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ORIGINAL ARTICLE

The negative predictive value of ultrasound-guided 14-gauge core needle biopsy of breast masses: a validation study of 339 cases

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Abstract

Purpose: To determine the negative predictive value of sonographically guided 14-gauge core needle biopsy of breast masses, with detailed analysis of any false-negative cases. **Materials and methods:** We reviewed 669 cases of sonographically guided 14-gauge core needle biopsies that had benign pathologic findings. Given a benign pathology on core biopsy, true-negatives had either benign pathology on surgical excision or at least 2 years of stable imaging and/or clinical follow-up; false-negatives had malignant histology on surgical excision. **Results**: Follow-up was available for 339 breast lesions; 117 were confirmed to be benign via surgical excision, and 220 were stable after 2 years or more of imaging or clinical follow-up (mean follow-up time 33.1 months, range 24–64 months). The negative predictive value was determined to be 99.4%. There were 2 false-negative cases, giving a false-negative rate of 0.1%. There was no delay in diagnosis in either case because the radiologist noted discordance between imaging and core biopsy pathology, and recommended surgical excision despite the benign core biopsy pathology. **Conclusions**: Sonographically guided 14-gauge core needle biopsy provides a high negative predictive value in assessing breast lesions. Radiologic/pathologic correlation should be performed to avoid delay in the diagnosis of carcinoma.

Keywords: *Core needle biopsy; breast neoplasms; ultrasonography; mammography; retrospective study.*

Introduction

A number of biopsy techniques are available for the diagnosis and management of breast lesions, including core needle biopsy (CNB), fine-needle aspiration biopsy, or open surgical biopsy. With the widespread implementation of screening mammography programs and subsequently the increased number of biopsies performed, continued assessment for safety and accuracy of all biopsy techniques in practice today is of great importance. Percutaneous image-guided CNB is currently the standard of care for the initial diagnosis of suspicious breast lesions[1,2]. It is less invasive, less time-consuming and less expensive than surgical excision, and causes minimal to no scarring.

Image-guided core biopsies may be done with ultrasound (US), stereotactic, or magnetic resonance imaging (MRI) guidance. Compared with the stereotactic and MRI techniques of NB, US guidance allows needle visualization in real time, increasing the accuracy of sampling[3]. This method is also less expensive, has a shorter procedure time, causes less patient discomfort, and does not involve ionizing radiation in comparison with stereotactic techniques[3–5]. US-guided CNB also has a much lower miss/false-negative rate (0–12%)[3,4,6–16] compared with clinically guided CNB (13%)[3,17]. It is preferable that CNB be carried out under some form of imaging guidance, regardless of which modality is used. Pijnappel et al.[18] have demonstrated that US-guided CNB has similar accuracy to needle-localized

open breast biopsy (NLBB), and is less traumatic and less costly.

Fine-needle aspiration (FNA) also has a potential role in the diagnosis and management of solid breast lesions, and had been demonstrated by Gordon et al.[19] to have a sensitivity of 95%, a specificity of 92%, and an overall accuracy of 93%. However, FNA has been replaced by CNB with few exceptions for many reasons. Most importantly, FNA biopsy even when accurate for malignancy, cannot distinguish between in situ and invasive disease.

The primary goal of our study was to determine the negative predictive value (NPV) of US-guided 14-gauge CNB. A secondary goal was to describe the false-negative cases in detail to determine the nature and causes of the missed diagnoses. In addition, we wanted to stress the importance of having a rigorous post-CNB follow-up protocol involving radiologic/pathologic correlation to minimize the occurrence of missed malignancies.

Materials and methods

The local Research Ethics Board was consulted before proceeding with the project and confirmed that the project falls under the category of quality assurance not requiring REB review/approval.

Patient population

Our practice (Vancouver Breast Center, British Columbia, Canada) offers screening mammograms for women according to the Screening Mammography Program (SMP) guidelines of British Columbia. Since its inception in 1988, our screening program has accepted self-referred women aged 40–79 years. The current recommendation is for women aged 40–49 years to attend annually, and women aged 50–79 years to attend at least every 2 years, but they may attend annually if they prefer. Women younger than 40 years who may be at higher risk for breast cancer can also be screened with physician's referral. Women aged 80 years and older are accepted with physician referral and assurance that the woman is in excellent health, with a life expectancy of at least 5–10 years. Our practice also offers imaging and if appropriate, biopsy, for palpable masses detected by breast self-examination or clinical breast examination.

