THE AMERICAN SOCIETY OF Breast Surgeons - Official Statement -

Consensus Guideline 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.

Associated ASBrS Guidelines or Quality Measures

1. Concordance Assessment of Image-Guided Breast Biopsies and Management of Borderline or High-Risk Lesions – Revised November 6, 2016

2. Image-Guided Percutaneous Biopsy of Palpable and Non-palpable Breast Lesions – Revised November 7, 2017

Methods

Literature review inclusive of recent randomized controlled trials 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 Research Committee developed a consensus 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 effective treatment, but results in a scar. Two percutaneous treatments 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 produce 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 for excision of small benign 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 al4 are similar to those reported above of 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 and 45 (3%) patients were found to have a local recurrence. 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. Focused microwave thermotherapy (FMT) has been approved by the FDA. Focused ultrasound ablation has been found to be a safe and effective treatment of fibroadenoma in studies conducted outside the United States[7]. Focused ultrasound ablation 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.

3. **Indications for percutaneous or transcutaneous ablative treatment of malignant tumors of the breast:** At this time, there are no FDA approved percutaneous or transcutaneous ablative treatments for breast cancer. At the present time, cryoablation is approved for treatment of soft tissue malignancies. However, there is emerging data from clinical trials utilizing percutaneous ablative therapies for patients with early stage breast cancer without surgical excision. Techniques being evaluated include ablation by focused ultrasound, laser, cryotherapy, microwave, and radiofrequency.8-11 Percutaneous excision by vacuum-assistance is also being investigated[12].

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.

2. **Indications for focused ultrasound ablation for the treatment of fibroadenoma**:

   Focused ultrasound ablation 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 "echotherapy" in the treatment of fibroadenomas.

3. **Indications for percutaneous and/or transcutaneous ablative treatments of malignant tumors of the breast:**

   Cryoablation is currently approved for treatment of benign and malignant soft tissue tumors by the FDA. Currently, there are no specific technologies that have FDA approval for breast tumors. Participation in registries and clinical trials evaluating the use of these technologies with and without surgical excision of a breast malignancy is advised as early data emerges on their efficacy.

- References -

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This statement was developed by the Society's Research Committee and on October 16, 2018, was approved by the Board of Directors.