A Prospective Analysis of Office-Based Breast Ultrasound

Tina J. Hieken, MD; José M. Velasco, MD

Objective: To determine the usefulness of office-based breast ultrasound.

Design: Prospective, nonrandomized study.

Setting: Academic-affiliated community teaching hospital.

Patients: Among 653 consecutive patients seen in our office during a 30-month period, we performed 660 ultrasound examinations. The presenting complaint included a palpable mass in 53%, abnormal mammogram in 39%, and nipple discharge or retraction in 3%.

Intervention: Ultrasound examination was performed using a handheld 7.5-MHz linear array transducer. Findings and pertinent clinicopathologic data were recorded prospectively in our Breast Ultrasound Registry.

Main Outcome Measure: Contribution of breast ultrasound to diagnosis and treatment.

Results: The sonogram was normal in 201 cases (30%), showed duct ectasia in 20 cases (3%), a simple cyst or seroma in 101 cases (15%), and a focal complex or solid abnormality in 338 cases (51%). Among the last group, 114 (97%) of 118 lesions thought to be benign on ultrasonography proved to be benign, whereas 13 (12%) of 111 indeterminate and 72 (75%) of 96 sonographically suspicious lesions proved to be cancer (including 13 cases with normal mammograms). Ultrasonographic features of malignancy included an anteroposterior-to-lateral dimension ratio of 1 or greater, heterogeneous hypoechogenicity, irregular shadowing, and fuzzy and/or jagged margins. Ultrasound-guided needle biopsy accurately diagnosed 46 benign nonpalpable lesions and 20 malignant nonpalpable lesions.

Conclusions: These data suggest that ultrasonography is a useful adjunct to clinical and mammographic evaluation of breast disease. Breast ultrasound identifies cysts, aids in differentiating benign from malignant lesions, and facilitates office needle biopsy of nonpalpable abnormalities, permitting timely and cost-effective patient care.

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RECENT technical advances in ultrasonography have expanded the potential usefulness of this modality for the evaluation of breast lesions. In the past, breast ultrasound (US) has chiefly been used to distinguish solid abnormalities from cystic ones. High-resolution probes, computer-enhanced imaging, and portable machinery have led to the widespread adoption of real-time US by breast surgeons. Consequently, breast US has become an increasingly integral part of the evaluation, diagnosis, and treatment of breast disease. While widespread adoption of screening mammography has led to improved early detection of breast cancer, in the course of detecting 5 cancers per 1000 women screened, mammography will identify about 40 indeterminate lesions. Skilled application of real-time US may facilitate clinical assessment of the breast and help guide targeted biopsy of imaged lesions at the time of initial clinical evaluation. This may be especially useful for the prompt and cost-effective evaluation of mammographically indeterminate lesions. Application of ultrasonography in the setting of a palpable mass may also allow the surgeon to image what is felt. Recognition of a mass as a simple cyst or benign fibrous tissue should reduce the number of excisional biopsies performed for diagnostic purposes. Therefore, we undertook this prospective study to determine the usefulness of office-based breast US in the evaluation, diagnosis, and treatment of breast disease in our surgical oncology practice.

RESULTS

On physical examination, 336 breast lesions were palpable (51%), 222 were nonpalpable (34%), and 102 were indeterminate.
PATIENTS AND METHODS

PATIENTS

We prospectively evaluated 660 consecutive breast US examinations performed on 653 patients in our office from March 1995 through August 1997. We studied 645 female and 8 male patients, ranging in age from 12 to 92 years (median, 50 years; mean ± SE, 52.1 ± 0.6 years). Patient demographic data are summarized in Table 1. Among the study patients, the presenting complaint was a palpable mass in 348 cases (53%), an abnormal mammogram in 235 (39%), nipple discharge or retraction in 23 (3%), and other, including follow-up of breast cancer and mastalgia, in 34 (5%).

US PROTOCOL

Breast US examination was performed using a handheld 7.5-MHz linear array transducer with a 3535 diagnostic US system (B & K Medical Inc, Billerica, Mass) using the technique initially described by others.8,9 Targeted real-time US was performed to examine the area of concern. Our breast US data sheet, completed at the time of examination, was used to record patient identification data, physical examination data, and sonographic impression. If a focal lesion was visualized, sonographic parameters, including lesion dimensions, echogenicity, shadowing, and margin characteristics were recorded.10-12 Focal lesions were further characterized as duct ectasia, simple cyst, complex cyst, fibroadenoma, indeterminate, or suspicious at the time of initial examination.

