Received: 22 August 2022 | Accepted: 7 September 2022

DOI: 10.1111/1759-7714.14666

ORIGINAL ARTICLE

WILEY

Comparison of ultrasound and mammography for early diagnosis of breast cancer among Chinese women with suspected breast lesions: A prospective trial

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Funding information
National Natural Science Foundation of China, Grant/Award Number: 52173149; Beijing Natural Science Foundation, Grant/Award Number: 7222129; Non-profit Central Research Institute Fund of the Chinese Academy of Medical Sciences, Grant/Award Number: 2019XK320033

Abstract

Background: Ultrasound is more widely used than mammography for early diagnosis of breast cancer in China as most Chinese women have small and dense mammary glands. This study compared the diagnostic performance of ultrasound and mammography for breast cancer among Chinese women with suspected breast lesions.

Methods: From November 2019 to November 2021, we compared the results of ultrasound and mammography for breast lesion diagnosis in 2737 consecutive participants with suspected breast lesions; all patients underwent biopsies. We measured the sensitivity, specificity, and diagnostic accuracy separately.

Results: Among the 2737 participants, 2844 breast lesions were detected, including 1935 (68.0%) breast cancers and 909 (32.0%) benign lesions. Of the breast cancers, ultrasound detected 1851 (95.7%), whereas mammography detected 1527 (78.9%). The sensitivity of ultrasound for breast cancer diagnosis was significantly higher than that of mammography (95.7% vs. 78.9%, $p < 0.001$), whereas the specificity was significantly lower than that of mammography (42.9% vs. 62.3%, $p < 0.001$). The receiver operating characteristic curves revealed that ultrasound was more accurate in detecting breast cancer than mammography (76.8% vs. 71.3%, $p < 0.001$). Age, body mass index, and breast density did not influence ultrasound sensitivity and accuracy.

Conclusions: Ultrasound is more sensitive and accurate than mammography and detects more breast cancers with a lower specificity.

KEYWORDS
breast cancer, early diagnosis, mammography, ultrasound

INTRODUCTION

GLOBOCAN's latest statistics show that breast cancer has replaced lung cancer as the most predominant cancer globally.[1] Breast cancer has long been the leading malignant tumor among Chinese women and has a very high mortality rate in China.[2] Nevertheless, early and effective diagnosis has been proven to improve the breast conservation rate and the survival rate of patients.[3]

Mammography is commonly used as the early diagnosis modality for breast cancer in Europe and the United States and has been shown to reduce mortality from breast cancer.[4–6] However, women who undergo long-term mammograms have an increased risk of radiation exposure. In addition, Asian women typically have a higher density of breast tissue than that of women of other races.[7–9] The age of patients with breast cancer is younger among Chinese women than that of European and American women.[10]

However, the effectiveness of mammography is reduced in women with high-density breast tissue and in younger women.[11,12] In recent years, some studies have found that breast ultrasound as a complementary modality to mammography may improve the diagnosis of breast cancer and may even replace it as the primary means of breast cancer diagnosis, especially for dense breasts.[5,13–16] In China, ultrasound is widely used for screening and early diagnosis of breast cancer.[2,15,17,18]

However, there is still a lack of clinical trial evidence comparing the accuracy of ultrasound and mammography among Chinese women.[15] Therefore, this study was designed to prospectively compare the performance of ultrasound and mammography in the early diagnosis of breast cancer.

METHODS

Study participants

Between November 2019 and November 2021, 2737 consecutive Chinese women aged 35 to 70 years who had at least one suspicious malignant lesion, detected by clinical examination or imaging, and who ultimately decided to have a biopsy in our hospital and signed an informed consent form, were recruited into this study. Participants were excluded if they had breast implants or were pregnant, lactating, or planning to become pregnant within half a year of study entry. A total of 2844 breast lesions were identified and biopsied among the 2737 participants.

