Cryoablation Is Option for Breast Fibroadenomas

BY BRUCE JANCIN
Denver Bureau

SAN ANTONIO — Cryoablation is an attractive alternative to surgery as primary definitive therapy for breast fibroadenomas, Sheldon Feldman, M.D., said at a breast cancer symposium sponsored by the Cancer Therapy and Research Center.

Interim results from the multicenter FibroAdenoma Cryoablation Treatment (FACT) Registry demonstrate that cryoablation is a safe, well-tolerated, minimally invasive procedure that conserves breast tissue.

The procedure is said to offer immunologic advantages over lumpectomy and hyperthermic techniques such as microwave and radiofrequency ablation.

Cosmesis is excellent, with little or no scarring. And unlike conventional open surgical excision of breast fibroadenomas, which typically is performed in an operating room and requires sutures, cryoablation is an office-based procedure performed through a 3-mm incision site using local anesthesia only, added Dr. Feldman, chief of the division of breast surgery at Beth Israel Medical Center, New York.

He reported on 439 FACT procedures in patients who underwent cryoablation at 55 U.S. sites. The mean baseline diameter of their fibroadenomas was 1.8 cm. A total of 79% were palpable at baseline, declining over time to 52% at 6 months after treatment and 33% at 1 year. Nearly all women who reported residual palpability described the treated area as softer and less prominent than pretreatment.

Treated fibroadenomas could be visualized using ultrasound in only 31% of cases at 6 months and 23% at 1 year.

The complication rate was low: a 0.8% infection rate and a 2.9% incidence of hematoma. Transient ecchymosis was observed in 41% of patients at short-term follow-up.

Physician ratings of cosmesis in the cryoablated area averaged 4.8 at 6 months and 4.9 at 12 months on a 5-point scale. No volume deficits occurred, unlike the case with open surgical excision, where permanent volume deficits are common, the surgeon continued.

At 6 months' follow-up, 85% of patients indicated they would recommend the procedure to a friend, as did 82% at 12 months.

Cryoablation was performed in this series using the Food and Drug Administration–approved Visica treatment system that's marketed by Sanarus Medical, Inc. The procedure, which takes about 30 minutes, entails ultrasound-guided insertion of the cryoablation probe into the fibroadenoma, followed by creation of an ice ball that engulfs the benign tumor, destroying the tumor cells. The body resorbs the dead tissue and ablated debris over the subsequent months.

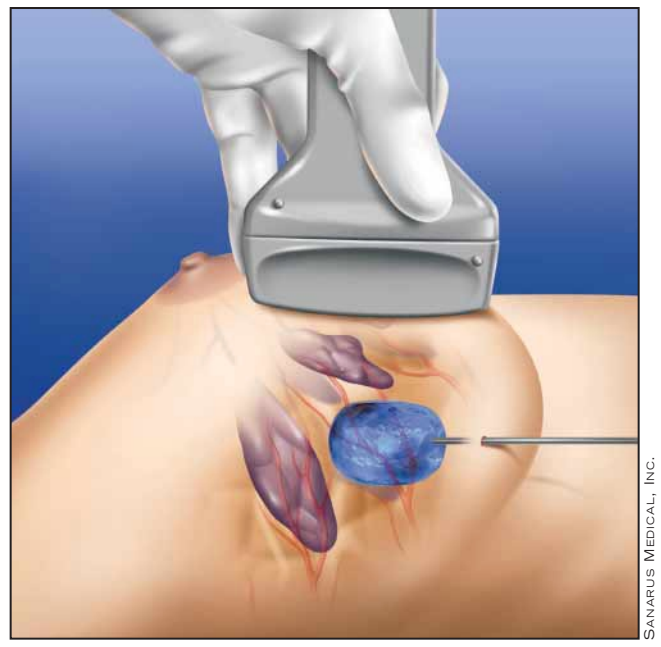
The Visica cryoablation system is being evaluated for in situ ablation of small breast cancers. In a separate presentation at the San Antonio meeting, Michael S. Sabel, M.D., said that cryoablation offers unique immunologic advantages over both lumpectomy and hyperthermic techniques such as radiofrequency, microwave, laser, and high-intensity ultrasound ablation.

Unlike other methods, cryoablation leaves behind intact tumor proteins and tumor-associated antigens. In an inflammatory microenvironment, these antigens can induce a tumor-specific immune response, said Dr. Sabel, a surgical oncologist at the University of Michigan Comprehensive Cancer Center, Ann Arbor.

In a mouse study, he demonstrated the induction of just such an augmented cryoimmunologic response as reflected in increased natural killer cell function, an increase in Th1- but not Th2-type cytokines, and an increase in tumor-specific T-cells in tumor-draining lymph nodes.

