

Focal Fibrosis of the Breast Diagnosed by a Sonographically Guided Core Biopsy of Nonpalpable Lesions

Imaging Findings and Clinical Relevance

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Objective. The purpose of this study was to evaluate the frequency of focal fibrosis of the breast diagnosed by a sonographically guided core biopsy of nonpalpable lesions, to characterize imaging features, and to evaluate their clinical relevance. **Methods.** In a retrospective review of 724 lesions that underwent sonographically guided core biopsy of nonpalpable breast lesions, 62 cases had a diagnosis of focal fibrosis. Two radiologists analyzed the sonographic and mammographic findings according to the Breast Imaging Reporting and Data System. The results were compared with histologic findings at surgery or imaging findings during surveillance. **Results.** The incidence of focal fibrosis was 8.6% (62/724). Sonographic films were available in 56 cases, so 56 cases were reviewed for their sonographic findings. Among the mammograms reviewed, 64.7% (33/51) had negative findings. Among the sonograms reviewed, the most common features were oval shape (32/56, 57.1%), parallel orientation (36/56, 64.3%), microlobulated margin (24/56, 42.9%), abrupt interface (50/56, 89.3%), isoechoic pattern (42/56, 75.0%), and a lack of posterior acoustic features (45/56, 80.4%). The Breast Imaging Reporting and Data System final assessment was category 3 in 27 (48.2%) and category 4 in 29 (51.8%). Most of the category 4 lesions were category 4A (26/29, 89.7%). Surgical excision (n = 7) and follow-up for at least 1 year (n = 49) showed no malignancy. **Conclusions.** Focal fibrosis was found in 8.6% by a sonographically guided core biopsy of nonpalpable breast lesions. Most of the lesions were categorized as probably benign (category 3) or having a low suggestion of malignancy (category 4A). Focal fibrosis diagnosed at core biopsy can be managed with a 6-month follow-up protocol. **Key words:** breast abnormalities; breast biopsy; fibrous nodule; sonography.

Abbreviations

BI-RADS, Breast Imaging Reporting and Data System

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Focal fibrosis of the breast is a histopathologic entity characterized by proliferation of the stromal connective tissue with obliteration of the mammary ducts and lobules.¹ It has been described by a variety of terms, including focal fibrosis, stromal fibrosis, focal fibrous disease of the breast, fibrous mastopathy, fibrous tumor of the breast, and chronic indurative mastitis.^{1,2} It has become a common diagnosis after a core needle biopsy of the clinically occult, mammographically or sonographically detected breast lesions. The incidence of focal fibrosis was reported to be 3.6% to 8.2% of lesions that underwent an imaging-guided core biopsy.²⁻⁷ Focal fibrosis has been described as having variable mammographic and sonographic features. Recent stud-

ies reported that many of them were presented as well-defined benign-looking masses on a sonographic examination, but sonographic evaluation using the Breast Imaging Reporting and Data System (BI-RADS) has not been reported. To our knowledge, imaging findings and clinical relevance of nonpalpable focal fibrosis diagnosed by sonographically guided biopsy have not been reported.

We conducted a retrospective review of records to evaluate the frequency of focal fibrosis of the breast diagnosed by a sonographically guided core biopsy of nonpalpable lesions, to characterize the sonographic features of focal fibrosis according to BI-RADS, and to evaluate its clinical relevance.

Materials and Methods

We retrospectively reviewed the pathologic reports of 724 cases of sonographically guided core biopsies of nonpalpable breast lesions performed from March 2001 to December 2002. Focal fibrosis was the diagnosis in 70 cases. Among these cases, the patients with a previous surgical biopsy at the site were excluded because a surgical scar usually shows only fibrosis on pathologic examination. One pathologist reviewed the pathologic slides, and our study included 62 lesions in 60 patients with the diagnosis of only focal fibrosis without evidence of diabetic mastopathy, fibromatosis, or other stromal lesions. The mean age of the patients was 47 years (range, 21–73 years). None of the patients had diabetes. Six patients had a history of breast cancer (5 contralateral and 1 ipsilateral), and 4 had a family history of breast cancer.

