Evidence Table

Clinical Area: Cryoablation for breast cancer or benign fibroadenomas of the breast

Study Type: Case Series
Study Aim: To evaluate the safety and efficacy of cryoablation for treating stage T1 breast cancers (Stage T1= Tumor ≤2.0 cm in greatest dimension),

Outcomes
- **Primary:** outcomes not specified in methods section. Reported on tumor volume
- **Secondary:** Adverse effects.

Design
- **Number of subjects:** N=30
- **Description of study population:** Study conducted in Germany. Median age=61.5 years (range=46-80 years); median size of tumors=12 mm (range=5-15mm)
- **Inclusion criteria:** At least 18 years old; T1 breast cancer with tumor diameters of ≤15mm.
- **Exclusion criteria:** Pregnancy, lactation, coagulation abnormality, history of allergy to local anesthetics; tumors <10mm to the skin or chest wall.
- **Consecutive patients?** Not specified.
- **Intervention:** Ultrasound-guided cryoablation using a 3-mm cryoprobe (Galil, Yokneam, Israel). Two freeze-thaw cycles were used. Both freeze cycles lasted 7-10 minutes, with passive thawing for 5 minutes in between. The target temperature of -115°C was reached within the first 2 minutes; the median minimum temperature was -146°C. A mean of 11 days after cryotherapy, all patients underwent open surgery to evaluate whether there was residual tumor. All patients underwent breast-conserving therapy.
- **Source of outcome data:** Histological specimens.
- **Length of follow-up:** Post-surgery which occurred a mean of 11 days after cryoablation.

Validity
- **Was population homogenous?** Yes, there was some variation in diagnosis, but all had stage T1 breast cancer.
- **Potential selection biases:** Bias could be introduced if patients were not consecutive.
- **Were intervention/ care/follow-up similar in each group?** Yes.
- **Did an objective observer assess outcomes?** Not specified, appeared to be objective.
- **Completeness of follow-up:** There was follow-up on 29/30 patients. Cryoablation was stopped early in one patient due to leakage in the cryoprobe.
- **Conclusions regarding validity of methods:** This was a case series, with no control or comparison group. An advantage was open surgery to confirm the impact of the cryoablation. A disadvantage is that there was no long-term follow-up. No financial links were disclosed, but this may not be routine for the journal, *Investigative Radiology.*
Results

Clinical diagnosis of n=30 patients at baseline

21 invasive ductal carcinomas (10 with additional DCIS)
5 invasive lobular carcinomas (2 with additional DCIS or lobular carcinoma in situ)
3 invasive tubular carcinomas
1 pure DCIS

Findings of open surgery

All specimens had a typical appearance

In all completed cryoablation procedures (n=29), there was no residual viable invasive tumor after open surgery.

In 5/30 patients (16.7%), remnant DCIS was found beyond the margins of the cryolesions.

Adverse effects

Two minor adverse effects were reported:
- One case of an arterial bleed after removal of the cryoprobe. The bleeding was stopped after 20 minutes.
- One case of a seroma with a diameter of 30mm at the cryosite which did not require intervention before surgery 7 days later.

Authors’ Conclusions

“Percutaneous cryotherapy is a feasible and safe procedure in minimally invasive therapy for small breast cancers. Residual ductal carcinoma in situ may be attributable to the beginning of a learning curve or by false-negative detection in preintervention imaging…”

Reviewer’s Conclusions

Findings from open surgery were that remnant DCIS was found beyond the margins of the cryolesions in 5 out of 30 patients. This study is limited by the lack of a control or comparison group.