Diagnosis and Treatment of Breast Fibroadenomas by Ultrasound-Guided Vacuum-Assisted Biopsy

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Hypothesis: Ultrasound-guided vacuum-assisted biopsy (UGVAB) can serve as an efficient tool for the diagnosis and excision of breast fibroadenomas.

Design: Patients with a clinically and radiographically suspected breast fibroadenoma were prospectively referred for UGVAB to confirm the diagnosis and to attempt to excise the lesion.

Patients: Fifty-two female patients, aged 19 to 68 years, were included in the 2-year study. All had at least 1 suspected fibroadenoma. The procedure was performed for a total of 56 lesions.

Interventions: Imaging modalities prior to biopsy to confirm the clinical suspicion included Doppler ultrasound and mammography or Doppler ultrasound alone. Tumor size and volume were recorded. Ultrasound-guided vacuum-assisted biopsy was performed in all cases, with guidance using the 11-gauge Mammotome handheld vacuum-assisted biopsy system (Ethicon Endo-Surgery Inc, Cincinnati, Ohio).

Main Outcome Measures: Major end points included diagnosis compatibility rate, excision rate, complications, and short-term follow-up.

Results: A tissue diagnosis was obtained in all cases and was compatible with the clinical diagnosis of fibroadenoma. Complete excision was achieved in all lesions less than or equal to 1.5 cm (mean volume, 0.25 mL). All lesions greater than 2 cm (mean volume, 1 mL) were incompletely excised. Of the 20 lesions measuring 1.5 to 2.0 cm, 11 (55%) were completely excised. The volume of all completely excised lesions was less than 0.9 mL. Four lesions with a volume less than 0.9 mL were incompletely excised due to bleeding. Ten of the 13 cases with incomplete excision were confident enough with the diagnosis to choose imaging follow-up instead of surgery. Two patients (16%) were referred by the radiologist for surgical excision. Only 1 patient with incomplete removal (8%) felt uncomfortable with the remnant lump and requested surgical excision.

Conclusions: Although the breast fibroadenoma is a common benign breast tumor, the treatment and follow-up of these lesions is still debatable. We suggest that UGVAB, which has a well-documented role in the diagnosis of breast lesions, may provide an option for the definitive treatment of breast fibroadenomas.

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FIBROADENOMA is the most common breast tumor in adolescent girls and women younger than 25 years. Although the peak incidence is between the second and third decades of life, it is not uncommon in postmenopausal women, with an increased incidence after hormone replacement therapy. Overall, it occurs in approximately 10% of women and accounts for about 50% of breast biopsies performed.

Fibroadenomas are benign tumors that are sharply demarcated from the surrounding tissue; some authors even consider them to be an aberration of normal development rather than a true neoplasm. They consist of combined proliferation of epithelial and connective tissue elements, and there is good histologic evidence that these tumors develop from a lobular origin. This may explain the high incidence of fibroadenomas in young women at the time of maximal lobular development and why the very rare cases of cancer that arise in fibroadenomas are of lobular origin (lobular carcinoma in situ).

The usual clinical presentation is a palpable lesion detected incidentally during a medical or self-examination. It is typically a solitary, nontender, smooth, freely mobile mass of 1 to 3 cm. Only 20% of cases are multiple or greater than 4 cm. Most fibroadenomas are static or cease growth at approximately 2 to 3 cm, about 15% of tumors regress spontaneously, and
only 5% to 10% progress. Cancer arising in the fibroadenoma is extremely rare (95% confidence interval, 0.002-0.01). The characteristic clinical presentation can provide an accurate diagnosis based on physical examination alone in only 50% to 67% of fibroadenomas; thus, diagnosis should be based on supporting data, such as findings from imaging and tissue study. Ultrasound examination is the method of choice in the evaluation and follow-up of fibroadenomas in younger patients. The characteristic sonographic appearance of a fibroadenoma is an ovoid smooth solid mass, narrower in its anteroposterior diameter than its transverse diameter, with even, low-level internal echoes. This appearance is not characteristic of all fibroadenomas, however. Mammographically, fibroadenomas are usually well-circumscribed lesions, but 25% may have features suggestive of malignancy (eg, irregular outline). Although the role of mammography in the diagnosis of fibroadenoma is limited in young women, it can be helpful in older women, especially in those with nonpalpable lesions. During the last decade, percutaneous tissue diagnosis has been a major tool in the evaluation of breast masses. Fine-needle aspiration or core-needle biopsy can achieve a reliable diagnosis. Fine-needle aspiration has several drawbacks, however. Predominantly among them is the high rate of insufficient tissue material obtained. Core-needle biopsy, the second most common method used in percutaneous breast biopsies, also has its drawbacks, such as the need for multiple reinsertions of the needle for each sample taken and insufficient material obtained in some cases of very dense breasts. A third method for obtaining tissue is the vacuum-assisted biopsy (VAB). The advantages of this method are that it requires only a single insertion without retargeting and it can obtain a larger amount of tissue for diagnosis, sometimes even allowing removal of the entire lesion. Fibroadenomas are usually readily accessible by biopsy under sonographic guidance, which allows for continuous real-time visualization of the needle and assurance of targeting accuracy.