All of the sonographic examinations were performed by 3 radiologists specializing in sonography of the breast using either an HDI 3000 or HDI 5000 system (Philips Medical Systems, Bothell, WA) and electronically focused near-field probes with a bandwidth of 5 to 10 or 5 to 12 MHz. The examiner knew the results of clinical examination and mammography at the time of the sonographic examination.

We reviewed the sonographic findings, including size, shape, orientation, margin, lesion boundary, echogenicity, and posterior acoustic changes of the nodules according to BI-RADS.⁸ The size of the lesions was measured in the long diameter on the sonogram. Other classifications included the shape (oval, round, or irregular),

margin (circumscribed, indistinct, angular, or microlobulated or spiculated), lesion's boundary (abrupt interface or echogenic halo), and echogenicity of the nodule (anechoic, hypoechoic, isoechoic, or hyperechoic compared with echogenicity of subcutaneous fat). The posterior acoustic phenomenon associated with the nodule was divided into 3 categories: no acoustic change, posterior acoustic enhancement, and posterior shadowing. Orientation of the nodule was classified as parallel or not parallel.

Mammograms were available in 51 cases. Mammography in 2 standard imaging planes (mediolateral oblique and craniocaudal) was performed with dedicated equipment (Senographe DMR; GE Healthcare, Milwaukee, WI). The mammographic findings were classified as having no abnormality, mass, mass with calcification, asymmetric density, calcification only, or architectural distortion. In cases of a mass, the findings were further divided by shape, border, and density. Mass shape was described as round, oval, lobular, or irregular. Mass margin was characterized as circumscribed, microlobulated, obscured, indistinct, or spiculated; and lesion density was categorized as high, equal, or low relative to that of the breast parenchyma. The final assessment was made by the 6-category system according to BI-RADS.⁸

The BI-RADS category is shown in Table 1, and it was assigned as follows: BI-RADS category 1 for normal; BI-RADS category 2 for lesions classified as benign; BI-RADS category 3 for lesions classified as probably benign; BI-RADS category 4 for lesions classified as suggestive; BI-RADS category 5 for lesions classified as highly suggestive of malignancy; and BI-RADS 6 for known malignancy. Category 4 was subdivided further as follows: category 4A for those with a low suggestion of malignancy, category 4B for intermediate concern of malignancy, and category 4C for moderate suggestion but not classic for malignancy. When the breast sonographic examination was performed with mammography, a single final assessment was made, which reflected the combined mammographic and sonographic findings.

The sonograms and mammograms were independently and retrospectively reviewed by 2 experienced radiologists. Both films were reviewed together for each patient. Any discrepancy was resolved by consensus.

All biopsy procedures were performed by dedicated breast-imaging radiologists using a freehand technique with a 14-gauge Tru-Cut

automated core biopsy needle and a spring-loaded biopsy gun (Promac 2.2; Manan Medical Products, Wheeling, IL) under sonographic guidance. At least 5 samples were obtained (mean, 6; range, 5–8).

Follow-up data were also analyzed, including after surgical excision ($n = 7$) and after imaging studies ($n = 49$).

Results

Focal fibrosis was diagnosed in 62 cases (8.6%) of 724 sonographically guided core biopsies. The mean size of the lesions was 9.4 mm with a range of 4–22 mm.

Sonographic films were available in 56 cases (summarized in Table 2). All lesions were represented as a mass on sonographic examination. The shape of the nodule was oval in 32 cases (57.1%; Figures 1 and 2), and in 24 cases (42.9%), it was round or irregular (Figures 3 and 4). In 36 cases (64.3%), the nodules were parallel oriented, whereas in the remaining 20 cases, the nodules were not parallel. The margin was not circumscribed in 36 cases (64.3%), including a microlobulated margin in 24 cases (42.9%; Figure 3), an indistinct margin in 9, and an angular or a spiculated margin in 3. The remaining 20 cases (35.7%) had a circumscribed margin. Fifty cases (89.3%) had an abrupt interface of the lesion boundary. Most of the lesions showed either an isoechoic or a hypoechoic (54/56, 96.4%; Figures 1–4) echo pattern to the subcutaneous fat. Eighteen cases (14.3%) showed posterior shadowing (Figure 4).

