THE AMERICAN SOCIETY OF Breast Surgeons - Official Statement -

Resource Guide on the Use of Transcutaneous and Percutaneous Ablation for the Treatment of Benign and Malignant Tumors of the Breast

Purpose

To outline current data on transcutaneous and percutaneous ablation methods for treatment of benign and malignant tumors of the breast.

Methods

Literature review inclusive of recent randomized controlled trials and other studies evaluating the use of transcutaneous and percutaneous ablation methods of treating benign and malignant tumors of the breast. This is not a complete systematic review but a comprehensive review of the modern literature on the subject. The ASBrS Critical Writing, Editing, and Review Committee developed a resource document which was reviewed and approved by the ASBrS Board of Directors.

Summary of Data Reviewed

1. Indications for percutaneous treatment of benign tumors of the breast (fibroadenoma): The malignant potential of fibroadenomas is low, thus treatment of a biopsy proven, clinically benign fibroadenoma is not required on an oncologic basis. However, for some patients, these tumors can be bothersome, and most surgeons will respect an informed patient's preference for treatment. Traditional open excisional biopsy is an effective treatment, but results in a scar, possible distortion or changes on mammogram, and potential changes to the contour and size of the breast. Two percutaneous therapies have also been investigated in the United States and abroad and have been found to be similar in efficacy to open surgical excision. Importantly, percutaneous treatments result in minimal to no visible contour or aesthetic changes and only a small scar from the placement of the biopsy device or treatment probe: ultrasound guided cryoablation[1-4] and ultrasound guided percutaneous excision.[5,6] Both cryoablation and ultrasound guided therapeutic excisional vacuum assisted biopsy are approved by the U.S. Food and Drug Administration (FDA) for treatment of small fibroadenomas.

Golatta et al.[1] evaluated cryoablation in the standard office setting for the treatment of 60 fibroadenomas. There were no significant adverse events. At one year follow-up, the fibroadenomas were not palpable, nor visible on ultrasound, in 93% of cases. At 12 months follow-up, 2% of patients reported pain, and 97% of patients reported cosmesis to be good or excellent. The results previously reported for cryoablation of fibroadenomas by Kaufman et al[2,3]and Edwards et al[4] are similar to those reported above by Golatta et al.[1]

Li and co-workers described the outcomes of 1,578 patients with benign breast tumors treated by ultrasound guided percutaneous excision in China.[5] Patients were followed for a median of 34 months. 1.9% of patients were found to have local recurrence and 1.1% of patients developed new lesions. Local recurrence was associated with $\geq$ 2 lesions, lesion size greater than 1cm, and procedure-related hematoma.

Fine et al. reported on a multicenter study evaluating ultrasound guided percutaneous excision in 216 women.[6] At 6-month follow-up, 98% of the lesions were no longer palpable, 98% of patients were satisfied with incision appearance, and 92% would recommend the procedure to others.

2. Indications for transcutaneous treatment of benign tumors of the breast (fibroadenoma): Transcutaneous ablative therapies are noninvasive and include focused microwave thermotherapy and focused ultrasound ablation. A systematic review and meta-analysis evaluating the safety and efficacy of focused microwave ablation (MWA) noted a limited number of small non-randomized studies which have demonstrated promising volume reduction and complete ablation rates with good cosmetic outcomes and minimal risk, however, large-scale clinical trials are needed.[7] Focused ultrasound ablation (FUA) has been found to be a safe and effective treatment of fibroadenoma in studies conducted outside the United States and Europe.[8,9] FUA for the treatment of fibroadenoma is currently under investigation in the United States but has yet to receive FDA approval. The primary advantage of transcutaneous treatment is that it results in no scar or visible changes to the breast and avoids a more invasive surgical procedure.

3. Indications for percutaneous ablative treatment of malignant tumors of the breast: Minimally invasive ablation therapies have been used for the treatment of many tumor types such as liver, kidney, lung, prostate and soft tissue tumors. These treatments have historically been reserved for those who are considered to be poor surgical candidates. Within the breast oncology literature, clinical trials have been conducted utilizing percutaneous ablative therapies for patients with early-stage breast cancer without surgical excision. Techniques evaluated include ablation by focused ultrasound, laser, cryotherapy, microwave, and radiofrequency.[10-16] Percutaneous excision by vacuum-assistance is also being investigated.[17]