This mechanistic investigation follows Dr. Sabel's recent report of a pilot safety study involving cryoablation in the treatment of 29 patients with primary invasive breast cancers not greater than 2 cm. Follow-up standard surgical resection showed the freeze method successfully destroyed all cancers less than 1 cm as well as invasive ductal carcinomas of 1-1.5 cm lacking a significant in situ component (Ann. Surg. Oncol. 2004;11:542-9).

Dr. Feldman disclosed that he receives compensation from Sanarus Medical Inc. for submitted data. ■



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Ultrasound is used to monitor the entire procedure as an ice ball engulfs the fibroadenoma, destroying the targeted area. Ice ball size is controlled by the Visica system under the operator's direction.

Circulating Tumor Cells Signal Outcome in Metastatic Breast Ca

BY BRUCE JANCIN
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SAN ANTONIO — An elevated circulating tumor cell count at any point during systemic therapy for metastatic breast cancer indicates a high likelihood of rapid disease progression and mortality from that time on, Daniel F. Hayes, M.D., said at a breast cancer symposium sponsored by the Cancer Therapy and Research Center.

The implication of this observation is that circulating tumor cell count as measured by a commercially available blood test may have an important role in patient monitoring and guidance of treatment in cases of metastatic breast cancer. A randomized prospective clinical trial is now underway to evaluate the impact of switching therapy in patients who develop an elevated circulating tumor cell (CTC) count during therapy, added Dr. Hayes, clinical director of the breast cancer program at the University of Michigan Comprehensive Cancer Center, Ann Arbor.

In a previously reported double-blind multicenter study involving 177 women who were about to start a new therapy for metastatic breast cancer, Dr. Hayes and his coinvestigators showed that the presence of at least 5 CTCs per 7.5 mL of whole blood using the CellSearch test was associated with significantly reduced progression-free and overall survival.

Circulating tumor cell count in the blood may have an important role in patient monitoring and treatment guidance for metastatic breast cancer.

The same held true for patients who developed a positive test at their first follow-up visit after initiation of treatment. They had a median 2.1-month progression-free survival from that time, compared with 7.0 months in women with 0-4 CTCs on the test. Their median overall survival was 8.2 months, compared with more than 18 months in those with a negative CellSearch test, said Dr. Hayes, a consultant to Immunicon, the company that developed the test.

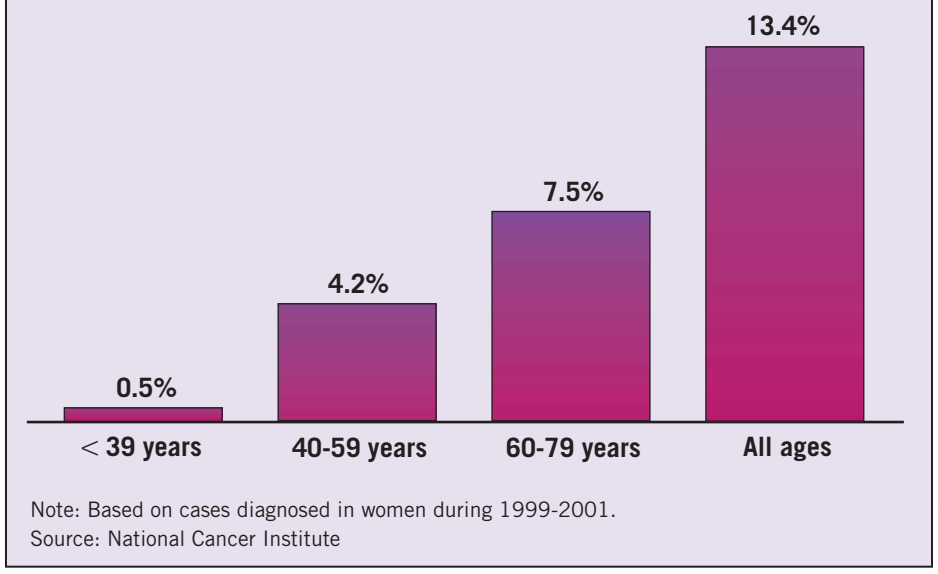
In a multivariate regression model, CTC count at baseline and the first follow-up visit were the strongest predictors of progression-free and overall survival, outperforming *HER2/neu* status, tumor receptor status, type of therapy, and other standard predictors (N. Engl. J. Med. 2004;351:781-91).

In Dr. Hayes's new analysis of the same patient cohort, he demonstrated that patients who developed an elevated CTC count at the second, third, or fourth follow-up visit also fared significantly worse than those who continued to have fewer than 5 tumor cells at their blood draw.

For example, women who developed a positive test at their third follow-up visit experienced a median 3.7 further months of progression-free survival and 6.7 months of overall survival, compared with 6.2 and greater than 17 months, respectively, in patients with 0-4 CTCs upon testing at that visit.

Other companies besides Immunicon are working on tests for CTCs, but last year CellSearch became the only test thus far to gain Food and Drug Administration clearance for the technology. CellSearch is marketed by Veridex LLC, a Johnson & Johnson company. ■

DATA WATCH



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