Patients with abnormal findings on screening mammograms were invited back for further evaluation on mammography and/or US. US-guided 14-gauge CNB was offered for suspicious lesions (Breast Imaging Reporting and Data System (BI-RADS)[20] category 4) and lesions highly suggestive of malignancy (BI-RADS category 5) seen on US. From March 2005 to April 2011, 2055 US-guided 14-gauge CNBs of breast lesions were performed at our practice. Of these, 1386 had malignant histology and 669 had benign pathologic findings.

This retrospective study followed up on the 669 benign lesions in 640 patients during that period. We excluded 330 biopsies from this study group because a benign biopsy result was not proven by surgical biopsy and they did not yet have at least 2 years of imaging and/or clinical follow-up after the initial biopsy. Our final study cohort was comprised of 339 biopsies from 319 patients that were either excised surgically (119) or the patients have had at least 2 years of imaging and/or clinical follow-up (220).

The mean age for these 319 patients was 47.0 years (age range, 20–89 years; median, 45 years). Fifteen patients had biopsies of 2 separate lesions, 1 had biopsies of 3 separate lesions, and 1 had biopsies of 4 separate lesions. Lesion size was determined using the maximum lesion diameter on US.

Biopsy procedure

US-guided CNBs were performed using a free-hand technique and a high-resolution US unit with 10- or 12-MHz linear array transducers (SonixTouch; Ultrasonix Medical Corporation, Richmond, BC, Canada). After obtaining informed consent, procedures were performed in an outpatient setting using local anaesthesia. Patients were in the supine or supine-oblique position depending on the location of the lesion to optimize the procedure. An automated biopsy gun (Bard-Magnum; Bard Biopsy Systems, Tempe, AZ) and 14-gauge needles with a 22-mm needle throw were used. All biopsies were performed by 4 radiologists at our practice with a range of 8–37 years of clinical experience in breast imaging and biopsy, as well as a number of fellows. A mean of 3.98 core samples per lesion were routinely obtained (range, 2–8), with the number of cores taken from each patient determined by the radiologist at the time of the procedure. In general, the number of cores was determined by the apparent accuracy of the targeting (judged by the pre- and post-fire images), the amount of tissue obtained with each core, and whether the cores floated or sank in the formalin, which was an indication of whether the tissue was fat or non-fat.

Pathologic assessment

Core biopsies were fixed in formalin and processed according to a standard protocol.

Post-biopsy management

The radiologist who performed the biopsy was responsible for reviewing the final pathology report and the US images obtained before and during the procedure. Specific recommendations for the management of patients were made to the referring physicians in a supplementary report. For patients with lesions that were benign on both imaging and on CNB pathology, the recommendation was usually clinical follow-up with the referring physician for those lesions that were palpable, and continued screening mammography (if the patient was of an age eligible for screening). For patients with

Table 1　**False-negative diagnosis after US-guided 14-gauge CNB**

Patient age at CNB (years)	Characteristics on US	Size of lesion (mm)		BI-RADS category pre-core biopsy	No. of cores	Core biopsy pathology	Final diagnosis
		At initial biopsy	At surgical excision				
53	Irregular, hypoechoic, posterior acoustic shadowing	$11 \times 10 \times 8$	$11 \times 10 \times 8$	4C	6	Fibrous mastopathy	Invasive ductal carcinoma
50	Subtle, hypoechoic, posterior associated shadowing	$7 \times 9 \times 4$	$7 \times 9 \times 4$	4C	4	Fragments of dense tissue with a few dilated ducts	Invasive mammary carcinoma

lesions that were classified as suspicious for malignancy on imaging but had benign pathology on CNB (imaging/pathology discordance), surgical excision was recommended.

Patient follow-up

Follow-up data were obtained from repeat visits of patients to our practice or other imaging clinics, attendance at the provincial mammography screening program, or surgical excision data collected from the patient's primary care physician or surgeon.

Data analysis

True-negative cases were defined as lesions that had benign pathology on surgical excision, or at least 2 years of stable imaging and/or clinical follow-up.

