Sclerosing adenosis (SA) is a less common histopathological lesion of the breast that can coexist with proliferative lesions as well as malignancies. We aimed to analyze the clinicopathological characteristics of SA and to investigate the radiological features of SA.

Patients who underwent breast surgery at our institute from 2007 to 2013 were retrospectively reviewed. A total of 815 breasts (722 patients) were included in the final analysis. Synchronous bilateral SA was defined as the detection of another SA arising in the contralateral breast within 1 month after surgery for the initial breast lesion. Baseline characteristics, imaging records (ultrasonography, mammography, and magnetic resonance imaging [MRI]), and pathology were included in the analysis.

The median age at diagnosis was 47 years old. The majority of patients had unilateral non-Bc-SA (457/722). Among 102 patients with bilateral SA, 78.4% were diagnosed synchronously. In total, 26 patients suffered from synchronous bilateral breast cancer. Upon final pathological investigation, 226 cases were SA involving breast cancer (Bc-SA), most (56.2%) of which were ductal carcinoma in situ (DCIS). In addition, lobular carcinoma in situ (LCIS) and diseases that involved LCIS also comprised up to 11.1% of cases. The majority of SA cases (405/497.7%) had no obvious symptoms except for imaging changes in mammography or ultrasound. Compared with non-Bc-SA cases, Bc-SA cases were more likely to exhibit features of mass (32.8% vs. 28.6%) and architectural distortion (20.4% vs. 13.0%) on mammography. Ultrasonography, mammography, and MRI revealed unsatisfactory sensitivity and specificity to differentiate Bc-SA from non-Bc-SA. MRI exhibited the highest sensitivity and lowest specificity, whereas the specificity of mammography was as low as 50.0%.

A tendency for synchronous bilaterality in both Bc-SA and non-Bc-SA was noted. DCIS was the most commonly observed malignancy involved in Bc-SA. Although most patients with SA were asymptomatic, the ability of imaging studies to accurately differentiate non-Bc-SA from Bc-SA remained unsatisfactory.

INTRODUCTION

Sclerosing adenosis (SA) is a histopathological description of human breast that was first clearly described in 1968. SA refers to proliferating fibrous and myoepithelial tissue that is disposed in whorls and distorts the normal architecture of the lobules accompanied by desmoplasia and epithelial hyperplasia. SA can also be observed in other proliferative lesions, such as papilloma and fibroadenoma. The condition even coexists with both invasive and in situ breast malignancies. Although SA is not a common condition, the number of cases has recently been increasing.

SA is difficult to distinguish from breast carcinoma based on radiology and frozen sections. SA mostly presents as a nonpalpable lesion with different mammographic and sonographic appearances, the features of which may occasionally mimic malignant conditions. Therefore, histopathological examination is mandatory for definite diagnosis.

The etiology of SA is not yet clear, but it is believed to be a benign lesion developing in response to an abnormal hormonal environment. SA itself is an independent risk factor for subsequent breast cancer associated with atypical lobular hyperplasia. Patients with SA have an increased risk for subsequent invasive breast cancer (range 1.7- to 3.7-fold), which is within the range of other benign proliferative lesions without atypia.

Due to the relatively low incidence of SA, our knowledge of SA is limited. In the present study, a retrospective review was performed in a cohort of 815 SA cases, with 226 cases involving malignancies. We aimed to analyze the clinicopathological characteristics of SA, investigate the radiological features of SA, and assess the ability of imaging studies to differentiate SA not involving breast cancer (non-Bc-SA) from SA involving breast cancer (Bc-SA).

MATERIALS AND METHODS

Patients who underwent breast surgery at Fudan University Shanghai Cancer Center (FUSCC) from 2007 to 2013 were included in the analysis. Baseline characteristics, imaging records (ultrasonography, mammography, and magnetic resonance imaging [MRI]), and pathology were included in the analysis. The median age at diagnosis was 47 years old. The majority of patients had unilateral non-Bc-SA (457/722). Among 102 patients with bilateral SA, 78.4% were diagnosed synchronously. In total, 26 patients suffered from synchronous bilateral breast cancer. Upon final pathological investigation, 226 cases were SA involving breast cancer (Bc-SA), most (56.2%) of which were ductal carcinoma in situ (DCIS). In addition, lobular carcinoma in situ (LCIS) and diseases that involved LCIS also comprised up to 11.1% of cases. The majority of SA cases (405/497.7%) had no obvious symptoms except for imaging changes in mammography or ultrasound. Compared with non-Bc-SA cases, Bc-SA cases were more likely to exhibit features of mass (32.8% vs. 28.6%) and architectural distortion (20.4% vs. 13.0%) on mammography. Ultrasonography, mammography, and MRI revealed unsatisfactory sensitivity and specificity to differentiate Bc-SA from non-Bc-SA. MRI exhibited the highest sensitivity and lowest specificity, whereas the specificity of mammography was as low as 50.0%.

