**Consensus Guideline on the Use of Transcutaneous and Percutaneous Methods for the Treatment of Benign and Malignant Tumors of the Breast**

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

**Associated ASBS Guidelines or Quality Measures:**

1. Concordance Assessment of Image-Guided Breast Biopsies and Management of Borderline or High-Risk Lesions -- Approved August 15, 2011
2. Image-Guided Percutaneous Biopsy of Palpable and Non-palpable Breast Lesions -- Approved May 15, 2014

**Methods:** Literature review inclusive of recent randomized controlled trials evaluating the use of transcutaneous and percutaneous 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 ASBS Research Committee developed a consensus document which was reviewed and approved by the ASBS 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 surgery. Importantly, they 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\(^5\),\(^6\).

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 authors concluded that “cryodestruction of the FA [fibroadenoma] using liquid nitrogen system proved functional and safe, while showing meaningful reduction in volume, palpability, pain and cosmetic satisfying outcomes.” 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 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\textsuperscript{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\textsuperscript{6}. At 6-month follow-up, 98\% of the lesions were no longer palpable. “Ninety-eight percent of patients were satisfied with incision appearance, and 92\% of patients would recommend the procedure to others.”

2. **Indications for transcutaneous treatment of benign tumors of the breast (fibroadenoma):** Focused ultrasound ablation has been found to be a safe and effective treatment of fibroadenoma in studies conducted outside the United States\textsuperscript{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 treatment of malignant tumors of the breast:** Ablative and minimally invasive percutaneous excisional treatments for early stage breast cancer are being investigated by various groups. Techniques being evaluated include ablation by focused ultrasound, laser, cryotherapy, microwave, and radiofrequency.\textsuperscript{8-11} Percutaneous excision by vacuum-assisted is also being investigated\textsuperscript{12}. At this time, there are no FDA approved ablative or minimally invasive treatments for breast cancer.

Ablative and percutaneous excisional treatments for breast cancer are investigational and should not be performed outside the realm of a clinical trial.

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

Percutaneous and/or transcutaneous treatments of malignant tumors of the breast are not specifically approved by the FDA, though some ablative technologies are approved for treatment of benign and malignant soft tissue tumors. Therefore, ablative and percutaneous excisional treatments for breast cancer are considered investigational and should not be performed outside the realm of a clinical trial.

References:


This statement was developed by the Society’s Research Committee and on June 22, 2017, was approved by the Board of Directors.