Mammographic findings are shown in Table 3. Eighteen cases (35.3%) had positive findings on the mammogram, but 33 cases (64.7%) had negative findings. These 33 lesions were detected only in the sonographic examination of mammographically dense breast ($n = 29$) and in a part of the breast separate from the palpable mass during the evaluation of palpable masses ($n = 4$). Mammographic findings included a mass with or without calcifications in 14 (27.4%), asymmetry in 2 (3.9%), and architectural distortion in 2 (3.9%; Figure 5). In the cases of masses identified on mammography ($n = 14$), the masses were round in 8, oval in 2, and lobular in 1 (Figure 1). The margin of the masses was circumscribed in 4, microlobulated in 2, obscured in 6, and indistinct in 2. The density was isodense in 10 and high in 4.

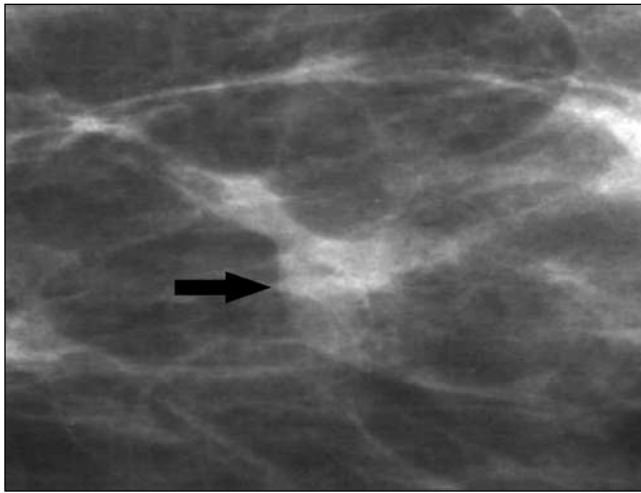
Table 1. Final Assessment Category by BI-RADS

Final Assessment Category	Definition
Category 1	Normal
Category 2	Benign
Category 3	Probably benign
Category 4	Suggestive
4A	Low suggestion of malignancy
4B	Intermediated concern of malignancy
4C	Moderate suggestion but not classic for malignancy
Category 5	Highly suggestive of malignancy
Category 6	Known malignancy

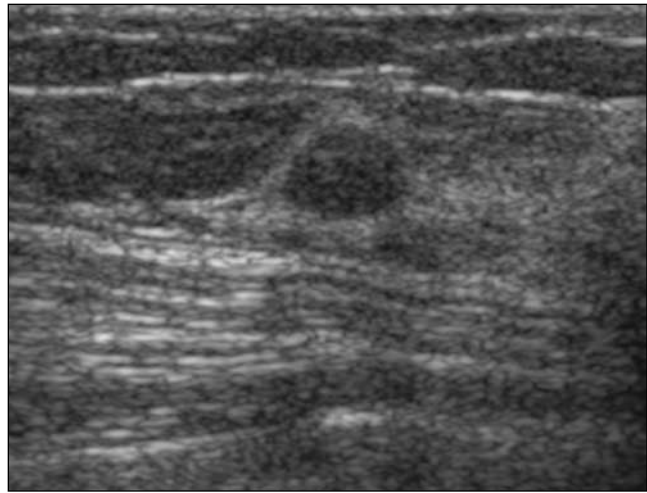
Twenty-seven (48.2%) lesions were classified as category 3 (Figure 1), and 29 (51.8%) lesions were classified as category 4 (Table 4). Most of the category 4 lesions were category 4A (26/29, 89.7%; Figures 2 and 3). Of 56 cases, 7 (12.5%) underwent excisional biopsy. The reasons for excisional biopsy were imaging-pathologic discordance ($n = 3$; Figures 4 and 5) and physician or patient desire ($n = 4$). The surgical results were all benign. This information is summarized in Table 5.