Study design

All participants underwent standard mammography and ultrasound examinations in random order within 3 months before the biopsy, and all images were independently double-interpreted by two experienced physicians who were unaware of the results of the other modality. We examined both breasts of all participants. In the case of multiple lesions in the same breast, only the most suspected malignant lesion was included in our study. All suspicious lesions included in the study were biopsied, and the pathological results were recorded after mammography and ultrasound examinations. We defined the pathological results as the gold standard, and the accuracy of the examination modality was calculated after comparing them with the biopsy findings. Institutional review board approval (JS-2367) from our hospital and written informed consent from participants were obtained for this study. In addition, this study was registered at ClinicalTrials.gov (identifier: NCT04429269).

Diagnostic methods

Bilateral view mammography in the mediolateral oblique position and craniocaudal position was performed using a digital mammography system. Bilateral handheld breast ultrasound was performed in transverse and sagittal planes using color doppler with a maximum frequency of at least 12 MHz and a high-resolution transducer. We independently evaluated the mammography and ultrasound findings and classified them into the following six categories according to the Breast Imaging Reporting and Data System (version 5): 0, incomplete and requiring further imaging evaluation; 1, negative; 2, benign; 3, probably benign; 4, suspicious abnormality; and 5, highly suggestive of malignancy.[19] We considered results with a score ≥4 as positive and those <4 as negative.[20] Breast density was assessed according to the American College of Radiology (ACR) breast composition classification as follows: ACR a, almost entirely fatty; ACR b, scattered areas of fibroglandular density; ACR c, heterogeneously dense; and ACR d, extremely dense.[21] The pathological results of all the biopsied suspicious lesions were interpreted by at least two senior pathologists. According to the pathological results, all biopsied lesions were classified as malignant or benign, while malignant lesions were classified as invasive or noninvasive breast cancer.

Statistical considerations

The findings from ultrasound and mammography were separately compared with those of the pathological results of the biopsy, which were defined as the gold standard. The sensitivity and specificity for the diagnosis of breast lesions were calculated for both imaging modalities. All diagnostic performance parameters were cross-tabulated, and statistical comparisons between the two examination modalities and exact *p*-values were calculated using the McNemar's test for paired binary data. The area under the receiver operating characteristic curve (AUC) was used to compare the diagnostic accuracy of both modalities. Pairwise comparison of AUC was performed according to DeLong et al.[22] Diagnostic accuracy was set as the primary endpoint of the ultrasound and mammography comparison. According to literature reports and our previous research, we considered that, in women aged 35 to 70 years, the accuracy of mammography was approximately 70%, and we assumed that ultrasound would improve the accuracy by 5% to 75%.[15,23] Based on the estimation that women aged 35 to 70 years who were admitted to our hospital had a breast cancer rate of 60%, we calculated that 2795 cases were needed to establish a significant difference, with 5% significance (bilateral) and 90% power.

To explore the effect of age, body mass index (BMI), and breast density on the diagnosis accuracy, we divided the data set into subgroups according to the following criteria: age: 35 to 40, 41 to 50, 51 to 60, and 61 to 70 years; BMI: <23, 23 to <25, and ≥25 kg/m^2[24,25]; and breast density: nondense breast (ACR breast composition grades a and b) and dense breast (ACR breast composition grades c and d).[26] Diagnostic performance parameters (sensitivity, specificity, and accuracy) were calculated for each modality in all subgroups. We also compared the diagnostic performance of the two modalities within each subgroup. Finally, we tested the proportions of diagnostic performance parameters for each subgroup and provided confidence intervals. By comparing whether the confidence intervals overlapped across subgroups, we assessed whether the diagnostic performance parameters for a particular modality varied with age, BMI, or breast density.

All statistical analyses were performed using SPSS Statistics (IBM Corp.) with R version 26.0.0.0 (The R Project, Vienna, Austria). Reported p-values and 95% confidence intervals are two-sided, and a 0.05 threshold was used for statistical significance assessment.