Fine-needle aspiration, combined with the clinical diagnosis of fibroadenoma, can improve the sensitivity of the diagnosis to 86% and the specificity to 76%. The combination of a clinical breast examination, imaging, and percutaneous tissue study is referred to as the “triple assessment approach.” It provides a 95% accurate differentiation between a benign and a malignant lesion.

The management of fibroadenomas is still debatable and dependent on patient age and clinical findings. For nonpalpable lesions, the recommended approach is a follow-up period of 1 to 3 years after the fibroadenoma is diagnosed by the triple assessment. For palpable lesions, some advocate complete surgical excision of all lesions that are clinically suspected of being fibroadenomas, as it provides a definitive diagnosis while removing the lesion as a source of patient concern. It also alleviates the need for short-term follow-up, often complicated by lack of patient compliance. However, surgical excision of every fibroadenoma is costly and associated with morbidity (cosmetic damage). Another disadvantage is that the lesion may regress or recur and, according to the information gathered to date, is unlikely to have an effect on the patient’s health. A second option is to use the triple assessment as a diagnostic tool. If a definitive diagnosis of fibroadenoma is obtained, then the patient can be managed conservatively by close clinical and imaging follow-up every 6 months until the patient is 35 years of age. An increase in lesion size during follow-up or a lack of regression by the age of 35 years warrants surgical excision. Excision can also be offered to patients who request removal of the lesion.

The purpose of this study was to evaluate a third approach to the management of breast fibroadenomas that integrates the advantages of the 2 treatment options. This approach is minimally invasive, using ultrasound-guided VAB (UGVAB) as a means of diagnosis, treatment, and complete excision of the lesion.

During 2 years (May 1999 through May 2001), 56 sonographically guided breast biopsies were performed for suspected fibroadenomas in 52 patients. All patients were referred for a UGVAB to obtain a tissue diagnosis and, if possible, to completely excise the lesion. Indications for referral for UGVAB were a palpable mass (n=22), nonconclusive previous tissue diagnosis (fine-needle aspiration [n=8]; core-needle biopsy [n=6]), nonconclusive imaging findings (n=8), a new mass (n=3), and unwillingness to undergo the procedure because of a history of open biopsies for fibroadenomas (n=9).

Imaging modalities performed to establish the diagnosis of fibroadenoma included mammography and ultrasound for patients older than 30 years (n=40) and ultrasound alone for patients younger than 30 years (n=12). Mammography demonstrated well-circumscribed masses. Ultrasound showed solid isoechoic or hypoechoic lesions with an anteroposterior-lateral ratio less than 1, with or without a capsule or posterior enhancement.

Mammography was performed with a dedicated mammography unit (Seno DMR+; GE Medical Systems, Cedex, France). Breast ultrasound examinations were performed by a radiologist specializing in breast imaging, using a variable 7.5- to 10-MHz transducer (128 XP/10 unit; Acuson, Mountain View, Calif). Color Doppler ultrasound was performed in all cases to evaluate lesion vascularization and to avoid major vessels during the biopsy procedure. Lesion size was measured in 3 dimensions based on the largest lateral and the largest anteroposterior diameter in the longitudinal scans, and the largest anteroposterior diameter in the transverse scans. Lesion volume was calculated based on these measurements.

The procedure was performed after the patient had been given a detailed explanation and informed consent had been obtained. A single, skilled radiologist experienced in interventional breast procedures performed all biopsies, using the 11-gauge Mammotome Handheld Vacuum Biopsy System (Endo-Surgery, Cincinnati, Ohio). The biopsies were guided by the same ultrasound unit mentioned previously.