Table 2. Sonographic Findings of Focal Fibrosis Diagnosed by Sonographically Guided Core Biopsy ($n = 56$)

Sonographic Findings	Cases (%)
Shape	
Oval	32 (57.1)
Round	16 (28.6)
Irregular	8 (14.3)
Orientation	
Parallel	36 (64.3)
Nonparallel	20 (35.7)
Margin	
Circumscribed	20 (35.7)
Not circumscribed	
Indistinct	9 (16.1)
Angular	2 (3.6)
Microlobulated	24 (42.9)
Spiculated	1 (1.8)
Lesion boundary	
Abrupt interface	50 (89.3)
Echogenic halo	6 (10.7)
Echo pattern	
Hyperechoic	1 (1.8)
Isoechoic	42 (75.0)
Hypoechoic	12 (21.4)
Complex	1 (1.8)
Posterior features	
None	45 (80.4)
Enhancement	3 (5.4)
Shadowing	8 (14.3)



A



B

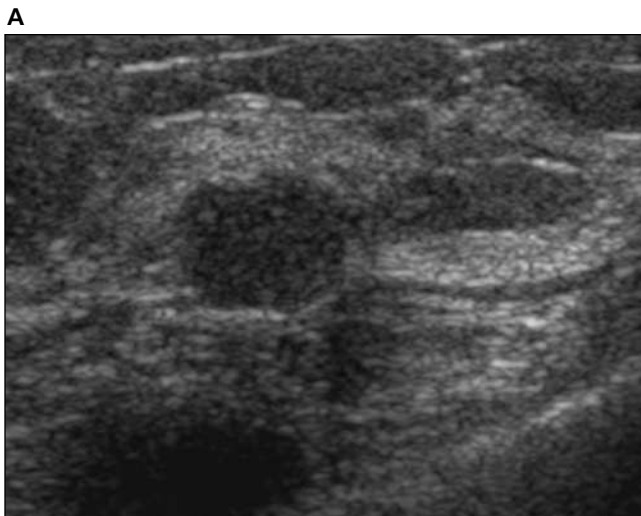
Figure 1. Focal fibrosis in a 42-year-old woman. A mammogram (**A**) reveals an oval isodense nodule (arrow) with an indistinct margin. A transverse sonogram (**B**) reveals an oval, circumscribed, isoechoic nodule with a parallel orientation. The diagnosis of the core biopsy was focal fibrosis. The lesion did not change during 36-month imaging follow-up.

The remaining 49 cases were followed by sonography and mammography for an average of 20 months (range, 12–38 months) of follow-up, including 39 cases (79.6%) of at least 2 years. The follow-up sonographic examinations were done in 6-month intervals for 2 years, and mammography was done yearly. Thirty-four (69.4%) cases showed no interval change of size on follow-up, and 15 cases (30.6%) showed a decrease in size.

Discussion

Recently, several articles about focal fibrosis have been published. This might be due to the commonly used imaging-guided biopsy,²⁻⁶ but focal fibrosis diagnosed solely by sonographically guided biopsy has not been reported yet. Interestingly, 33 (64.7%) of 51 women who underwent mammography had a negative result in our study. The fibrosis was incidentally found

Figure 2. Focal fibrosis in a 41-year-old woman. A mammogram (not shown) revealed heterogeneously dense breasts without remarkable findings. Transverse (**A**) and longitudinal (**B**) sonograms reveal an oval, hypoechoic nodule with a parallel orientation. The lesion has indistinct margins, especially on the lateral side. We suggested it was a category 4A lesion, and focal fibrosis was diagnosed by a sonographically guided core biopsy. The lesion did not change during 32 months.



