Excision Plus RFA Explored for Early Breast Ca

BY NEIL OSTERWEIL

PHOENIX — Call it visionary, hubris, or heresy, but University of Arkansas cancer surgeons assert that radiotherapy may not be necessary to prevent local recurrence of breast cancer in some women.

Instead—in a select population of patients with early breast cancer—they propose the use of local excision followed by intraoperative radiofrequency thermal ablation to effectively extend surgical margins an additional 1 cm.

"Short-term follow-up suggests that for patients with favorable breast cancer or those who don't or won't take breast irradiation, excision followed by radiofrequency ablation [RFA] can reduce local recurrence without the need for—or complications of—radiation," said Dr. V. Suzanne Klimberg of the University of Arkansas in Little Rock. But that assertion did not sit well with many of the oncologic surgeons attending a symposium sponsored by the Society of Surgical Oncology.

"There have been multiple prospective randomized trials that have asked the question, 'Can we identify a subgroup of women who don't need radiation?' and the answer to that has always been 'No,' " said Dr. Monica Morrow, chief of the breast service at Memorial Sloan-Kettering Cancer Center, New York, in an interview. Dr. Morrow was not involved in the study.

"Given the fact that we now know that every form of local recurrence prevented translates into one life saved from breast cancer, we need to be very careful about things that maintain local control," she added. "And why radiofrequency ablation to achieve a negative margin should be any different from large surgical resection to achieve a neg-

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ative margin, I don't know. So that would be my concern about this study."

"Lumpectomy followed by radiation is no doubt the standard of care and the preferred method for treating breast cancer," Dr. Klimberg acknowledged. But she also said that radiotherapy, performed to ensure that any residual malignancy in the tumor bed is destroyed, does not always give the best cosmetic result.

Whole-breast radiation only reduces recurrence at the tumor bed, and brachytherapy "only gives a 100% dose 1 cm around the cavity, and that's what we shoot for, because [according to] several studies, most disease is within a centimeter of a T1 mass," said Dr. Klimberg.

The goal of excision plus RFA, then, is for the surgeon to perform the best possible surgical excision, followed by insertion of an RFA probe into the incision to deliver thermal energy to the tumor margins.

Dr. Klimberg and her colleagues performed a phase II trial of the technique in 94 women with breast cancer who expressed a preference for treatment with lumpectomy. The mean patient age was 67 years. Ductal carcinoma in situ was diagnosed in 32 patients and invasive cancer in 62 patients, 6 of whom also had node-positive disease. The tumors were grade I in 48 patients, grade II in 26, grade III in 19, and of unknown grade in 1.

Pathology showed that 71 of the tumors were estrogen receptor positive and 10 were negative; the remaining 13 were not tested for ER status. Sixty of the samples were HER2 (human epidermal growth factor receptor 2) negative, 14 were positive, and 20 were not tested for HER2 status.

The women underwent lumpectomy followed by RFA with a probe placed 1 cm circumferentially into the lumpectomy cavity and maintained at 100° C for 15 minutes. The surgeons used intraoperative Doppler ultrasound to follow the thermal ablation through detection of nitrogen off-gassing.

In all, 24 patients had inadequate margin resection (defined as less than 2 mm); of these, 8 had grossly positive margins and 4 had focally positive margins. Eight of the patients, who underwent a second resection, were excluded from the analysis.

Postoperative complications included one burn, which prompted the addition of ultrasound to monitor the margins of ablation; one hematoma; two cases of wound dehiscence; and one wound infection, which was treated with antibiotics only.

The women did not receive adjuvant radiation therapy, but most received systemic therapy with tamoxifen (25 patients), an aromatase inhibitor (26), a tamoxifen/AI combination (9), chemotherapy (7), or trastuzumab (1). The remaining 26 underwent observation only.

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Dr. V. Suzanne Klimberg cited the merits of RFA plus excision in select patients.

Cosmesis, scored according to Radiation Therapy Oncology Group criteria in 62 patients 2 weeks after surgery, showed excellent results in 28 patients, good in 25, and fair in 9.

After a mean 23 months of follow-up, there were no local recurrences in the tumor bed. Four "elsewhere" recurrences (defined as a recurrence greater than 5 cm away from the primary tumor) were observed, three in the same breast and one in the contralateral breast. All recurrences were seen within 1 year of surgery "and therefore they were probably there to begin with," Dr. Klimberg commented.

Disease-free survival was 95% at 3 years, regardless of whether patients had ductal carcinoma in situ or invasive pathologies, but the lack of a difference may be due to small numbers, she noted.

Dr. Klimberg concluded that excision plus RFA "may represent a new paradigm in achieving optimal breast conservation without radiation."

Dr. Morrow remained unconvinced: "This was a feasibility study in a highly selected group of patients, and we need longer-term follow-up, and this is certainly not something that is ready for routine clinical use, in my opinion."

Dr. Klimberg disclosed that she owns stock and has received research support from RITA Medical Systems Inc., a maker of RFA equipment. ■