All biopsies were performed in an ambulatory setting under local anesthesia and sterile conditions at our breast imaging center. An 11-gauge needle was used in all procedures. The probe was adjusted below the lesion in patients most palpatable or through the lesion in patients with lesions larger than 2 cm at the longest diameter. An attempt was made to continue the biopsy until there was no sonographic evidence of the lesion. Complete excision of the lesion was achieved when fluid-filled cavity or air bubbles were demonstrated by ultrasound. A marking exam

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clip was inserted at the biopsy site in cases where complete excision was achieved. Patients were scheduled for follow-up ultrasound examination at 15 days, 30 days, 3 months, 6 months, and 12 months.

RESULTS

A total of 56 sonographically guided breast biopsies were performed in 52 patients. Forty-eight patients had 1 lesion and 4 had 2 lesions (1 in each breast). A tissue diagnosis was obtained in all cases and was compatible with fibroadenoma. One case was diagnosed as fibroadenoma with multiple foci of lobular carcinoma in situ.

Overall, 22 lesions (39%) were palpable, mostly in younger patients (<40 years). Only 3 lesions were clinically palpable in patients older than 40 years. Of the nonpalpable lesions, only 4 were in patients younger than 40 years. Three were in women older than 50 years who received hormone replacement therapy and developed a new breast mass. There was no side predilection, with 29 lesions in the right breast and 27 in the left. The longest lesion diameter ranged from 0.3 cm to 2.8 cm (mean, 1.03 cm). Lesion volume ranged from 0.06 mL to 1.4 mL (mean, 0.74 mL). The number of cores obtained in each case was between 8 and 25 (mean, 17 cores), depending on lesion size and technical feasibility.

The Table presents a summary of lesion excision by size and volume. Complete excision was achieved in 32 lesions that were less than or equal to 1.5 cm with calculated volumes of 0.06 to 0.64 mL (mean, 0.25 mL). Of the 20 lesions measuring 1.51 to 2 cm, 11 lesions (55%) were completely excised (Figure 1) and 9 were partially excised (groups 2a and 2b, respectively). The volume range of the completely excised lesions was 0.16 to 0.98 mL (mean, 0.57 mL) and of the partially excised lesions was 0.54 to 1.00 mL (mean, 0.97 mL). Four lesions in the partially excised group were less than 0.9 mL but the excision was not completed, owing to bleeding. The remaining 3 lesions were greater than 0.9 mL and incompletely excised. Four lesions were greater than 2 cm, with a volume range of 1.0 to 1.4 mL (mean, 1.15 mL) and all were incompletely excised. We find that lesions with volumes less than 0.9 mL, even if the longest diameter is greater than 1.5 cm (but less than 2 cm), can be completely excised if bleeding does not stop the procedure. For lesions incompletely excised, the volume reduction ranged from 55% to 80%.

The average biopsy procedure time was 40 minutes (range, 20-60 minutes). The procedure was interrupted when major bleeding occurred. Most patients were compliant during the procedure and experienced no or minimal pain. There were no major complications, such as shock or infection. Only 2 patients (3.6%) had more extensive bleeding, which was controlled by the use of local iced compression and pressure. All patients returned to work the day after the procedure and resumed their daily activities.

A follow-up ultrasound examination was performed an average of 12 days after the biopsy, when patients came to collect the biopsy results. At this time, most

<table>
<thead>
<tr>
<th>Group</th>
<th>Excision Completion</th>
<th>Size, cm</th>
<th>No. of Lesions</th>
<th>Volume, Mean (Range), mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Completely</td>
<td>≤1.5</td>
<td>32</td>
<td>0.25 (0.06-0.64)</td>
</tr>
<tr>
<td>2a</td>
<td>Completely</td>
<td>1.51-2.0</td>
<td>11</td>
<td>0.57 (0.16-0.98)</td>
</tr>
<tr>
<td>2b</td>
<td>Incompletely</td>
<td>1.51-2.0</td>
<td>9</td>
<td>0.97 (0.54-1.3)</td>
</tr>
<tr>
<td>3</td>
<td>Incompletely</td>
<td>&gt;2.0</td>
<td>4</td>
<td>1.15 (1.0-1.4)</td>
</tr>
</tbody>
</table>

Figure 1. A, Lateral mammogram shows a well-circumscribed mass (arrow) in the inferior quadrant. B, Ultrasound of this mass shows the typical appearance of a fibroadenoma (a solid hypoechoic oval mass). The longest diameter of this lesion is 1.8 cm, with a calculated volume of 0.53 mL. C, Mediolateral oblique mammogram after complete removal of the lesion with ultrasound-guided vacuum-assisted biopsy. A micromark identifies the site of the biopsy.
patients had an asymptomatic hematoma, demonstrated by ultrasound as fluid cavities at the biopsy site. In all cases, complete resolution was seen after 30 days.