A



B

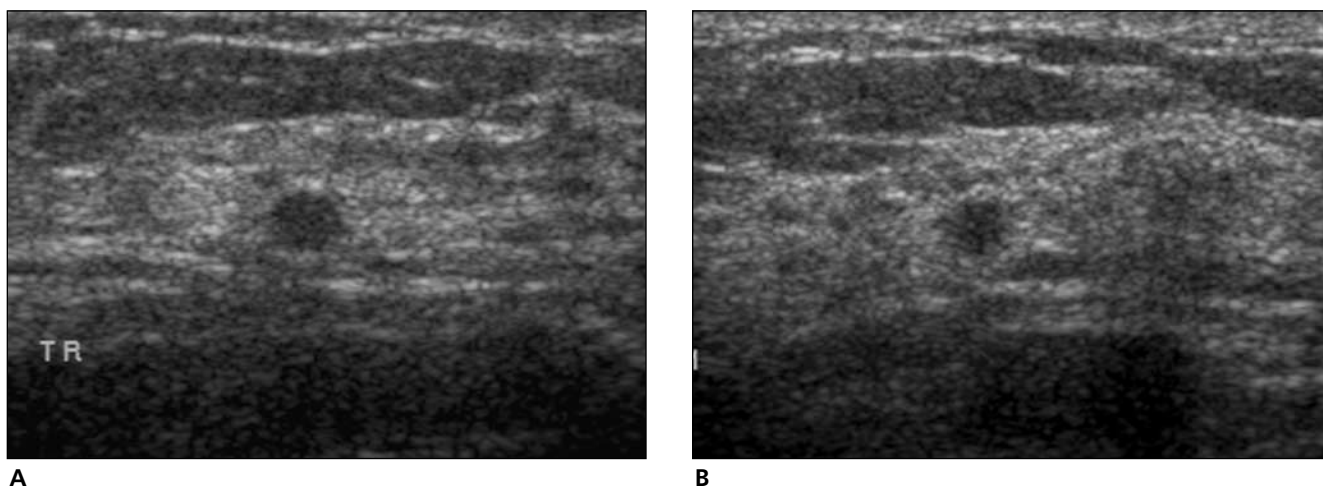


Figure 3. Focal fibrosis in a 48-year-old woman. A mammogram (not shown) revealed a heterogeneously dense breast without remarkable findings. The patient had a history of contralateral breast carcinoma 2 years previously. Transverse (**A**) and longitudinal (**B**) sonograms reveal a round, isoechoic nodule with a microlobulated margin. We suggested it was a category 4A lesion, and focal fibrosis was diagnosed by a sonographically guided core biopsy. The lesion was diminished in size on follow-up sonographic examination after 26 months.

during the sonographic examination of mammographically dense breasts or during the examination of palpable masses. Several articles about the sonographic examination of mammographically dense breasts have been published.⁹⁻¹⁵ In 1 study, 21 sonographically guided core needle biopsies (1.4%) were performed in 1517 women with breast tissue density designated as BI-RADS density categories 2, 3, and 4.¹⁴ Among these, 14 had benign results, and the diagnosis of 3 (21.4%) of 14 was fibrosis. Their sonographic

findings, however, were not described. We can project that the full-scale sonographic examination would show more nonspecific suggestive nodules and increase focal fibrosis diagnosed by a sonographically guided core biopsy.

The incidence of focal fibrosis was found to be about 3.6% to 8.2% of lesions in patients who underwent an imaging-guided core biopsy.²⁻⁶ In our study, the incidence was relatively high (8.6%). We suggest it is partly because our study population was a homogeneous group, which

Figure 4. Focal fibrosis in a 41-year-old woman. A left mediolateral oblique mammogram (**A**) reveals architectural distortion in the upper outer breast (arrow). A transverse sonogram (**B**) of the same area reveals an irregularly shaped and spiculated mass with an echogenic halo (arrows), highly suggestive of a malignancy (category 4C). The core biopsy revealed focal fibrosis. Excisional biopsy revealed fibrosis.