STATISTICAL ANALYSIS

Data were collected prospectively and were retrospectively analyzed after establishing a tissue diagnosis (n = 427) or a clinical diagnosis (n = 233) after a mean (± SE) follow-up of 8.4 ± 0.4 months. Differences between means were evaluated with the Student t test and differences between groups were evaluated using the χ² test and differences between groups were evaluated using the Student t test and differences between groups were evaluated using the χ² test. The SAS statistical software package (SAS Institute, Cary, NC) was used for all analyses. P values less than .05 were considered statistically significant.

Table 1. Patient Demographic Data

<table>
<thead>
<tr>
<th>Parameter</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Race*</td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>33 (7.4)</td>
</tr>
<tr>
<td>Black</td>
<td>14 (3.1)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>26 (5.9)</td>
</tr>
<tr>
<td>White</td>
<td>371 (83.6)</td>
</tr>
<tr>
<td>Menopausal status</td>
<td></td>
</tr>
<tr>
<td>Premenopausal</td>
<td>316 (48.2)</td>
</tr>
<tr>
<td>Postmenopausal</td>
<td>329 (50.3)</td>
</tr>
<tr>
<td>Male</td>
<td>8 (1.5)</td>
</tr>
<tr>
<td>Family history of breast cancer†</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>126 (26.1)</td>
</tr>
<tr>
<td>No</td>
<td>357 (73.9)</td>
</tr>
</tbody>
</table>

Table 2. Sonographic Impression of 338 Focal Complex or Solid Abnormalities

<table>
<thead>
<tr>
<th>Sonographic Impression</th>
<th>Palpable, No.</th>
<th>Nonpalpable, No.</th>
<th>Total, No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complex cyst</td>
<td>17</td>
<td>16</td>
<td>33 (10)</td>
</tr>
<tr>
<td>Fibroadenoma</td>
<td>62</td>
<td>14</td>
<td>76 (22)</td>
</tr>
<tr>
<td>Indeterminate</td>
<td>71</td>
<td>53</td>
<td>124 (37)</td>
</tr>
<tr>
<td>Suspicious</td>
<td>63</td>
<td>33</td>
<td>96 (28)</td>
</tr>
<tr>
<td>Other</td>
<td>5</td>
<td>4</td>
<td>9 (3)</td>
</tr>
<tr>
<td>Total</td>
<td>218</td>
<td>120</td>
<td>338 (100)</td>
</tr>
</tbody>
</table>

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US in 18 younger women who did not have a prior mammogram.

We further analyzed the group of 338 patients with focal complex or solid abnormalities found on US as summarized in Table 2. Among these patients, 114 (97%) of 118 lesions thought to be benign on ultrasonography proved to be benign, whereas 13 (12%) of 111 indeterminate and 72 (75%) of 96 sonographically suspicious lesions proved to be malignant. The cancers seen on ultrasonography included 15 cases with normal mammograms. Eighty-nine (86%) of the 104 cancers in this series of patients were visualized by ultrasonography and classified as either suspicious or indeterminate sonographic lesions, with the exception of 1 recurrent inflammatory breast cancer that had the sonographic appearance of widespread duct ectasia and 4 cases incorrectly classified as fibroadenomas. On review, the 4 false-negative cases represented 5% of the 76 lesions classified sonographically as fibroadenomas. Each of these cancers exhibited the characteristic ultrasonographic features of a fibroadenoma, including smooth margins, bilateral shadowing, hypoechogenicity, and a lateral-to-anteroposterior dimension ratio of 1 or greater.13 Eight (53%) of the 15 cancers not visualized by ultrasonography presented solely as mammographic microcalcifications and 1 patient had a normal mammogram. Only 3 of 11 cases of pure carcinoma in situ were visualized by ultrasonography. However, most of the cases of invasive cancer exhibited several sonographic characteristics associated with malignancy as summarized in Table 3.
Ultrasound-guided needle biopsy in the office accurately established the diagnosis in 46 (73%) of 73 nonpalpable benign lesions, with the remainder being nondiagnostic (13 cases), atypia (3 cases), or cancer (1 case). Among 32 nonpalpable malignant lesions, the diagnosis was accurately established in 20 (71%) of 28 cases in which US-guided needle biopsy was performed. The remaining cases included 3 specimens classified as benign breast tissue, 2 as fat necrosis, and 3 cases of atypia. Ultrasound-guided core needle biopsy accurately diagnosed 11 (100%) of 11 nonpalpable cancers in our series.