Patients were followed up for 2 years, and no evidence of recurrence was seen. Of the 13 cases that were incompletely excised, only 3 underwent surgical excision. One patient felt uncomfortable with the palpable breast lump and requested surgery. Another patient was referred for surgery because of the presence of lobular carcinoma in situ in the biopsy specimen (Figure 2). The excised specimen showed the same pathologic grading as the core biopsy. The third patient showed an increase in lesion size at the 6-month follow-up and thus, surgery was recommended. The pathologic finding was fibroadenoma without evidence of malignancy. The remaining patients opted for a conservative follow-up, confident with the diagnosis and management.

**COMMENT**

Fibroadenoma of the breast is an extremely common problem, usually demonstrated as a palpable mass in young females. After establishing a confident diagnosis of fibroadenoma with the triple assessment approach, ie, typical clinical setting, imaging studies (usually sonography, sometimes mammography), and a reliable tissue diagnosis, the patient is offered either surgical removal or conservative management in the form of close follow-up. In practice, solitary fibroadenomas in young women are surgically removed, mainly to alleviate patient anxiety and concern due to the palpable mass. Other considerations supporting surgical removal are the potentiality of losing a patient to follow-up or the extremely remote possibility of missing malignant transformation or unsuspected breast cancer.

Minimally invasive procedures, already established as an irreplaceable tool for diagnosis, are increasingly becoming the preferred modality of treatment in many conditions (eg, angioplasty and percutaneous ablation of inoperable liver tumors). We suggest that for a breast mass suspected to be a fibroadenoma based on clinical and imaging findings, a minimally invasive procedure in the form of an ultrasound-guided vacuum-assisted MammoToxe procedure is appropriate. This large-core-needle biopsy, using an 11-gauge needle, will serve both as a means for tissue diagnosis and may offer a definitive treatment option. As shown in our study, all lesions less than 1.5 cm at the longest diameter can be excised. Even lesions up to 2 cm can be completely excised, providing that the calculated lesion volume is less than 0.9 mL and that bleeding does not hamper the procedure.

This conservative option requires both surgeon and patient to feel confident with the diagnosis and treatment. Although some surgeons may still prefer a surgical approach, we feel that in a multidisciplinary breast center, surgeons are comfortable referring patients to radiologists for the nonsurgical removal of a fibroadenoma. As in recent studies, our trial has shown that most patients are content with the conservative approach, and feel confident enough to opt for the minimally invasive procedure over surgery as a means of lesion removal.

A major concern with the percutaneous tissue diagnosis was the high false-negative rate when the diagnosis was based on fine-needle aspiration findings. When removing most or all of a lesion, as in our approach, miss-
ing malignancies is almost certainly avoided. Further re-
assurance is provided by a 2-year follow-up to ascertain
the lack of change in imaging characteristics that could
suggest recurrence or malignancy. The one case of lobu-
lar carcinoma in situ in our group is proof that if there
were malignant cells in a lesion, the tissue sample was
large enough to diagnose it.

While our results are encouraging, it must be taken
into account that our data are not based on a random-
ized, comparative study. To recommend UGVAB as the
gold standard in the treatment of breast fibroadenomas,
further studies comparing UGVAB with standard surgi-
cal excision should be done.

The efficacy of percutaneous ultrasound-guided bi-
pisy in the diagnosis of breast lesions is well docu-
mented. Advantages of minimally invasive procedures over
surgical intervention include patient convenience, fewer
complications, the absence of a residual scar, and lower
cost. We suggest that UGVAB is a safe and successful
method of treatment for small fibroadenomas. This treat-
ment option should be reserved for lesions that are prob-
able fibroadenomas based on imaging studies and clin-
ical assessment. The procedure should be explained in
detail to ensure patient cooperation, and patients should
feel confident that this option is as good as surgery. The
success rate using the 11-gauge needle is higher for le-
sions less than 2 cm in diameter if the calculated vol-
ume is less than 0.9 mL. Further randomized studies com-
paring UGVAB with the standard surgical excision are
underway.

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