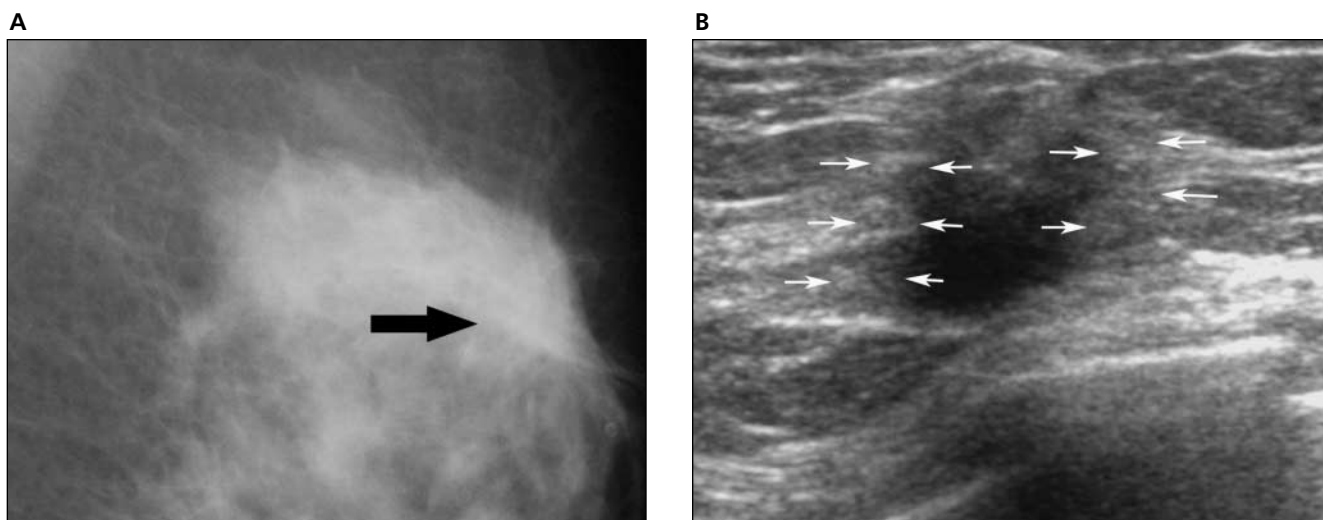


Table 3. Mammographic Findings of Focal Fibrosis (n = 51)

Mammographic Findings	Cases (%)
Negative	33 (64.7)
Mass without calcifications	12 (23.5)
Mass with calcifications	2 (3.9)
Asymmetry	2 (3.9)
Architectural distortion	2 (3.9)
Total	51 (100)

Table 4. Final Assessment According to BI-RADS (n = 56)

Final Assessment Category	Cases (%)
Category 3	27 (48.2)
Category 4	29 (51.8)
4A	26 (46.4)
4B	2 (3.6)
4C	1 (1.8)

was confirmed by sonographically guided biopsy of nonpalpable lesions, in contrast to another study, which included a sonographically guided core biopsy as well as a stereotactic biopsy or surgical excision.²⁻⁷ In addition to this, focal fibrosis is frequently shown as a mass on sonographic examinations, so this is more frequently diagnosed by a sonographically guided core biopsy than by a stereotactic biopsy, which frequently targets microcalcifications rather than masses.

Imaging findings of focal fibrosis that have been reported are nonspecific and variable.²⁻⁷ Most of them may be present with well-circumscribed benign-appearing masses and are suitable for a follow-up protocol, but some cases of focal fibrosis have a suggestive finding of an irregularly shaped, not circumscribed or parallel-oriented, hypoechoic mass with posterior shadowing.²⁻⁷ However, in our study, 51.8% of the cases of focal fibrosis were categorized as 4 (suggestive of malignancy) and needed biopsy, but most of them were category 4A lesions, so we could regard the benign biopsy results as a concordant finding. Sklair-Levy et al⁵ evaluated the imaging findings of 64 cases of focal fibrosis, including 26 palpable lesions. They found that only 25% of focal fibrosis had a combination of sonographically suggestive findings. They evaluated the sonographic findings according to the criteria of Stavros et al,¹⁶ but they did not regard the irregular margin as a suggestive finding. An irregular margin, including the suggestive classification, would have raised the rate to at least 40.6% (26/64). In addition, they reported that 90.6% (58/64) of focal fibrosis were hypoechoic, but in our study, 75% (42/56) were isoechoic, and only 21.4% (12/56) were hypoechoic. We suggest that it is noteworthy that our study only included nonpalpable lesions (mean size of mass, 9.4 mm; theirs, 19 mm). Posterior features were also different. In our study, 14.3% (8/56)

Figure 5. Focal fibrosis in a 35-year-old woman. The patient had a lump in her right breast, which turned out to be fibroadenoma. A nonpalpable lesion was found during the examination of her palpable breast mass. Transverse (A) and longitudinal (B) sonograms reveal an irregularly shaped, hypoechoic nodule with an angular margin (category 4B). The lesion has a nonparallel orientation. The diagnosis from the core biopsy was focal fibrosis, and the surgical excision revealed focal fibrosis.

