

Cryoablation as a Primary Treatment of Low-Risk Breast Cancers: An Interim Update of the Ice 3 Trial

Wednesday 3:00-3:10 PM | SSM01-01 | Room: E351

PURPOSE

The Ice 3 Trial is the first of its kind large scale multi center trial in the world to assess image guided cryoablation as a primary treatment for breast cancer without surgical lumpectomy. We report updated interim results and important imaging findings.

METHOD AND MATERIALS

This HIPPA compliant and IRB approved trial seeks enrollment of between 150 and 200 patients for cryoablation of low risk carcinoma of the breast. The study is limited to female patients ages 60 and over with biopsy proven primary, unifocal cancer. Cancers must measure 1.5cm or less with tumor prognostic panels that are ER+/PR+ or ER+/PR-and HER 2-. All patients underwent ultrasound guided cryoablation using the IceSense 3 system (IceCure Medical). Following local anesthesia, patients underwent a freeze, thaw, freeze cycle of cryoablation with the goal of a visible ice ball producing at least a 10mm margin of ice around the tumor. Patients will be followed for recurrence with mammography at 6 and 12 months and then annually for 5 years. Additional imaging with MRI or Ultrasound may be utilized as needed but is not a requirement. All patients have the option of post cryoablation chemotherapy, hormone therapy and or radiation therapy as clinically indicated. Patients will not undergo surgical lumpectomy following cryoablation.

RESULTS

A total of 157 patients have been treated with since enrollment began in October 2014 at 17 participating centers across the United States. Patients ranged from 60-90 years of age. Tumor sizes ranged from 3 to 15mm. No serious adverse events were reported. There has been 100% procedural success. All patients have had at least 6 months follow up. 78 patients have had at least 24 months follow up. 24 patients have had at least 36 months follow up. There has been no recurrence in 156/157 patients with at least 6 months follow up (99.4% success rate). Common imaging findings include fat necrosis, scarring and a mammographic "halo" effect.

CONCLUSION

Cryoablation of the breast is safe and well tolerated with a 100% initial procedural success rate. The overall clinical success rate for 157 patients with at least 6 months follow up is 99.4%. Long term results are also promising.

CLINICAL RELEVANCE/APPLICATION

Interim results suggest that cryoablation is a safe and effective primary treatment for women with small low risk breast cancers as an alternative to surgical lumpectomy.