In conclusion, these data suggest that breast US is a useful adjunct to clinical and mammographic evaluation of breast disease. Breast US aids in guiding and assessing the completeness of cyst aspiration, helps distinguish benign from malignant breast masses, and facilitates office needle biopsy of nonpalpable abnormalities, thus permitting timely and cost-effective patient care.

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REFERENCES


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**DISCUSSION**

Joseph P. Crowe, Jr, MD, Cleveland, Ohio: Let me begin by putting this study into perspective. Several years ago this study would not have been done. Why? Surgeons did not do breast US, but the pathway for breast cancer diagnosis is changing quickly. Traditionally, surgeons were at the center of the diagnostic arena. We were the physicians who accepted the responsibility for either making or not making a timely breast cancer diagnosis. With advances in breast imaging and now with core biopsy sampling procedures, the radiologist is assuming a much greater role. This should not by itself constitute a problem and should theoretically enhance patient care if done in a multidisciplinary fashion that must include the surgeon, radiologist, pathologist, and patient. But in some communities, the surgeon is being bypassed entirely, leaving the patient somewhere between her primary care physician and the radiologist, neither of whom typically has the experience of the surgeon in clinical breast evaluation and follow-up. Surgeons have countered this trend by learning breast US and by performing image-guided core biopsy. This presentation is an excellent example of surgeons utilizing this additional technology in an office setting for the benefit of the patient.

I have several questions for the authors. First, fine-needle aspiration cytology of palpable breast masses is used routinely in the office. In your practice, where does fine-needle aspiration of palpable lesions fit in with respect to the US? Second, if I understand your numbers in the manuscript correctly, there are 15 false-negatives out of 104 cancers ultrasonographically and 4 of these look like fibroadenomas. Therefore, when would you not remove a solid lesion identified ultrasonographically?

Jay K. Harness, MD, Oakland, Calif: Later in this program there will be a paper on the learning curve of surgeons and US. I would like to ask the authors to describe the process they went through to learn breast US prior to utilizing it in their practice. Our experience in Oakland has been that surgeons are extremely quick learners of this technology. My assumption is that it was surgeons who performed the breast USs in your office. This is a really important difference between radiologists and surgeons in that radiologists utilize technicians to do these studies. As surgeons have a much greater clinical correlation than radiologists by performing our own US studies. It is also important to point out that breast US is not a screening tool. I would like to ask the authors to comment about their use of breast US as a part of their routine follow-up examinations.

Sylvia Ramos, MD, Albuquerque, NM: I have a very similar experience with over 800 office-based, diagnostic, breast USs in my practice. I want to find out 3 things from the authors. Do you have a protocol for the follow-up of patients in whom you do a fine-needle aspiration or a core biopsy in the office and do not go on to an open excisional biopsy? Have you noticed a decrease in the number of needle wire-guided biopsies that you do in the operating room because you are doing the US-guided fine-needle aspiration or core biopsies in the office? I have found that my accuracy using the US for even palpable lesions has increased markedly and that I get fewer nondiagnostic readings from my pathologists when I do a US-guided as opposed to a “blind” palpable fine-needle aspiration. What is the utility of the US for the palpable lesion?

Monica Morrow, MD, Chicago, Ill: You conclude that US is a cost-effective way of improving the patient workup. For your clinically evident lesions, the normal approach would be to do a fine-needle aspiration to establish a diagnosis for solid masses or to diagnose and treat cysts. How did US change your management? Did it cause you to biopsy anyone you would not have biopsied? Did it allow you to avoid other procedures, or was it simply an added cost in clinically evident cases?

Raymond Joehl, MD, Chicago: Breast US adds time and cost to the evaluation of these patients. How many of these US examinations were unnecessary? In your analysis of this series, how do you now select your patients for US, based on history, physical examination, and mammogram?

Robert Janes, Jr, MD, Fort Smith, Ariz: Our surgical group of 6 surgeons has experience with about 900 stereotaxic core needle biopsies that we have done since the equipment became available. The only comment I have is that now almost 70% of these abnormal mammographic lesions that need biopsy can be done by US so it is a significant part of breast practice that is changing just within the last couple of years and it is not regulated the same way as the stereotaxic biopsy, so the credentialing problems are not as great. I think breast US is something that is very important to surgeons.