A tendency for synchronous bilaterality in both Bc-SA and non-Bc-SA was noted. DCIS was the most commonly observed malignancy involved in Bc-SA. Although most patients with SA were asymptomatic, the ability of imaging studies to accurately differentiate non-Bc-SA from Bc-SA remained unsatisfactory.
retrospectively reviewed. A total of 771 cases were identified with SA as the final pathology. An additional pathologist reviewed the sections from all Bc-SA cases. Given that SA has a tendency for bilaterality, sections from breast cancer patients with non-Bc-SA in the contralateral breast were also reviewed by the pathologist to determine whether it was accompanied by previously undiscovered SA. After careful reexamination, the pathologist identified 48 additional SA cases. Among the 819 cases, 3 were excluded because they had their breasts removed in other hospitals, and no imaging studies were available for pre-operative evaluation. Another case who received neoadjuvant chemotherapy was also excluded from the study. Therefore, a total of 815 breasts were included in the final analysis. The protocol for the present study was approved by the Ethics Committee of FUSCC.

The information regarding all study patients was obtained from the electronic medical history system in our institute and reviewed by researchers. Baseline characteristics (age, family history, and breast disease history), imaging records (ultrasonography, mammography, and magnetic resonance imaging [MRI]) with Breast Imaging Reporting and Data System (BI-RADS)9 classification and lesion features, and pathology records were included in the analysis. In the subgroup analysis, patients were categorized into 3 groups according to BI-RADS classification to investigate the diagnosis of SA using imaging methods: BI-RADS 0, BI-RADS 1–3 and BI-RADS 4–5.

Synchronous bilateral Bc-SA was defined as the detection of another SA/cancer arising in the contralateral breast within 1 month after surgery for the initial breast lesion.

We used SPSS version 20 (SPSS Inc., Chicago, IL.) for statistical analysis. For descriptive statistics, we used medians (interquartile range [IQR]), and for categorical variables, frequency was used. Comparative analysis was carried out using $\chi^2$ test. $P$-value < 0.05 was considered to be statistically significant. Sensitivity and specificity were used to assess the imaging methods to differentiate non-Bc-SA from Bc-SA.

| TABLE 1. Baseline Characteristics of All SA Patients |
|-----------------------------------------------|
| Characteristics                                | N (%) |
| Median age at biopsy (IQR)                     | 47 (41–52) |
| Sex (female)                                  | 722 (100%) |
| Site of SA                                    |       |
| Unilateral SA                                 | 620 (85.9%) |
| Non-Bc-SA                                     | 457    |
| Bc-SA                                         | 125    |
| Non-Bc-SA with contralateral malignancy not involving SA | 26    |
| Bc-SA with contralateral malignancy not involving SA | 12    |
| Bilateral SA                                  | 102 (14.1%) |
| Bilateral non-Bc-SA                           | 25     |
| Bilateral Bc-SA                               | 24     |
| Unilateral Bc-SA                              | 53     |
| Timing of bilateral SA                        |       |
| Synchronous SA*                               | 80 (78.4%) |
| Bilateral non-Bc-SA                           | 23     |
| Bilateral Bc-SA                               | 21     |
| Metachronous SA                               | 22 (21.6%) |
| Bilateral non-Bc-SA                           | 2      |
| Bilateral Bc-SA                               | 3      |
| Family history (N = 494)                      |       |
| Any malignancy                                | 156 (31.6%) |
| Breast cancer                                 | 60 (12.1%) |
| Ovary cancer                                  | 5 (1.0%) |
| Other malignancy                              | 107 (21.7%) |
| Previous benign breast disease confirmed by pathology (N = 101) |       |
| Pathology type                                |       |
| Fibroadenoma                                   | 53 (52.5%) |
| Papilloma                                      | 11 (10.9%) |
| Adenosis                                       | 27 (26.7%) |
| Dysplasia                                      | 4 (4.0%) |
| Others*                                       | 6 (6.0%) |
| Site of the disease                           |       |
| Ipsilateral breast                            | 52 (51.5%) |
| Contralateral breast                          | 27 (26.7%) |
| Bilateral breast                              | 22 (21.8%) |

IQR = interquartile range; SA = sclerosing adenosis; Bc-SA = SA involving breast cancer; non-Bc-SA = SA not involving breast cancer.

