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Percutaneous Excision: A Viable Alternative to Manage Benign Breast Lesions

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Abstract

Objective: Benign breast masses, such as fibroadenomas, are common, and their management is variable, depending on symptoms and patient concerns. We undertook this study to determine the safety, efficacy, and patient acceptance of percutaneous excision of benign breast masses by using a hand-held vacuum-assisted device.

Methods: By using sonographic guidance, percutaneous removal was performed in 40 patients with 42 lesions by using a 9-gauge ($n = 13$) or 12-gauge ($n = 29$) probe (ATEC; Suros Surgical). Technical success, procedural complications, and patient experience were recorded at the time of excision and at 48 hours. Clinical, imaging, and/or surgical follow-up was obtained for 39 of 42 lesions (93%). Three of 42 lesions (7%) were lost to follow-up.

Results: Of 42 lesions, maximal diameters ranged from 0.6−4.0 cm (mean 1.6 cm), with lesion volumes between 0.05 and 11.2 mL (mean [SD] 1.4 ± 2.1 mL, median 7 mL). The procedure was well tolerated by all patients, and no residual mass was visible in any case at the conclusion of the procedure. All the patients preferred this approach to open surgical biopsy. After percutaneous excision, surgery was performed on 3 of 42 lesions (7%) for atypia ($n = 2$) or malignancy ($n = 1$), with a residual mass found only for the malignant case. Of the 26 of 42 lesions (62%) with imaging follow-up, 24 (92%) had no lesion recurrence. Overall, the procedure either completely removed the mass and/or relieved the patient's symptoms of a mass in 36 of 39 lesions (92%) for which clinical, imaging, and/or surgical follow-up was available. Three lesions were lost to follow-up.

Conclusion: Ultrasound-guided percutaneous excision of benign breast masses is a safe, effective, and well-tolerated minimally invasive procedure for the diagnosis and removal of benign breast masses. It may serve as an alternative to surgical excision for women with a known benign or probably benign breast mass who desire excision but prefer to avoid surgery or who are poor surgical candidates.

Résumé

Objectif: Les tumeurs bénignes au sein comme les fibroadénomes sont fréquentes et leur traitement varie selon les symptômes et les préoccupations des patientes. Nous avons réalisé cette étude afin de déterminer à quel point l'excision percutanée des tumeurs bénignes au sein réalisée au moyen d'un appareil à pression négative tenue à la main était sécuritaire, efficace et acceptée par les patientes.

Méthodes: À l'aide d'un sonographe, une ablation percutanée a été effectuée chez 40 patientes qui présentaient un total de 42 ; lésions au moyen d'une sonde de calibre 9 (n = 13) ou de calibre 12 (n = 29) de marque ATEC de Suros Surgical. On a consigné la réussite de l'intervention, les complications chirurgicales et la tolérance des patientes au moment de l'excision et après 48 heures. Un suivi clinique, chirurgical ou en imagerie a été effectué pour 39 des 42 lésions (93 %). Trois des 42 lésions (7 %) n'ont fait l'objet d'aucun suivi.

Résultats: Sur les 42 lésions, le diamètre maximal variait de 0,6 à 4 cm (moyenne de 1,6 cm) et le volume, de 0,05 à 11,2 ml (moyenne [écart type] de 1,4 ± 2,1 ml, médiane de 7 ml). Toutes les patientes ont bien toléré l'intervention et, dans tous les cas, aucune tumeur résiduelle n'était visible à la fin de la procédure. Les patientes ont toutes préféré cette méthode à la biopsie chirurgicale ouverte. Après l'excision percutanée, on a pratiqué une chirurgie pour trois des 42 lésions (7 %) en raison d'une tumeur atypique (n = 2) ou maligne (n = 1) et on a décelé une masse résiduelle uniquement dans le cas de la tumeur maligne. Sur les 26 des 42 lésions (62 %) ayant fait l'objet d'un suivi en imagerie, il n'y a eu aucune récidive dans 24 cas (92 %). Dans l'ensemble, l'intervention a permis de retirer complètement la tumeur ou de

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soulager les symptômes de la patiente pour 36 des 39 lésions (92 %) ayant fait l'objet d'un suivi clinique, chirurgical ou en imagerie. Trois lésions n'ont fait l'objet d'aucun suivi.

