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Cryoablation Shows Promise as a Non-Surgical Alternative Treatment for Early Stage Breast Cancer

Faster, Gentler Treatment Leaves Breast Cancer Out in the Cold

Abstract: A Phase II Trial Exploring the Success of Cryoablation Therapy in the Treatment of Invasive Breast Carcinoma: Results from ACOSOG (Alliance) Z1072

April 30, 2014, Las Vegas--Non-surgical cryoablation of breast cancer – destruction of diseased tissue by exposure to freezing temperatures – shows promise as an alternative to surgery for selected women with early stage invasive ductal cancer (IDC), according to a new phase II clinical trial presented this week at the American Society of Breast Surgeons (ASBrS) Annual Meeting. The study found that 100% of patients' tumors less than 1 cm in size treated with cryoablation had no residual invasive cancer on pathological examination of the targeted lesion. The success rate for cancers of any size was 80.5%. For 69% of patients, cryoablation was successful when defined as no residual IDC or ductal cancer in situ (DCIS), a precursor to cancer.

“With cryoablation, a woman need not even enter the operating room for treatment, and the procedure can be as brief as 20 minutes,” comments Rache Simmons, MD, Chief of Breast Surgery at New York Presbyterian/Weill Cornell Medical Center and lead author of the study. “Compared to surgery, cryoablation is far less invasive and provides better cosmetic results, shorter procedure time and faster recovery.”

The technique is well-established for treatment of non-cancerous breast fibroadenomas and has been routinely used for other cancers for some time. Earlier studies also suggested that cryoablation is an effective non-surgical treatment for breast cancer in a certain early stage patients.

The new study examined 86 patients with 87 breast cancers from 19 treatment centers. For the procedure, a cryoprobe was inserted under ultrasound guidance through the skin into the targeted
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lesion. Patients underwent ablation using a freeze-thaw-freeze cycle lasting approximately 6-10-6 or 8-10-8 minutes, respectively. Following ablation, the treated tumor was surgically removed for pathological evaluation to determine the procedure's success. "We found that the smaller the cancer, the greater the rate of complete cryoablation," says Dr. Simmons.

A secondary study objective was to evaluate the accuracy of MRI in visualizing residual IDC or DCIS imaging following cryoablation to determine whether the patient was cancer-free. In the study, MRI findings were consistent with subsequent pathology reports for 85.9% of patients with negative findings for IDC and 75% of patients with negative reports for both IDC and DCIS—suggesting an important role for MRI in evaluating cryoablation results.

"Clearly the benefits of cryoablation for breast cancer treatment are numerous. This study shows that it can be quite effective," says Dr. Simmons. "Possibly some women may be able to take advantage of the technique within the next few years by participating in a trial of cryoablation used without follow up surgery—perhaps even sooner."

Abstract

Presenter: Rache Simmons

Institution: Weill Cornell Breast Center

Title: A Phase II Trial Exploring the Success of Cryoablation Therapy in the Treatment of Invasive Breast Carcinoma: Results from ACOSOG (Alliance) Z1072

Objective: Cryoablation is a well established technique for treatment of fibroadenomas. Pilot studies suggest this could be an effective non-surgical treatment for breast cancer. ACOSOG Z1072 is a phase II trial exploring the effectiveness of cryoablation in the treatment of early stage invasive ductal breast cancers (IFDC).

Methods: Z1072 was a single-arm, phase II trial with a target accrual of 99 patients. A total of 19 centers contributed 99 patients; 86 patients (87 breast cancers) were evaluable for data analysis. A cryoprobe was inserted percutaneously under ultrasound guidance into the targeted lesion. Patients underwent ablation using a freeze-thaw-freeze cycle lasting approximately 6-10-6 or 8-10-8 minutes, respectively. The primary endpoint was the rate of complete tumor ablation, with complete tumor ablation defined as no remaining IFDC or ductal carcinoma in situ (DCIS) present on pathological examination of the targeted lesion. A secondary objective was to evaluate the negative predictive value of MRI in the post-ablation setting to determine residual IFDC or DCIS.

Results: Of the 87 cancers treated with cryoablation and eligible for evaluation, pathologic assessment revealed successful cryoablation in 60 (69.0%) cancers and residual IFDC and/or DCIS in 27 (31.0%). The 90% confidence interval for the estimate of successful cryoablation is 59.8% to 77.1%, with the one-sided lower-sided 90% CI of 61.8%. There were 70 (80.5%) cancers that showed successful cryoablation when defined as no residual IFDC and 17 (19.5%) failures, with the one-sided lower bound 90% confidence interval for successful ablation of 73.9%. The negative predictive power of post-ablation MRI to predict residual IFDC was 85.9% (90% CI: 76.7% to 92.5%). The negative predictive power of post-ablation MRI to predict residual IFDC or DCIS was 48/64 or 75.0% (90% CI: 64.5% to 83.7%).

There were 66 (75.9%) breasts that underwent successful cryoablation, as defined as no residual IFDC/DCIS or enhancement on the post-ablation MRI. Using this same definition, there were 21 (24.1%) failures due to the existence of residual IFDC/DCIS and no post-ablation MRI enhancement. The 90% confidence interval for the estimate is 67.1% to 83.2%. The one-sided lower-sided 90% CI is 69.0%.

Conclusion: In highly selected patients with early stage IFDC undergoing cryoablation followed by surgical resection, 69.0% had complete ablation. Including the MRI findings, 75.9% had residual IFDC/DCIS predicted by MRI or a complete ablation. Further studies with modifications in technique could be considered to evaluate the role for cryoablation as a non-surgical alternative for breast cancer treatment.