Synchronous SA is defined as SA of bilateral breasts that were diagnosed within 1 month.

Six cases of other pathology type included 2 cases of mastitis, 1 case of breast cyst, 1 case of lipoma, 1 case of benign phyllodes tumor, and 1 case of SA.
RESULTS

Baseline Characteristics
A total of 815 cases (722 Asian female patients) were included in the final analysis, among which 620 patients had unilateral SA and 101 patients had bilateral SA. In addition, 1 patient had synchronous bilateral SA, and her right breast developed SA again 1 year later. The baseline characteristics of all patients are summarized in Table 1. The median age at diagnosis was 47 years old (IQR: 41–52), and all patients were female. The majority of patients had unilateral non-Bc-SA (457/722). Among 102 patients with bilateral SA, 53 had unilateral Bc-SA, and 24 patients had bilateral Bc-SA. In total, 78.4% of bilateral SA cases were diagnosed synchronously. A total of 240 patients in our cohort had breast cancer, among whom 204 (85%) had unilateral breast cancer and 36 (15%) had bilateral breast cancer. Up to 26 patients suffered from synchronous bilateral breast cancer.

In terms of family history, 31.6% of patients had a family history of malignant tumors, and 12.1% had breast cancer family history. Previous surgeries for benign breast disease in these patients were also reviewed. Among a total of 14.0% of patients who had previous breast biopsy or surgery, fibroadenoma was the most common disease (52.5%) followed by adenosis (26.7%) and papilloma (10.9%). Most of the benign disease (51.5%) occurred in the ipsilateral breast, whereas 21.8% of cases occurred in bilateral breasts.

The Clinicopathological Study of SA Cases
The initial symptoms of SA cases varied: 361 cases (44.3%) presented with palpable breast lump; 41 cases (5.4%) had nipple discharge; 13 cases (1.6%) reported mastalgia as the chief complaint; and the majority of cases (405; 49.7%) had no obvious symptoms except for imaging changes in mammography or ultrasound. Upon final pathological investigation, 226 cases were classified as Bc-SA (Table 2), most (56.2%) of which were ductal carcinoma in situ (DCIS). Notably, lobular carcinoma in situ (LCIS) or diseases that involved LCIS accounted for 11.1% of all cases. For non-Bc-SA, the most common pathological description included fibroadenoma (24.7%), dysplasia (15.4%), and papilloma (12.4%).

The Diagnosis of SA by Ultrasonography, Mammography, and MRI
In 815 SA cases, 759 were subject to breast ultrasonography, 623 were subject to mammography, and 434 were subject to MRI (Table 3). For ultrasonography, 71.9% cases presented with a solid mass, and 6.1% presented a shadow

| TABLE 2. Pathology Diagnosis Accompanied by SA in 815 Cases |
|-------------------------------------------------------------|
| Pathology Diagnosis                                         | N (%) |
| Bc-SA, N = 226                                              |       |
| Ductal carcinoma in situ (DCIS)                             | 127 (56.2%) |
| Invasive ductal carcinoma (IDC)                             | 74 (32.7%) |
| Invasive lobular carcinoma (ILC)                            | 1 (0.4%) |
| Other invasive carcinoma                                    | 8 (6.3%) |
| Lobular carcinoma in situ (LCIS)                            | 25 (11.1%) |
| or diseases involve LCIS                                     |       |
| Non-Bc-SA, N = 588                                          |       |
| Fibroadenoma                                                | 145 (24.7%) |
| Papilloma                                                   | 73 (12.4%) |
| Dysplasia                                                   | 91 (15.4%) |
| Adenosis and other benign breast disease                    | 279 (47.4%) |
| SA involving borderline phyllodes tumor, N = 1              |       |

Bc-SA = SA involving breast cancer; DCIS = ductal carcinoma in situ; IDC = invasive ductal carcinoma; ILC = invasive lobular carcinoma; LCIS = lobular carcinoma in situ; non-Bc-SA = SA not involving breast cancer; SA = sclerosing adenosis.

