

Cryosurgery for breast fibroadenomas

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Abstract: Fibroadenomas are the most common benign tumors in the breast of women during their second and third decades of life, and account for 30% and 50% of all breast biopsies, and these rates rise to about 75% for biopsies in women under the age of 20. The tumors commonly present a painless, palpable, solid, rubbery, well-circumscribed, and movable mass with no associated risk of carcinoma. With the vast array of image-guided biopsy devices, fibroadenomas can be easily sampled and diagnosed. With use of ultrasound-guided cryoablation for breast fibroadenomas, there is little or no pain, targeted lesions are reduced in size or eliminated, scarring is minimal, cosmesis is outstanding, and patient satisfaction is excellent. Cryosurgery should be a preferred option for those patients desiring definitive therapy for their fibroadenomas without surgical intervention.

Key Words: Breast fibroadenomas; cryosurgery; cryoablation; cosmesis



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Introduction

Fibroadenomas are the most common benign tumors in the breast of women during their second and third decades of life, and account for 30% and 50% of all breast biopsies, and these rates rise to about 75% for biopsies in women under the age of 20 (1). The tumors commonly present a painless, palpable, solid, rubbery, well-circumscribed, and movable mass with no associated risk of carcinoma.

With the vast array of image-guided biopsy devices, fibroadenomas can be easily sampled and diagnosed. Because these lesions have the potential to increase in size under the influence of oral contraceptives, pregnancy, or other hormonal stimuli, it is suggested that excision should be the management of choice. However, there is different opinion that because about one third of fibroadenomas spontaneously regress over time, a more conservative approach is indicated (2-4).

In recent years, the treatment of fibroadenomas has transitioned from open surgical excision to more minimally invasive techniques. These include radiofrequency and laser

ablation, sequential piecemeal excision using automated vacuum-assisted biopsy devices, and cryoablation (5).

At present, percutaneous cryoablation has been considered a choice modality for breast fibroadenomas.

Indication

Asymptomatic and small breast fibroadenoma should be followed-up if the diagnosis is confirmed by histology. Percutaneous cryoablation is adaptable for breast fibroadenoma with tumors <4 cm in size and <3 in number, with no malignant component proved by histology and no evidence of bleeding tendency and local skin infection (5).

Technology

The cryoablation procedure for breast fibroadenoma is relatively simple. After the lesion is localized under ultrasound guidance, a cryoprobe is introduced into the breast and guided into the center of the lesion, and cross-

Table 1 The results of cryoablation for breast fibroadenomas

	Cases	Volume reduction (%)		Satisfaction of the patient (%)
		6 months	12 months	
Edwards <i>et al.</i> (6)	310	51	97	100
Caleffi <i>et al.</i> (7)	124		91	92
Kauman <i>et al.</i> (8)	54		87	92
Littrup <i>et al.</i> (9)	42		73	N/R

sectional diameters are measured. The effort is made to place the probe through the long axis of the fibroadenoma; this is facilitated by rotating the ultrasound probe to obtain a transverse image with the cryoprobe visualized in the center of the lesion. Real-time ultrasound is used simultaneously to guide the ice-ball formation. A double freeze-thaw cycle is always used. The forming ice-ball edge is highly echogenic, allowing for precise monitoring under ultrasound. Dripped and injected sterile saline between the skin and forming ice-ball that increases their distance from each other are available for skin protection. At the end of the procedure, the system should actively warm the cryoprobe to facilitate its prompt removal from the patients.

If the patient has two adjacent tumors, both are treated as one target with the probe passing through the middle of each. Some patients have two lesions within the breast treated at one setting. Two treatments in different quadrants of the breast are counted as two separate tumors.

The patients are also warned to expect that the tumor may actually feel larger for up to the first 3 months after treatment but will then begin to regress in size. Ultrasound measurements of the target site are obtained at the 6- and 12-month follow-up visits, and mammograms are performed in age-appropriate patients at the 12-month visit. Mammographic evaluation at 6 months sometime may be performed as well.

Clinical results

Several studies have demonstrated the safety, efficacy, durability, and reproducibility of cryoablation as a primary therapy for breast fibroadenoma. *Table 1* shows several studies reporting 1-year results with volume reductions of 73-97% (as observed on ultrasound) and consistently high patient satisfaction rates of 91-100%. No significant complications were observed in any of the studies.

Edwards *et al.* (6) reported an early experience with office-based cryoablation of breast fibroadenomas. Early

follow-up on 256 lesions showed that the procedure was well tolerated with infrequent minor complications immediately after the procedure. At 6 and 12 months after cryoablation, the remaining fibroadenoma volume progressively involuted. Patient's cosmesis and satisfaction were excellent.

