**Objective:**
- Cryoablation is shown to be effective for small breast cancers as shown in the ACOSOG Z1072 trial.
- The ICE3 Trial is aimed to evaluate efficacy and safety of cryoablation without lumpectomy on low risk early stage breast cancer in women.
- Primary outcomes are local recurrence rate (IBTR - Ipsilateral Breast Tumor Recurrence) and long-term survival.
- Cryoablation is an office procedure that percutaneously destroys lesions by exposing them to extremely low temperatures. Cryoablation may be followed by whole breast radiation and, if appropriate, adjuvant endocrine treatment. Patients participating in this study are expected to benefit from a cryoablation procedure under local sedation without the risks associated with surgical removal of the cancer.

**Methods:**
This study is a multi-centered, single arm, non-randomized clinical trial. The ICE3 trial is currently enrolling patients at 18 sites nationwide. This trial should enroll up to 200 patients. Inclusion criteria include unifocal invasive ductal cancer which is ≤1.5 cm, ER and/or PR, Her2 in women ≥60 years (some sites were IRB approved >50 years). The lesion must be visible sonographically. The cryoablation procedure is performed under ultrasound guidance with local anesthesia. The entire cryoablation process is 20-40 minutes depending on lesion size and appropriate zone of treatment.

**Results:**
Patients mean age is 76, range is (58-94), Mean tumor size is: 7.5 mm Transverse, range is (2.8 mm-14.9 mm) 8.6 mm Sagittal, range is (3 mm-14 mm).

**Quality Of Life:**
95% patients and physicians reported satisfaction from the cosmetic results.

**Safety:**
The results to date show no significant device related adverse events or complications reported. Most of the adverse events reported were minor (ex: edema, bruising, minor bleeding, minor hematoma), 2 patients (1.3%) had moderate skin burn that were topically treated.

**Conclusions:**
The ICE3 trial, the largest controlled liquid nitrogen–based cryoablation trial without subsequent tumor excision, offers the benefits of a minimally invasive alternative to surgical treatment of early-stage, low-risk breast cancer with minimal procedure related risks. At the present time, 70% of patients have been followed for 12-23 months. In this group, the recurrence free survival is >99%. These results support the fact that cryoablation is a safe and effective treatment for early stage breast cancer in patients >60 years old.

79 Years Old Caucasian woman, Left Breast, UOQ, 0.5cm, Hypoechoic Irregular Nodule, Invasive ductal ca with tubular features, Grade I, ER+, PR+, HER2 (-)