| TABLE 3. Imaging Features of SA Cases With Ultrasonography, Mammography, and MRI |
|-----------------------------------------------|-----------------------------------------------|
| Imaging Features                             | All SA Cases, N = 815                         |
|                                              | Non-Bc-SA Cases, N = 588                      |
|                                              | Bc-SA Cases, * N = 227                        |
|                                              | P-Value                                         |
| Ultrasonography, N = 759                     |                                               |
| Solid mass                                    | 546 (71.9%)                                   |
| Shadow without mass                           | 46 (6.1%)                                      |
| Others                                       | 167 (22.0%)                                    |
| Shadow without mass                           | 382 (71.3%)                                   |
| Others                                       | 31 (5.8%)                                      |
| Others                                       | 123 (22.9%)                                    |
| Mammography, N = 623                         |                                               |
| Calcification                                 | 237 (38.0%)                                   |
| Mass ± calcification                         | 186 (29.9%)                                   |
| Architectural distortion                      | 95 (15.2%)                                     |
| Asymmetric density                           | 47 (7.5%)                                     |
| Negative or not specified                    | 58 (9.3%)                                     |
| Enhancing mass                               | 213 (49.1%)                                   |
| Non-mass enhancement                         | 143 (32.9%)                                   |
| Structure distortion                         | 23 (5.3%)                                     |
| Negative or not specified                    | 55 (12.7%)                                     |

| Magnetic resonance imaging, N = 434           |                                               |
| Enhancement                                  | 142 (49.5%)                                   |
| Non-enhancement                              | 94 (32.8%)                                    |
| Structure distortion                         | 14 (4.9%)                                     |
| Negative or not specified                    | 37 (12.9%)                                     |

Bc-SA = SA involving breast cancer.
* One case of borderline phyllodes tumor was also grouped into malignant SA cases in the analysis.
* P-value was calculated by Pearson x² test.
* Other ultrasound characteristics included cyst formation, structure distortion, and cases with no specific characteristics described.
without mass. For mammography, the percentages of calcification, mass, architectural distortion, and asymmetric density were 38.0%, 29.9%, 15.2%, and 7.5%, respectively. For MRI, the 2 most commonly reported features were enhancing mass (49.1%) and nonmass enhancement (32.9%). Some of the typical features of SA in mammography and MRI were illustrated in Figures 1 and 2. Compared with non-Bc-SA cases, Bc-SA cases were more likely to have features of mass (32.8% vs. 28.6%) and architectural distortion (20.4% vs. 13.0%) on mammography with a tendency for significance ($P = 0.051$). However, no significant differences were detected in imaging features of ultrasonography ($P = 0.581$) or MRI ($P = 0.950$).

BI-RADS classification was used to categorize breast lesions in 756 (99.6%) ultrasonography cases, 580 (93.1%) mammography cases, and 431 (99.3%) MRI cases (Table 4). Moreover, 4.2% cases assessed by ultrasonography, 15.3% assessed by mammography, and 0.5% assessed by MRI were reported as BI-RADS 0, which required further investigation. The sensitivities of the 3 imaging methods to differentiate non-Bc-SA from Bc-SA were 66.3%, 72.8%, and 88.4%, respectively. The specificities of the three imaging methods were 64.1%, 50.0%, and 41.5%, respectively. MRI had the highest sensitivity and lowest specificity, whereas the specificity of mammography was as low as 50.0%.

**DISCUSSION**

The median age at diagnosis of SA was 47 years old in patients in this study, which is younger than the median age of breast cancer diagnosis in China.\(^{10}\) Previous studies also revealed that DCIS arising from SA occurred on average at the age of 42.6 years old, which is younger than the average age of breast cancer diagnosis.\(^{11,12}\) Up to 14.0% of patients in this cohort had previous benign breast disease confirmed by pathology, and 12.1% had a family history of breast cancer. These features correlated with a previous study from Mayo Clinic that found that SA was more common in women with a strong family history of breast cancer.\(^{13}\) The etiology of SA and its role in carcinogenesis remains elusive. Some suggested that SA might result from age-related regression or abnormality after lactation.\(^{7}\)
As noted in previous studies, SA was reported to have tendency for bilaterality.\textsuperscript{14,15} The frequency of bilateral breast cancer in all breast cancer patients was 1.6% to 7%,\textsuperscript{16,17} whereas the frequency of bilateral breast cancer in Bc-SA was as high as 27%.\textsuperscript{17} In a retrospective study analyzing 117 synchronous bilateral breast cancer and 7400 unilateral breast cancer patients, the author indicated that the presence of SA was a risk factor for developing synchronous bilateral breast cancer (hazard ratio: 11.8; 95% confidence interval: 5.3–26.3; \textit{P} < 0.001).\textsuperscript{16} Our cohort also revealed a tendency for bilaterality in SA, among which 78.4% were synchronous.