Results

Findings on US and US-guided 14-gauge CNB

The mean size of 339 ultrasonographically visible breast lesions was 15.3 mm (median, 13 mm; range, 4–51 mm). One hundred and five (31.0%) of the 339 lesions had a diameter of 10 mm or less, and 234 (69.0%) of the lesions had a diameter greater than 10 mm. The average number of cores obtained per lesion was 3.98 (range, 2–8). There were 169 (49.9%) fibroadenomata and 119 (35.1%) non-specific benign lesions. The other lesions present in our study cohort included fat necrosis, sclerosing adenosis, papillary lesions, stromal fibrosis, fibrocystic changes, hamartoma and pseudoangiomatous stromal hyperplasia.

NPV of US-guided 14-gauge CNB

Of the 339 ultrasonographically visible breast lesions shown to be benign on CNB in 319 patients, 117 were confirmed to be benign via surgical excision, 209 were shown to be stable on ≥2 years of imaging follow-up (mean follow-up time 33.2 months, range 24–64 months), and 11 palpable masses were confirmed by the patient's primary health care professional to have not increased in size over at least 2 years of clinical

follow-up. The reasons for surgical excision of some lesions with benign findings on CNB pathology included imaging/pathology discordance, patient preference, anticipated pregnancy, and significant increase in size on follow-up imaging. The NPV of US-guided 14-gauge CNB was therefore 99.4% (337 of 339 cases).

There were 2 false-negative US-guided 14-gauge CNB cases. Therefore, of the 1388 lesions with a final diagnosis of cancer, 2 yielded benign findings on CNB, for a false-negative rate of 0.1% (2/1388). In both cases (Table 1), the radiologist noted discordance between imaging and core biopsy pathology, and recommended surgical excision.

When the imaging impression was considered in addition to the core biopsy histology, no cases of malignancy were delayed in diagnosis. Therefore, the effective NPV was 100% when radiologic/pathologic review was performed.

Discussion

The results of our retrospective study show that US-guided 14-gauge CNB has an NPV of 99.4% (337 of 339 cases). The false-negative rate of 0.1% is in the lower range of false-negative rates in previous studies in the literature (ranging from 0% to 12%, Table 2).

Two cases with benign CNB pathology were shown to be invasive carcinomas on surgical excision. In the first case, the finding was an $11 \times 10 \times 8$ mm irregular hypoechoic mass with angular margins, anti-parallel orientation and posterior acoustic shadowing (Fig. 1a). This corresponded to a 1-cm spiculated mass noted on a screening mammogram (Fig. 1d,e), and confirmed with magnification views (Fig. 1f,g). It had been assigned a BI-RADS category of 4C. Six 14-gauge core specimens were obtained and targeting appeared accurate based on the pre- and post-fire films (Fig. 1b,c), and a clip marker was placed. Pathology was reported as fibrous mastopathy. The radiologist noted the discordance between imaging and CNB pathology and recommended surgical excision, which confirmed this lesion to be an invasive ductal carcinoma. Surgical histology was invasive carcinoma, and demonstrated a focal area of fat necrosis and the clip placed during the US-guided core biopsy, indicating

Table 2 **False-negative rates of US-guided CNB in various studies**

Study	Year	Number (%) of false-negatives
Parker et al.[6]	1993	0 (0)
Liberman et al.[4]	1998	0 (0)
Yeow et al.[7]	2001	0 (0)
Smith et al.[8]	2001	0 (0)
Schoonjans et al.[9]	2001	0 (0)
Buchberger et al.[10]	2002	3 (1.3)
Schueller et al.[11]	2008	11 (1.6)
Dillon et al.[3]	2005	13 (1.7)
Youk et al.[12]	2008	31 (2.4)
Memarsadeghi et al.[13]	2003	5 (3.1)
Crystal et al.[14]	2005	12 (3.7)
Sauer et al.[15]	2005	24 (3.9)
Hatada et al.[16]	2000	7 (12.1)
Current study	2011	2 (0.1)

that the surgeon had excised the same mass that was biopsied.

In the second case, the mass biopsied under sonographic guidance was irregular and hypoechoic, anti-parallel in orientation and with posterior acoustic shadowing (Fig. 2a). It measured $7 \times 9 \times 4$ mm. It was originally detected as an area of architectural distortion on the screening mammogram (Fig. 2d,e), and confirmed with magnification views (Fig. 2f). A BI-RADS category of 4C was assigned. Four cores were obtained at the time of the biopsy. Targeting appeared accurate based on the pre- and post-fire images (Fig. 2b,c). The pathology of the core biopsy showed fragments of dense tissue with a few dilated ducts. Discordance with the imaging findings was noted, and surgical excision was recommended with the final pathology confirmed to be invasive mammary carcinoma. Again, both the metal clip placed during the core biopsy procedure and the fine wire placed before surgery were present in the surgical specimen.