The ICE3 trial evaluated the safety and efficacy of breast cryoablation in women over 60 years with low-risk breast cancer. This prospective, multi-center, single-arm, non-randomized trail included 194 women with unifocal, ultrasound visible invasive ductal carcinoma 1.5cm or smaller, classified as low to intermediate grade and hormone receptor positive/ HER2 negative. Patients with lobular carcinoma, extensive intraductal component, evidence of lympho-vascular invasion and node positive disease were excluded.[6,18] The three-year interim analysis published in 2021 demonstrated an ipsilateral breast tumor recurrence (IBTR) rate of 2.06% at a mean follow-up of 34.83 months. The five-year follow up results were presented and published in 2024. At a mean follow-up of 54.16 months, IBTR was 4.3% and breast cancer survival was 96.7%. Of the patients who received endocrine therapy only, the IBTR was 3.7%.[1817] Based on this data, the FDA General and Plastic Surgery Devices Panel voted "yes" to the proposal that the benefits of cryoablation for low-risk breast cancer outweigh the risk from the proposed indication for use in November 2024. In October 2025, the FDA completed its review and granted Class II approval for the use of cryoablation in the local treatment of biologically low-risk (as defined under "Recommendations #3") ≤1.5cm invasive ductal carcinoma in patients ≥70 years old. This approval was granted with the requirement for post-market clinical validation performance testing of the device to assess long term tumor recurrence and other serious adverse events.

Recommendations

1. **Indications for cryoablation or percutaneous excision of a fibroadenoma:**
   - **a.** The lesion must be easily visualized on ultrasound.
   - **b.** The diagnosis of fibroadenoma must be confirmed histologically on core biopsy prior to treatment.
   - **c.** The diagnosis of fibroadenoma must be concordant with the imaging findings, patient history, and physical exam.
   - **d.** Lesions should be less than 4 cm in largest diameter.

e. For cryoablation, caution must be taken to avoid thermal injury if the lesion is close (≤5mm) to skin or chest wall. Saline hydrodisplacement and/or warm packs may be used to protect from hypothermic injury to surrounding structures.

f. This procedure may be performed by physicians with considerable ultrasound experience through extensive clinical exposure or credentialed courses, as precise needle placement is key to technical success.

2. **Indications for focused ultrasound ablation (FUA) for the treatment of fibroadenoma**: FUA for the treatment of fibroadenoma is currently under investigation in the United States and is not approved by the FDA for this indication. This technique is considered investigational and should not be performed outside the realm of a clinical trial. There is an ongoing FDA-approved clinical trial for FFUA in the treatment of fibroadenomas.

3. **Indications for cryoablation of malignant tumors of the breast:**
   - **a.** The lesion must be easily visualized on ultrasound.
   - **b.** Patients ≥70 years old.
   - **c.** The malignant mass should be ≤1.5cm in size.
   - **d.** On core needle biopsy, histologic diagnosis must be an invasive ductal carcinoma that is biologically low-risk, defined as grade 1-2, estrogen receptor and/or progesterone receptor positive and HER2 negative, Ki67 <15% and/or with genomic testing indicative of low-risk breast cancer.
   - **e.** Ultrasound of the axilla should be performed to confirm clinically node-negative status.
   - **f.** Contraindications to cryoablation include patients with lobular carcinoma, extensive intraductal component (defined as core biopsy specimen containing 25% or more of intraductal neoplasia), multifocal and or/multicentric disease, the presence of multifocal calcifications on mammogram, evidence of lymphovascular invasion, prior surgical biopsy for diagnosis or treatment of the index lesion, known coagulopathy or thrombocytopenia and those received neoadjuvant therapy.
   - **g.** This procedure may be performed by a radiologist or a surgeon with considerable ultrasound experience through extensive clinical exposure or credentialed courses, as precise needle placement is key to technical success. Caution must be taken to avoid thermal injury if the lesion is close (≤5mm) to skin or chest wall. Saline hydrodisplacement and/or warm packs may be used to protect from hypothermic injury to surrounding structures.

Cryoablation must be considered in the context of a comprehensive treatment plan with input for a multidisciplinary team. Axillary management as well as systemic therapy and radiation therapy recommendations must be carefully addressed. Follow up breast imaging recommendations after cryoablation are unclear and can pose a challenge in monitoring response and future surveillance. While the ICE3 trial and recent FDA advisory panel vote in favor of cryoablation for early-stage low risk breast cancer moves the use of cryoablation for breast tumors forward, ongoing deliberation and implementation with associated special controls is anticipated, as are additional, larger scale trials. There is a significant learning curve in performing safe and effective cryoablation. As such, surgeons should have competency and adequate education, training and mentorship experience with percutaneous techniques prior to adoption of cryoablation into practice. Participation in registries and clinical trials is advised as ongoing data emerges on their use.

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