Don M. Morris, MD, Albuquerque: How many patients were seen during the time period who did not have US? What were the indications that made you decide to get an US on a particular patient?

Dr Velasco: Dr Harness, after 3 or 4 months we felt comfortable with the technique, we stopped second-guessing ourselves, and began to chart patients so that their course could be followed from the beginning. We did not change the patients during those months.

Dr Crowe and Dr Ramos asked how US helps in the management of a palpable mass. It helps to define the mass better. All of us have experience with false-negative blind fine-needle aspiration. There were 3 patients who presented with ill-defined masses where fine-needle aspiration biopsy came back negative. Those 3 patients returned to the office a month later. Ultrasound detected an underlying mass and a directed biopsy was obtained. Ultrasound can measure the size of a lesion or detect multifocal tumors that otherwise would not have been seen.

Of the 15 false-negative USs that we had, 4 of them were fibroadenomas. In 11 of those patients, 50% presented as microcalcifications on mammogram. We know US of the breast is not optimal to visualize tumors that present as microcalcifications.
These findings correspond with the experience that has been published in the literature: up to 30% of patients with carcinomas that are 1 cm may be seen on US as fibroadenomas. One of the features that we did not find to be significant was the shape of the mass. Fibroadenomas had been reported to have a smooth margin and to have rounded shape. It has been reported that 50% of carcinomas, mistakenly seen as fibroadenomas will have elongated shape. So the conclusion is that a solid mass needs histologic confirmation after correlation with clinical and mammographic findings.

What is the use of US in our practice? Any abnormal mammogram, a focal lesion, an ill-defined lesion, or a palpable abnormality warrants an US. The reason for that is to further characterize the lesion, to try to avoid unnecessary open or image-guided biopsy, as well as to try to achieve the diagnosis. We have found that the number of stereotactic biopsies has gone down and our ability to obtain tissue via US has gone up.

Has the incidence of open biopsy increased? I cannot answer that. I think we do less negative open biopsies, that the yield is higher, but I have not reviewed the numbers to give you exact data.

Do we use it as a screening tool? Only in younger patients, not in older patients. Is it cost-efficient? An US is cheaper than stereotactic biopsy. The charges for US are much less than the charges from the radiology department. An US-directed biopsy after an examination is always more efficient and effective than a radiologist-directed one.

ARCHIVES OF INTERNAL MEDICINE

Screening for Colorectal Cancer: A Comparison of 3 Fecal Occult Blood Tests
Bernard Levin, MD; Kenneth Hess, PhD; Constance Johnson

Background: Colorectal cancer is the second leading cause of cancer deaths in the United States. Fecal occult blood testing has become a standard screening test for large-bowel cancers in the average asymptomatic population. Performance characteristics of the test and physician and participant compliance are the 2 major elements that impact the success of screening and early detection.

Objectives: To evaluate the nonhydrated Hemoccult, rehydrated Hemoccult, and Hemoccult SENSA tests (SmithKline Diagnostics Inc, Palo Alto, Calif) and to assess participant and physician compliance.

Methods: A mass community-based screening study in an urban setting. Kits were distributed by a local pharmacy and at community sites. Diagnostic tests were completed through physicians’ offices and clinics. Participants were asymptomatic and aged 30 years or older. Those who tested positive were advised to follow up with a physician.

Results: An overall positivity rate of 16% was reported for the 8293 kits that were processed. Rehydrated Hemoccult had a positivity rate of 13%; Hemoccult SENSA, 7%; and nonhydrated Hemoccult, 3%. The positive predictive value of nonhydrated Hemoccult was 14%; rehydrated Hemoccult, 7%; and Hemoccult SENSA, 11%. Of those who tested positive, 59% had a colonoscopy or flexible sigmoidoscopy and double-contrast barium enema examination on follow-up. Recommended follow-up was more frequent for those who consulted a gastroenterologist.

Conclusions: Rehydrated Hemoccult yielded a higher positivity rate and lower positive predictive value than either Hemoccult SENSA or nonhydrated Hemoccult. Hemoccult SENSA approached the positive predictive value of nonhydrated Hemoccult. Adequacy of follow-up of patients testing positive for fecal occult blood needs improvement. Arch Intern Med. 1997;157:970-976

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