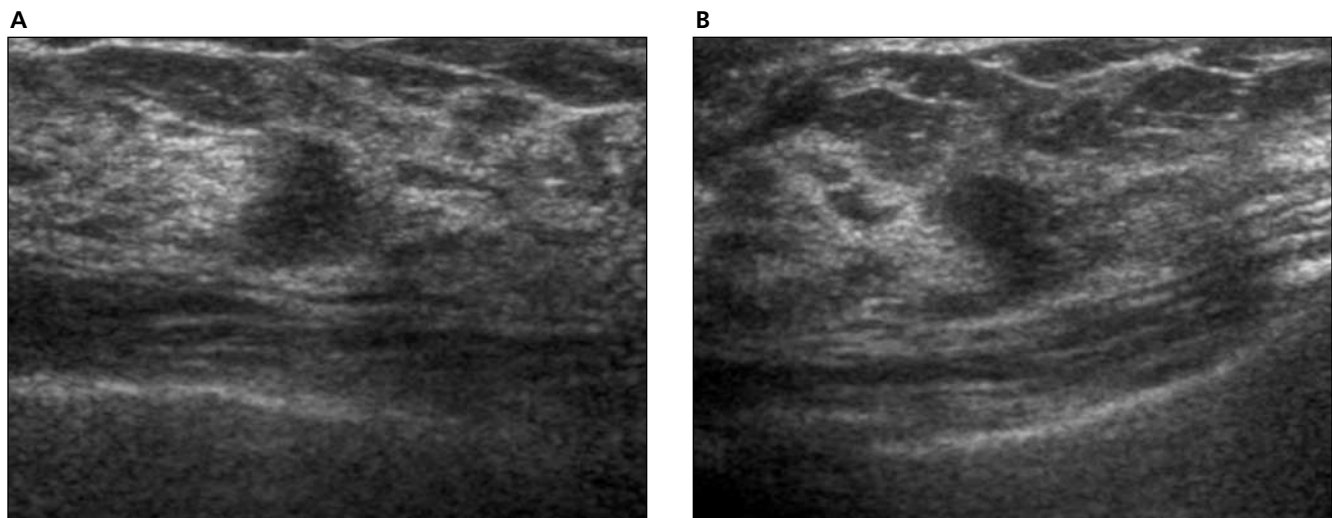


Table 5. Results of Surgical Biopsy

Surgical Biopsy Result	Cases (n = 7)
Focal fibrosis	3
Fibrocystic change	2
Ductal hyperplasia	1
Radial scar	1

and 5.4% (3/56) showed posterior shadowing and enhancement, respectively, but they had rates of 39.1% (25/64) and 17.2% (11/64). We also suggest that the size of the lesions in our study was relatively small for showing sufficient posterior features.

Rosen et al³ and Harvey et al⁶ reported no false-negative biopsy results in their study of focal fibrosis, and Sklair-Levy et al⁵ reported a 2.7% (2/74) false-negative biopsy rate, including 1 case of diagnosis delayed for 6 months. There were no known false-negative biopsy results in our study. We followed the 49 cases by sonographic examination and mammography for at least 12 months (mean, 20 months), and there were no cases of lesion enlargement on the follow-up images. However, strict radiologic-pathologic concordance is critical to avoid false-negative biopsy results. Generally, a 6-month follow-up protocol for patients having a concordant diagnosis of a nonspecific benign result on core biopsy is recommended.¹⁷⁻²¹

Our study was limited in that only 7 of the 56 lesions had surgical excision, and 4 of the 7 excised lesions did not confirm the core biopsy diagnosis of focal fibrosis. They were fibrocystic changes, ductal hyperplasia, and a radial scar at excision. All of them may have had pathologic partial fibrosis internally. However, because the altered surgical pathologic results did not change the management plan, we do not think the diagnosis of focal fibrosis by the sonographically guided core biopsy was inadequate.

In conclusion, focal fibrosis of the breast is a relatively common pathologic diagnosis in sonographically guided core biopsy and frequently has the characteristics of a low suggestion of malignancy. Therefore, in cases of focal fibrosis diagnosed by sonographically guided core biopsy of nonpalpable lesions, which show an oval to round nodule with a microlobulated margin, we suggest a 6-month follow-up management protocol.

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