Nurko *et al.* (10) analyzed the data from 444 treated fibroadenomas from 55 different practice settings across the United States. Results showed that in patients with smaller lesions (≤ 2 cm), the disappearance rate of the tumor on ultrasound was 65% and 73%, respectively, at 6 and 12 months after the treatment. In patients with lesions > 2 cm, these values were 61% and 68%, respectively. Patient satisfaction with the procedure was rated as high at 91% and 88% at 6 and 12 months follow-up, respectively.

Caleffi *et al.* (7) showed that evolution of cryoablation freezing techniques, coupled with improvements in cryoprobe design, has resulted in significant improvements in both safety and effectiveness for breast fibroadenomas. They compared two different treatment techniques, which were conducted in 12 centers, 124 lesions in 102 patients with benign breast tumors. In patients treated with the Tailored Freeze technique, significantly better results were recorded 12 months after the procedure: the median reduction in tumor volume was 91%, 73% of all tumors treated were nonpalpable, 84% of lesions less than 2.5 cm in maximum diameter were nonpalpable, and none of the 31 mammograms performed yielded abnormal findings.

Littrup *et al.* (9) reported that 42 biopsy-confirmed fibroadenomas in 29 patients who underwent percutaneous cryoablation. All patients were very comfortable with the resolution of palpable mass effect and cosmetic results. Mammograms showed comparable resolution of mass effects with mild surrounding parenchymal reaction. Two patients received either removal or biopsy of a residual mass, which revealed a shrunken hyaline matrix with preserved collagenous architecture.

In 2002, Kaufman *et al.* (11) reported to use a table-top

cryoablation system to treat 57 core biopsy-proven benign fibroadenomas in 50 patients. Tumor diameter varied from 7 to 42 mm (mean 21 mm). Lesions showed progressive shrinkage and disappearance over 3 to 12 months. In 2004, Kaufman *et al.* (8) again reported the results of a prospective nonrandomized trial of percutaneous cryoablation for 78 benign breast lesions in 63 patients. Eighty-five percent of lesions were fibroadenomas. At 1 year after cryoablation, tumor volume resorption on ultrasound was 88.3% overall (87.3% for fibroadenomas), and 73% of the entire group became nonpalpable to both clinician and patient (75% for fibroadenomas). Two of the fibroadenoma patients had their palpable residual nodule excised, both revealing necrotic debris and no viable tumor in the treated volume. One year later, Kaufman *et al.* (12) further showed the effectiveness and safety of cryoablation as a primary therapy for breast fibroadenomas. Thirty-seven treated fibroadenomas received an average follow-up period of 2.6 years, only 16% remained palpable. A median volume reduction of 99% was observed with ultrasound. Ninety-seven percent of patients and 100% of physicians were satisfied with the long-term treatment results.

Discussion

There are many treatment of fibroadenomas, including (I) conservative management, because that complete regression of one third of fibroadenomas will occur within 5 years (13,14); (II) surgical excision is the definitive therapeutic modality, but it has certain disadvantages which include the usual scheduling delays with the procedure; some cases have postoperative complications and incisional scarring, which compromises skin cosmesis and the anatomic contour of the breast; (III) ultrasound-guided vacuum-assisted fibroadenoma aspiration is a minimally invasive alternative, but its downside is that complete excision of the tumor is difficult to achieve (15).

Heat-based ablative techniques, such as radiofrequency and laser, could be used for treating fibroadenomas. However, these modalities are poorly visualized by ultrasound, thus limiting the accuracy of real-time monitoring (16,17). With intense heating, liquefied fat may disperse the ablative energy in an unpredictable fashion. These procedures are commonly performed in the operating room or stereotactic treatment facility of a hospital (17,18). Because of heat-induced pain, anesthetic sedation is required.

Compared with the above techniques, ultrasound-guided

cryoablation of fibroadenomas has been shown to be a cost-effective alternative with a low morbidity risk (7-9,15,19). A number of potential advantages include:

- ❖ Cryoablation for tumor destruction is well suited for ultrasound guidance and monitoring because the hyperechoic effect obtained with ice-ball formation can be easily identified and therapy can be directed with precision;
- ❖ This technique is a mini-invasive and virtually painless procedure, can be performed under local anesthesia in an office-based breast clinic;
- ❖ There is an excellent cosmesis without tissue removal and minimal scarring. To date, it has had no serious adverse effects reported.

Conclusions

Approximately 10% of women will experience a fibroadenoma in their lifetime. Several studies have demonstrated that the percutaneous cryoablation under ultrasound guidance is a safe and effective modality, and should be used as a primary alternative to surgical excision for breast fibroadenoma.

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