Prompt recognition of imaging/pathology discordance prevented a delay in the diagnosis of both carcinomas in this study.

The most likely reason for CNB to miss a carcinoma, especially when it is small, is the needle being deflected off rather than piercing the mass as it advances. To avoid this phenomenon, some radiologists choose to use a vacuum needle to biopsy small masses[21]. In both of our cases, the needle looked well positioned on the post-fire images (Fig. 1c and 2c) but this can occur artifactually, even when the needle is adjacent to the mass, due to volume averaging[22]. To ensure that cancer had not been overlooked by the pathologist, both false-negative cases were reviewed by the lead pathologist for the screening program. One showed dense sclerotic breast tissue and atrophic ducts and neither showed evidence of mass, calcifications, atypia, or malignancy.

In response to Shah et al.'s[17] study analyzing reasons for 27 cases of missed breast cancers, Verkooijen et al.[23] emphasized that false-negative CNBs can

never be completely avoided. Some cases were considered unavoidable even after thorough review. However, CNB has been shown to miss a low proportion of carcinomas[3,4,6–16]. It is essential that radiologic/pathologic review be conducted for each core biopsy to prevent delay in the diagnosis of cancer when the needle biopsy is false-negative.

Shah et al.[17] stated that a benign diagnosis in a CNB of a breast lesion that had suspicious features on clinical and/or radiological examination is often due to a non-representative sample. Delay in diagnosis and treatment can be avoided by establishing a standard post-CNB follow-up protocol[17]. This method allowed prompt diagnosis of 2 invasive carcinomas in this study that might have been missed had the CNB pathology not been correlated with the imaging impression. Schueller et al.[11] also recommended surgical excision for all cases in which the histologic findings do not explain the imaging features. Ideally, radiologists should provide adequate clinical and/or radiologic findings to pathologists when submitting the samples, but this is not always done[24].

The National Health Service Breast Screening Programme, a large-scale population screening program in the United Kingdom, mandate multidisciplinary team (MDT) discussion of biopsies performed on screening assessment of patients[25]. The MDT consists of specialist breast cancer surgeons, pathologists, oncologists, radiologists, specialist nurses, and coordinators who hold regular weekly formal meetings. In addition to facilitating direct conversation between the radiologist and pathologist regarding biopsy results, the MDT formulates individualized treatment plans for every patient[25]. The MDT works according to evidence-based guidelines, and audits its clinical activity and reports results at regular intervals[25]. The introduction of multidisciplinary care for the treatment of breast cancer has been shown to reduce breast cancer mortality by 18% and all-cause mortality by 11% at 5 years[25].

