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Criteria for excision of suspected fibroadenomas of the breast

Jennifer L. Hubbard, M.D.*, Kathleen Cagle, R.N., M.P.H., James W. Davis, M.D., Krista L. Kaups, M.D., Miya Kodama

Department of Surgery, University of California San Francisco, 2823 Fresno Street, Fresno, CA 93721, USA

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Abstract

BACKGROUND: Fibroadenomas are benign breast tumors; however, more aggressive lesions may mimic or arise within fibroadenomas. We sought to define criteria identifying patients who should undergo surgical excision.

METHODS: Patients with a preoperative diagnosis of fibroadenoma, who underwent surgical excision between 2002 and 2011, were retrospectively reviewed. Patients with final pathologic diagnosis of fibroadenoma were compared with those with non-fibroadenoma pathology.

RESULTS: Of the 723 patients, 681 (94%) had fibroadenomas on final pathology. The incidence of non-fibroadenoma pathology was 6% (42 patients) and included benign phylloides (23), malignant phylloides (2), atypical ductal hyperplasia (1), intraductal papilloma (5), and other benign pathology (11). No cases of adenocarcinoma were identified. Non-fibroadenoma pathology was associated with age >35, immobile or poorly circumscribed mass, size >2.5 cm, and biopsy not definitive for fibroadenoma.

CONCLUSION: Patients with age >35 years, immobile or poorly circumscribed mass, size >2.5 cm, or biopsy not definitive for fibroadenoma should undergo surgical excision.

Fibroadenomas are benign, solid neoplasms of the breast consisting of fibroepithelial elements. Their size is hormonally influenced, as evidenced by fluctuation in size with the menstrual cycle and regression in postmenopausal women. Fibroadenomas are often solitary masses, but 25% of patients present with multiple lesions. They have a characteristic clinical presentation: rubbery, mobile, and firm. Despite this, previous reports have indicated that diagnosis by clinical examination is accurate in only 50% to 75% of patients.[1]

One of the clinical dilemmas facing both surgeons and patients is the concern that the mass is something more ominous than a fibroadenoma. Both benign and malignant phylloides tumors may mimic fibroadenomas. Additionally, published reports have described adenocarcinoma and ductal carcinoma in situ arising within fibroadenomas or misdiagnosed as fibroadenomas. Because of the potential for more aggressive pathology masquerading as fibroadenomas, management has been debated and recommendations changed several times in recent decades. Until the mid-1980s, standard practice was excision of all fibroadenomas.[2] Subsequent studies in the 1980s and 1990s demonstrated the safety of observing the presumed fibroadenomas in women under

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* Corresponding author. Tel.: +1-559-459-3722; fax: +1-559-459-3719.

E-mail address: jhubbard@fresno.ucsf.edu

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age 35 who had a fine-needle aspirate biopsy that did not contain malignant or suspicious cells.[1,3] More recently, the question has been asked whether biopsy is even necessary. Smith and Burrows[4] concluded that patients under the age of 25 with benign ultrasound findings could be safely observed without a biopsy.

We hypothesized that risk factors for more aggressive pathology could be identified in women with presumed fibroadenomas. Identification of these risk factors would assist physicians in counseling and treating women with presumed fibroadenomas and allow the development of guidelines for biopsy or excision.

Patients and Methods

The study was approved by the institutional review board of the University of California San Francisco, Fresno. The patient population was drawn from a large community hospital system in Fresno County that includes several outpatient clinics and 2 major hospitals. We reviewed the electronic and handwritten medical records of all patients with a preoperative diagnosis of fibroadenoma who underwent surgical excision between 2002 and 2011. Men were excluded from the study. Patient demographics and risk factors for breast cancer were collected. Past or current use of hormonal therapy, including contraceptives, was recorded. Additionally, the patient's ultrasound results, estimated preoperative size of the mass, preoperative biopsy results, and final size and pathology were recorded. In patients who underwent an ultrasound, mass characteristics including increasing size on serial studies, height versus width, Breast Imaging Reporting & Data System (BI-RADS) category, and echogenicity were also collected. Because of the variability of percutaneous biopsy pathologic interpretation, we categorized results as either fibroadenoma or non-fibroadenoma. Non-fibroadenoma pathology included fibroepithelial neoplasm, spindle-cell neoplasm, possible phylloides tumor, and other nonspecific diagnoses.

Most of the data were collected from preoperative history and physical examinations that were handwritten, before the implementation of electronic medical records. To make the greatest use of our data, we made some a priori assumptions that history was negative if not otherwise documented and physical examination was normal if not documented. Indications for surgical excision were based on size (or increase in size), characteristics of the mass (ill-defined, poorly circumscribed, hard), patient discomfort, and/or ultrasound characteristics, with the final determination made by the attending surgeon.

Statistical analyses were performed using paired Student *t* test, *z* test, Fisher's exact test, Mann–Whitney *U* test, chi-square analysis, and Mantel–Haenszel estimates (odds ratio analysis). A *P* value of .05 was considered significant. Statistical analysis was performed using IBM SPSS software (IBM Corp, Armonk, NY).

Following analysis and identification of significant risk factors, criteria for observation versus excision were created and applied retrospectively to the patient database to calculate how many patients could have safely avoided an operation and how many with more aggressive pathology would have been missed in our dataset.

Results

Characteristics of the study cohort, including demographics, are listed in Table 1. Of the 723 patients meeting inclusion criteria, 94% (681patients) had a fibroadenoma on final pathology. The other 6% (42 patients) had pathology demonstrating benign phylloides (23), malignant phylloides (2), atypical ductal hyperplasia (1), intraductal papilloma (5), and other benign pathology (tubular adenoma, mastitis, adenomyoepithelioma, benign neurofibroma, fibrocystic changes, stromal sclerosis, and nonspecific fibroadipose tissue). We did not identify any cases of adenocarcinoma or carcinoma in situ in this cohort of patients.

Patient ethnicity was largely Hispanic and Caucasian and mirrors the ethnicity of Fresno County, which is 50.9% Hispanic/Latino and 32.4% Caucasian (US Census Bureau, 2011 Fresno County Data). Most of the known risk factors for breast cancer were not associated with non-fibroadenoma pathology (Table 2). Family history of cancer (other than breast cancer), nulliparity, smoking history, breastfeeding history, early menarche, personal history of breast cancer, history of prior breast biopsy, and 1st pregnancy with advanced maternal age were not significantly different between the fibroadenoma and non-fibroadenoma group. However, patients aged >35 years were significantly more likely to have non-fibroadenoma pathology (OR 2.8, $P = .002$, Table 2).

Physical examination

The classical description of a fibroadenoma as a well-circumscribed and mobile mass was found to hold true among the patients in our study (Table 2). The positive predictive value of a mobile mass being a fibroadenoma was 93%. A well-circumscribed mass correlated with a 95% positive predictive value and a sensitivity of 99%. Conversely, patients with an immobile mass were 9 times more likely to have non-fibroadenoma pathology and patients with poorly defined masses were 15 times more likely to have non-fibroadenoma pathology.

Imaging

None of the criteria recorded on ultrasound (height vs width, BI-RADS categories, and echogenicity) were found to be statistically significant. There was great heterogeneity in both the reporting of ultrasound diagnoses and descriptions of the mass. Table 3 shows the distribution of BI-RADS assessments given for fibroadenoma and non-fibroadenoma pathology. There was no statistical significance between all BI-RADS scores. Patients with masses