Conclusion: L'excision percutanée guidée par ultrasons des tumeurs bénignes au sein est une intervention à effraction minimale, sécuritaire, efficace et bien tolérée permettant le diagnostic et l'ablation de tumeurs bénignes au sein. Cette technique peut servir de solution de rechange à l'excision chirurgicale pour les femmes connue porteuse d'une tumeur mammaire bénigne ou probablement bénigne et qui souhaitent subir une excision, mais préfèrent éviter la chirurgie ou dont le cas se prête mal à la chirurgie.

Key Words: Breast; Benign breast disease; Breast biopsy; Breast ultrasound; Fibroadenoma

Introduction

Although breast cancer will affect 1 in 8 women in their lifetime [1], current data estimate that 60% of all adult women will acquire some form of benign breast disease during their lifetime. Moreover, up to 90% of clinical breast presentations are related to benign disease rather than malignancies [2]. Although benign breast diseases are not life threatening, they may cause the patient emotional distress and physical discomfort, such as pain, lump, or discharge. Not only do these lesions cause anxiety for the patient, but, also, these lesions may grow over time by making their ultimate removal more difficult and less cosmetically pleasing [2].

One of the most common lesions is the fibroadenoma. Although this neoplasm is benign, its management is variable and depends primarily on the presence or absence of symptoms, interval growth, or patient concern for contiguous malignancy. Surgical excision remains the mainstay for some fibroadenomas, but it carries certain risks, including suboptimal cosmesis, which could potentially complicate interpretation of subsequent mammograms [3]. In addition, 16%−20% of women with multiple symptomatic fibroadenomas, most of whom are under the age of 50 years, often have to undergo many surgeries that result in multiple visible scars.

For 2 decades, a diagnosis of fibroadenoma and other benign breast masses has been undertaken by using image-guided core needle biopsy. Results of multiple studies have shown that needle biopsy is safe and accurate in the diagnosis of a benign breast mass and with even greater certainty when performed with a vacuum-assisted device rather than a spring-loaded device, because of larger sample sizes [3−17]. With the introduction of vacuum-assisted devices, it now is technically possible to percutaneously excise a mass. Although these devices are not approved by the U.S. Food and Drug Administration for percutaneous excision, many women seek less-invasive treatments for symptomatic benign or probably benign diagnoses in hopes of symptomatic relief and improved cosmesis.

Several studies used 1 of the early vacuum-assisted devices (Mammotome; Ethicon EndoSurgery Inc., Cincinnati, OH) for the percutaneous removal of fibroadenomas and small malignancies [8−15]. In these studies, the procedure was well tolerated and successful in 38%−85% of patients with a benign mass and was less effective in patients with small cancers, with success being defined as no imaging evidence of residual mass at the time of excision and/or on follow-up imaging. The variable success rate likely reflects differences in devices, patient selection, and operator experience. To date, there are no published reports of using newer vacuum-assisted devices for this purpose. Such devices include the Bard Vacora (Bard Peripheral Vascular Inc., Phoenix, AZ), EnCor device (SenoRx, Aliso Viejo, CA), and automated tissue extraction and collection device (ATEC; Suros Surgical Systems, Hologic, Bedford, MA). We describe our clinical experience with the ATEC and aim to establish its safety, efficacy, and patient acceptance for percutaneous excision of benign breast masses.

Subjects and Methods

Forty patients (39 women, 1 man; age range 17−79 years, mean 38.2 years) with 42 documented benign or probably benign breast masses presented to our institution between May 2003 and March 2005 and prospectively opted to undergo percutaneous excision rather than surgery for treatment of their lesion by using the ATEC device. Because the device was used clinically in patients for a diagnosis of breast disease, our institution's human studies subcommittee determined that approval of this protocol by the institutional review board was unnecessary. Recruitment into this clinical study entailed an extended conversation between the breast imager and prospective patient regarding the management options of close interval follow-up, percutaneous core needle biopsy, conventional surgery, and percutaneous excision for their particular imaging finding. Realistically, because a majority of the patients had an enlarging mass on imaging, imaging follow-up did not represent a reasonable option, and some interventional procedure was preferred by both the patient and the provider. However, because the radiologist explained the pros and cons of each procedure, in addition to the usual complications of bleeding and infection with any biopsy, the patients were informed of the possibility of incomplete removal that might necessitate a second procedure in the future if they opted for percutaneous excision. The potential benefits of percutaneous excision instead of surgery were improved cosmesis and less required preprocedure patient preparation. The potential benefits of surgery were guaranteed removal, but this would require general anesthesia, potentially suboptimal cosmesis, and additional preprocedural preparation. At our institution, all of