Our screening program, located in British Columbia, Canada, is more similar to others in North America, and unlike those in Europe and the United Kingdom. It maintains quality control on the screening process, but only collects data on the diagnostic process. Women with abnormal screens are referred at the discretion of their family physician to a diagnostic facility, which may be office or hospital based. The diagnostic radiologist then determines what tests (mammogram, US, or both) to perform, and whether core biopsy is required. When core biopsy is performed, it is the responsibility of the radiologist to review the radiologic/pathologic correlation and issue final recommendations regarding patient care. Multidisciplinary review is performed at some facilities, usually for stereotactic core biopsies, but that would be the exception. The screening program then collects all outcome data, including if any of these patients are subsequently diagnosed with cancer.
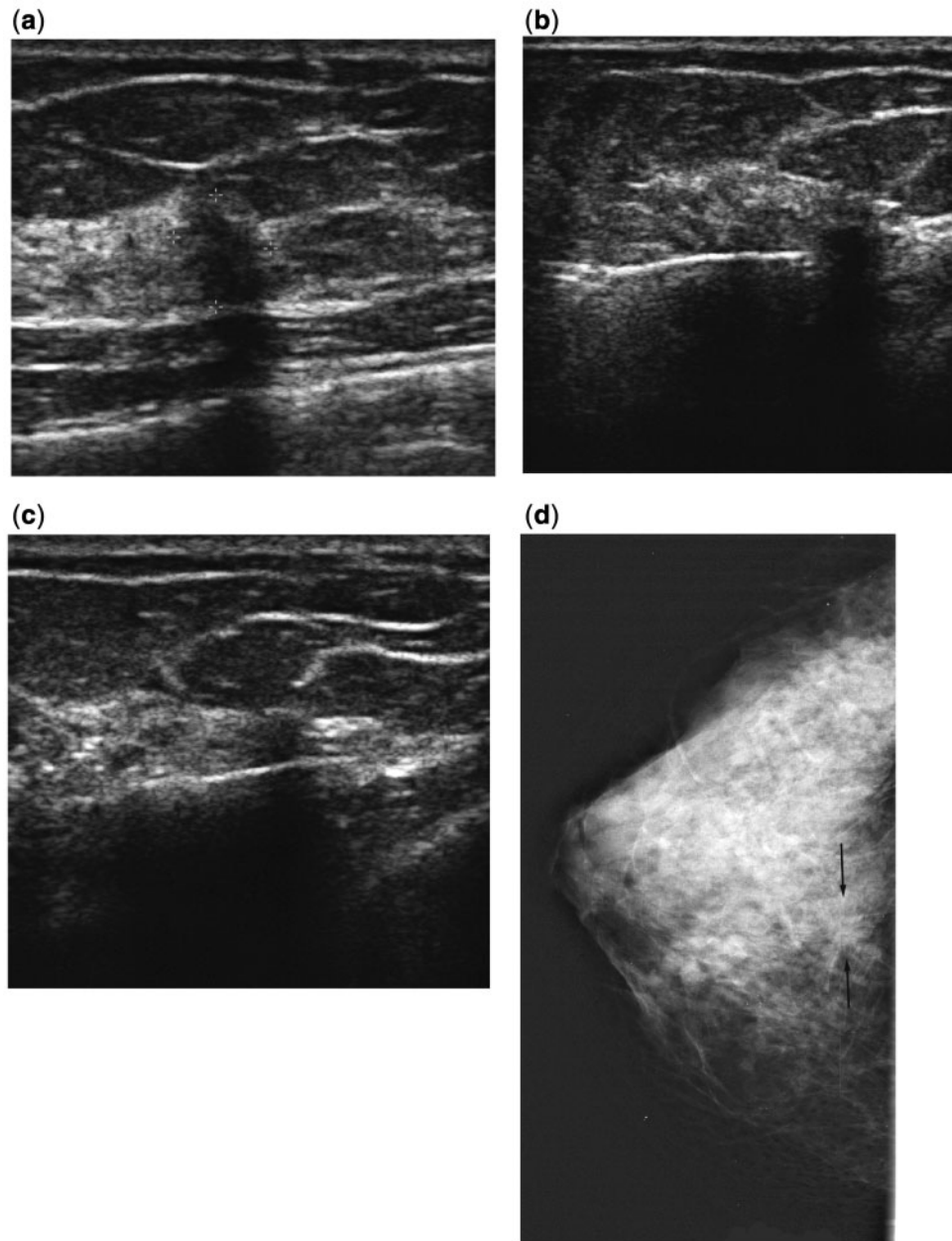
Figure 1   Transverse US image (a) of the 11 × 10 × 8 mm irregular hypoechoic mass, with angular margins, anti-parallel orientation and posterior acoustic shadowing. The pre- and post-fire images show the 14-gauge needle adjacent to (b) and appearing to skewer the mass (c). Craniocaudal (d) and mediolateral oblique (e) views on the screening mammogram show heterogeneous dense tissue with architectural distortion (black lines), confirmed with right craniocaudal spot magnification (f) and right mediolateral oblique spot magnification views (g).

Discordant lesions (BI-RADS category of 4 or 5 on imaging, with benign pathology on CNB) have been shown to have malignancy rates of up to 50%[26]. Youk et al.[27] suggested that radiologists should immediately contact the interpreting pathologist to have a thorough discussion regarding the lesion. A surgical biopsy should be recommended at this stage[27]. Vacuum-assisted needle biopsy may be considered as an alternative option to surgical excision to obtain a definitive pathologic diagnosis for discordant lesions[28]. However, if there is persistent discordance after vacuum biopsy, then surgical excision is appropriate.

