of handling the silicone devices in the consultation room can influence the selection. This makes it all the more critical, he stressed, that a woman fully understands the pros and cons of both implant types before making her decision.

"The silicone gel implants are softer, more natural feeling. It's alluring to place one on the table and then put it in the patient's hand. You put a saline [implant] in the other hand and, sure enough, 99% of patients say, 'I've got to get that silicone gel,' " the surgeon said.

Silicone breast implants' purported association with connective tissue diseases—the debunked controversy that prompted the former FDA moratorium—has distracted attention from other, very real problems with silicone gel implants, he said.

An estimated 45% of women receiving silicone implants undergo reoperations within 10 years. In practical terms, this means that among women receiving silicone gel breast implants this year, there will be 138,600 reoperations for device rupture, contracture, pain, or loss of shape within the coming decade. In contrast, the 10-year reoperation rate with saline implants is 20%-26%—roughly half the rate for silicone gel implants. "These numbers are really important to me. They directly impact how I advise patients in order to minimize complications in their lives at 10 years," Dr. Nuveen continued.

©SPENCER PLATT/GETTY IMAGES

An estimated 45% of women receiving silicone implants undergo reoperations within 10 years.

Extracapsular rupture of a silicone gel implant with resultant migration of a silicone stream is a major problem. The silicone must be surgically removed before it can reach the lungs or other vital organs—and that involves a lumpectomy or mastectomy. The extracapsular rupture rate is 1% at the time of implantation, 7% at 5 years, and estimated at 10% at 10 years.

In contrast, rupture of a saline implant is less problematic. Implant deflation is immediately apparent, and the saline is readily absorbed by surrounding tissue. There is no need to remove substantial breast tissue. The rupture rate with saline implants is 3%-10% at 10 years, depending largely on surgeon expertise.

The reoperation rate for capsular contraction is substantially lower with saline implants than silicone gel.

Silicone gel implants require a larger placement incision—a minimum of 5 cm—because they go in full. The implants themselves are more expensive than saline ones. Moreover, silicone gel recipients have to bear a continuing lifelong expense for FDA-mandated MRI evaluation in order to detect silent rupture. The initial MRI is required at 3 years, then every 2 years thereafter. It's not covered by insurance. MRI has an 89% sensitivity for detection of implant rupture. In contrast, physical examination of the breast has only 10%-30% sensitivity. Mammography is quite poor at detecting silicone implant rupture while it's still intracapsular and therefore far more easily treated. Moreover, mammography is the No. 1 cause of implant shell failure.

These days the clinical situation in which Dr. Nuveen said he is most comfortable in recommending silicone gel is in the thinnest patients, who are more likely to find saline implants uncomfortable.

Dr. Nuveen said the future of breast augmentation may be a highly cohesive silicone gel known as style 410. It is the most widely used type of implant in Europe but remains investigational in the United States, where large clinical trials are underway. This type of silicone implant is supposed to have unparalleled durability, shape retention, and freedom from rippling, folding, and silicone migration.

Dr. Nuveen reported having no conflicts of interest. ■