Some studies suggested that invasive lobular carcinoma (ILC) and LCIS presented in the majority of Bc-SA,\textsuperscript{18,19} which might explain the increased frequency for bilateral breast cancer. However, in our series, only 1 case of SA was associated with ILC, which was unilateral breast cancer. Moreover, 11.1% cases were associated with LCIS, 9 of which were bilateral. In contrast, DCIS (56.2%) and invasive ductal carcinoma (IDC) (32.7%) were the most commonly observed pathology types. Another hypothesis is that there is a strong association with hormonal environment or gene disorder in bilateral breast cancer, and the association is especially strong for synchronous tumors occurring within 1 month (odd ratio (OR) = 25.9). Therefore, it is possible that malignant SA is also related to these factors.\textsuperscript{20,21} Some studies have previously demonstrated that SA cases are often considered to be hormone positive.\textsuperscript{22,23}

Given that most SA cases were asymptomatic, imaging studies were essential to diagnose and differentiate the disease. Our results revealed no differences in imaging features between non-Bc-SA and Bc-SA in terms of ultrasonography (\textit{P} = 0.581), mammography (\textit{P} = 0.051), or MRI features (\textit{P} = 0.950). Nevertheless, architectural distortion was more commonly observed in Bc-SA on mammography (20.4% vs. 13.0%), and calcification was more commonly observed in non-Bc-SA (40.0% vs. 33.3%). This result was consistent with a study of 43 non-Bc-SA cases in which 24 (55.8%) had microcalcifications in mammographic findings.\textsuperscript{7} In addition, several studies reported that architectural distortion was more often associated with Bc-SA. Yoshida et al\textsuperscript{15} reported that architectural distortion was more frequent in patients with SA-DCIS compared with those with non-SA DCIS (15, 54% vs. 5, 2%, \textit{P} < 0.01) on mammography; Ogura et al\textsuperscript{7} reported 13 (46%) cases with architectural distortion in a study of 28 Bc-SA cases. One possible explanation was that architectural distortion became apparent as cancer developed or grew into the sclerotic stroma of SA.\textsuperscript{17} On ultrasound, non-Bc-SA presented as a focal, ill-defined mass with acoustic shadowing or a circumscribed mass with a well-defined, microlobulated, or irregular margin, which shared numerous features with breast cancer.\textsuperscript{2,23}

All the above evidence suggested that non-Bc-SA lesions might mimic malignancy on ultrasound, mammography, and MRI,\textsuperscript{24–27} which correlated with our findings that BI-RADS had a relatively low accuracy to differentiate non-Bc-SA from malignant cases. In our cohort, ultrasonography had the highest specificity and was adopted in nearly all cases (99.6%). The sensitivity of MRI was the highest among the three methods (88.4%), whereas the specificity was as low as 41.5%. Although all three methods exhibited unsatisfactory sensitivity and specificity to differentiate Bc-SA from non-Bc-SA, ultrasound and mammography might be considered as the initial diagnostic methods; or the combination of ultrasound and mammography might be considered to increase sensitivity. MRI must be used with caution because of its low specificity and high cost.

The strengths of the study includes that it reported a relative large cohort of patients in a less common breast disease relating to breast cancer. This is also the first study to compare the accuracy of different imaging methods to differentiate Bc-SA from non-Bc-SA using BI-RADS. Nevertheless, it is a retrospective study and no radiologist reviewed the imaging studies of SA cases, so that it was impossible to make direct connections of certain imaging features with specific pathologic conditions. Future prospective studies are awaited to directly evaluate the diagnostic value of ultrasound, mammography, and MRI in SA.

### CONCLUSIONS

The current study demonstrated that 240 out of 722 SA patients had Bc-SA. A tendency for synchronous bilaterality was noted in both Bc-SA and non-Bc-SA. The frequency of synchronous bilateral breast cancer in all Bc-SA patients was as high as 10.8%. Moreover, 56.2% of Bc-SA was DCIS, and 11.1% involved LCIS. Most patients with SA were asymptomatic. The sensitivity and specificity of the imaging studies to differentiate non-Bc-SA from Bc-SA were unsatisfactory.
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