For patients with lesions that were probably benign or of low suspicion on imaging, and benign on CNB pathology (i.e. imaging and CNB pathology concordance), routine clinical and imaging follow-up should be sufficient. Youk et al.[27] recommended a follow-up sonogram 6 months after biopsy and then annually for at least
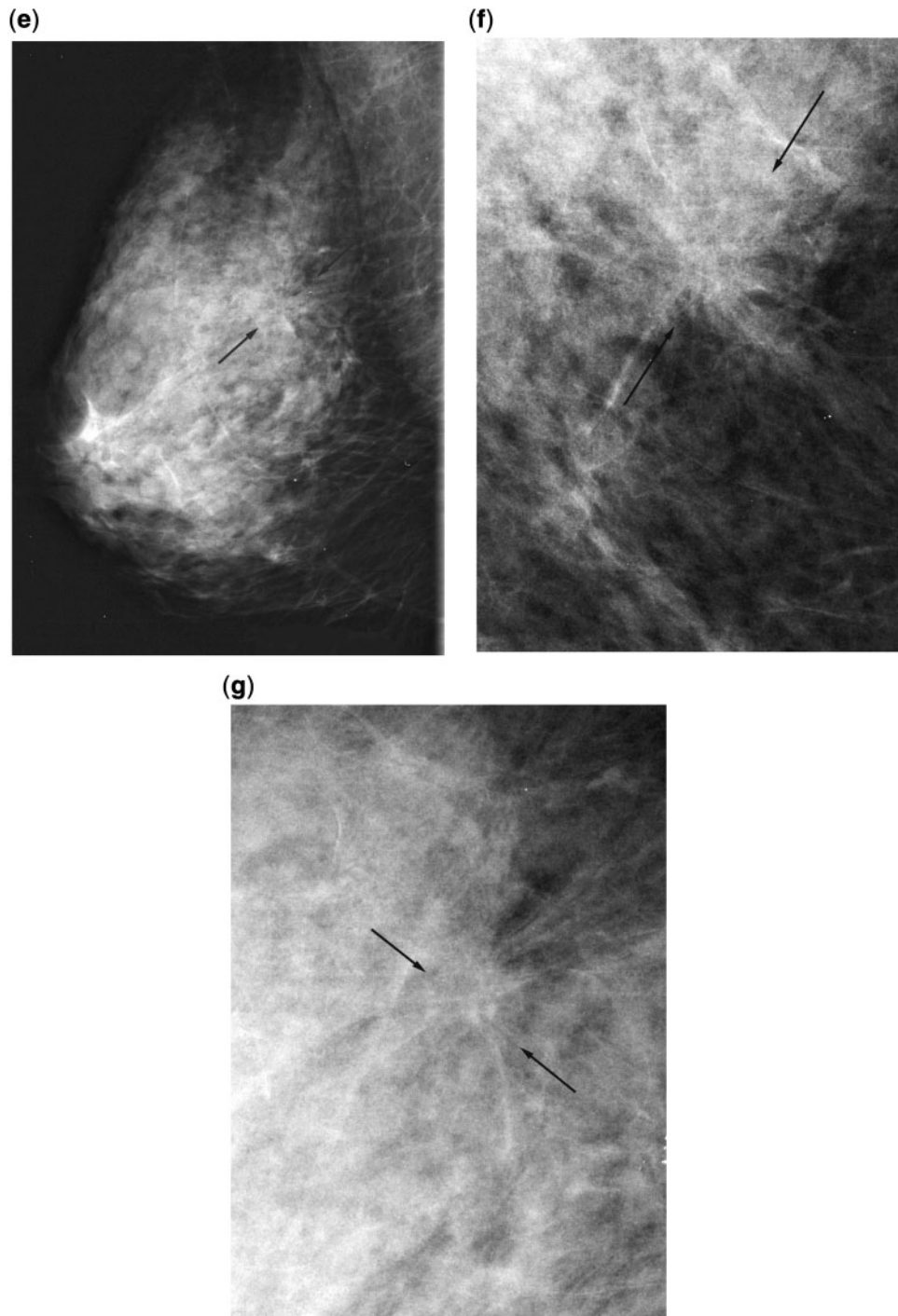
(e)

(f)

(g)

Figure 1 **Continued.**

2 years for these cases. Given our results, imaging follow-up for 2 years for all cases may be excessive, especially in cases where the lesion is palpable and can be followed up clinically. For mammographically visible masses found on screening, additional US would be redundant as they will be seen on subsequent exams. However, each practice, and ideally each radiologist, should audit their own results.

In this study, an average of 3.98 cores was obtained for each lesion undergoing CNB (range, 2–8). A previous study by Fishman et al.[29] demonstrated that a minimum of 4 cores are necessary to minimize the chance of missing a diagnosis of malignancy; cells indicating the final diagnosis were contained in the third core specimen in 96% of cases. A prospective study by Bolivar et al.[30] showed diagnostic yield with 1, 2, 3, and 4 specimens per
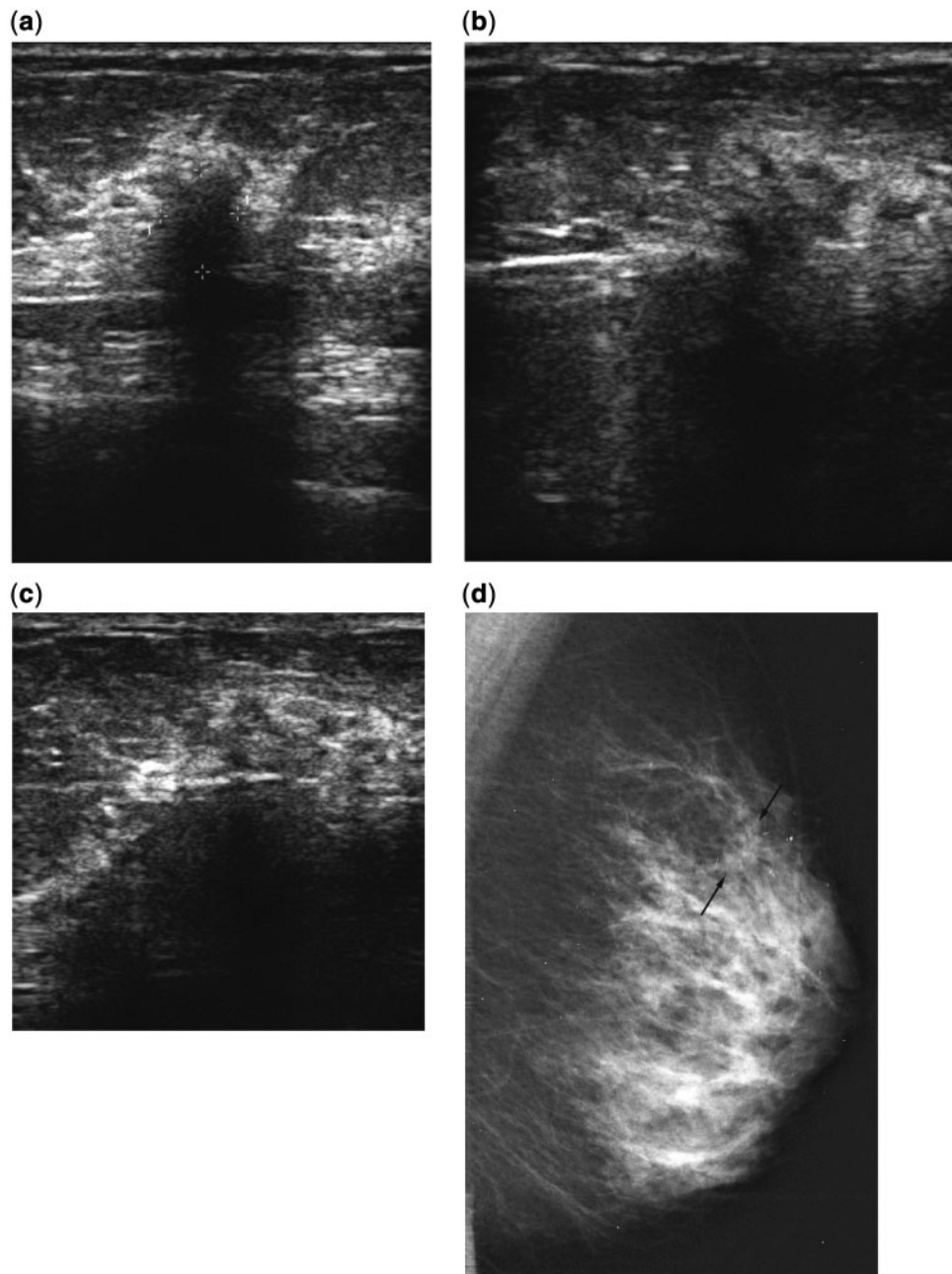
Figure 2 **Transverse US image (a) of the 7 × 9 × 4 mm ill-defined, irregular, and hypoechoic mass, with anti-parallel orientation and posterior acoustic shadowing. The pre- and post-fire images show the 14-gauge needle adjacent to (b) and appearing to skewer the mass (c). Mediolateral oblique (d) and craniocaudal (e) views on the screening mammogram show heterogeneously dense tissue and subtle architectural distortion (arrows). Craniocaudal magnification view (f) confirmed the subtle architectural distortion.**

lesion to be 73.5%, 88%, 95% and 97.5%, respectively, leading to their conclusion that a minimum number of 3 cores should be taken per lesion to achieve a high diagnostic yield. In our practice, we do not obtain a fixed number of cores for every patient; we consider the accuracy of targeting, estimated from pre- and post-fire images and the size of the core specimens, and whether they sink or float in formalin (an indication of whether they are fat or non-fat tissue) when deciding how many specimens to obtain. Six cores were obtained in our first false-negative case and 4 in the second.

There are certain limitations to our study. The cases included in this study were not consecutive. Benign biopsy results that were not proven by surgical biopsy and did not have at least 2 years of imaging and/or clinical follow-up after the initial biopsy were excluded.
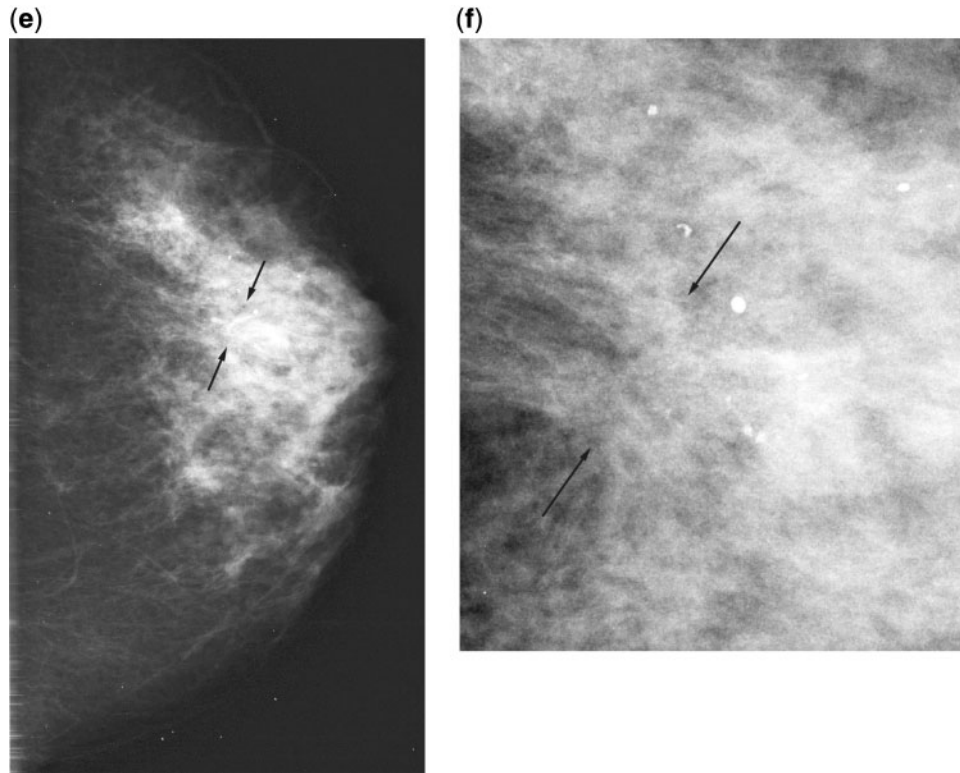
Figure 2 **Continued.**

Therefore, a selection bias may exist, and it is theoretically possible that there were additional false-negative diagnoses in the excluded cases. Another limitation is that for 11 patients, only clinical follow-up by the referring physician was available, which is arguably less precise and objective than a measurement made on an imaging study. However, the NPV would remain unchanged if these cases were not included (326/328, 99.4%).

Results from our validation study confirm that US-guided 14-gauge CNB is safe and accurate, and is a time-saving and cost-effective alternative to surgical biopsy. Data from our investigation, in which core biopsies were performed both by radiologists with extensive clinical experience in breast imaging and biopsy as well as fellows, should provide further confidence to health authorities and patients with regard to the role of US-guided 14-gauge CNB in the diagnosis and management of breast lesions. US-guided 14-gauge CNB provides a high NPV in assessing breast lesions and radiologic/pathologic correlation should be performed to avoid delay in the diagnosis of carcinoma.

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