RESULTS

Patient characteristics

Among the 2737 patients, 2844 suspicious breast lesions were detected and biopsied. Of them, 107 patients had bilateral lesions. The median age of the participants was 49 years (interquartile range, 42–57 years). The BMI distribution of the participants was 23.4 ± 3.15 kg/m^2. Table 1 shows the demographic data of the total breast lesions, including the age, BMI, and breast density of the participants. The 41 to 50-year subgroup accounts for 35.2% of breast cancers and rates the highest among all age subgroups. The prevalence of breast cancer in patients with BMI <23 kg/m^2 was 43.4%, which was significantly less than the 56.6% prevalence in patients with BMI ≥23 kg/m^2 ($p < 0.001$). Of all the breast lesions, 2593 (91.2%) patients had dense glands, which were significantly greater in number than the patients with nondense glands (251, 8.8%).

Breast cancer diagnosis

Table 2 demonstrates the overall breast lesion diagnosis results through mammography and ultrasound. Of the 1935 breast lesions with pathologically confirmed malignancy, 1851 (95.7%) cases were positive on ultrasound; in addition, 1527 (78.9%) cases were positive on mammography, and 1483 (76.6%) cases were positive on both modalities. Furthermore, 368 (19.0%) breast cancers had positive ultrasound and negative mammography results, whereas 44 (2.3%) breast cancers had positive mammography and negative ultrasound results. Among the 1935 breast cancer cases, 180 (9.3%) were noninvasive, whereas 1755 (90.7%) were invasive cancers. In the mammography-only–positive group, 16 (36.4%) cases were noninvasive carcinoma and 28 (63.6%) cases were invasive carcinoma. By contrast, in the ultrasound-only positive group, 38 (10.3%) cases were noninvasive carcinoma and 330 (89.7%) cases were invasive carcinoma.

As shown in Table 3, the sensitivity of ultrasound was significantly higher than that of mammography (95.7% [1851/1935] vs. 78.9% [1527/1935], $p < 0.001$), but the specificity was lower (43.9% [390/909] vs. 62.3% [566/909], $p < 0.001$). By plotting the receiver operating characteristic curve (Figure 1), we found that the diagnostic accuracy of ultrasound (AUC) was 76.8% (95% CI, 75.2%–78.4%), which was significantly higher than that of mammography (71.3%; 95% CI, 69.6%–72.9%; $p < 0.001$; Table 3).

TABLE 1 Characteristics of patients with breast lesions

	Total (% of total) ($n = 2844$)	Malignant (% of malignant) ($n = 1935$)	Benign (% of benign) ($n = 909$)
Age range, years			
35–40	513 (18.0)	245 (12.7)	268 (29.5)
41–50	1089 (38.3)	682 (35.2)	407 (44.8)
51–60	739 (26.0)	571 (29.5)	168 (18.5)
61–70	503 (17.7)	437 (22.6)	66 (7.3)
Body mass index, kg/m^2			
<23	1335 (46.9)	840 (43.4)	495 (54.5)
23 to <25	721 (25.4)	503 (26.0)	218 (24.0)
≥25	788 (27.7)	592 (30.6)	196 (21.6)
ACR breast composition			
a, almost entirely fatty	32 (1.1)	24 (1.2)	8 (0.9)
b, scattered areas of fibroglandular density	219 (7.7)	174 (9.0)	45 (5.0)
c, heterogeneously dense	2440 (85.8)	1637 (84.6)	803 (88.3)
d, extremely dense	153 (5.4)	100 (5.2)	53 (5.8)

Abbreviation: ACR, American College of Radiology.

TABLE 2 Overall diagnostic results of breast lesions

	Malignant				
	noninvasive carcinoma ($n = 180$)	**Invasive carcinoma ($n = 1755$)**	**Total ($n = 1935$)**	**Benign ($n = 909$)**	**Total ($n = 2844$)**
MG+, US−	16	28	44	120	164
MG+, US+	117	1366	1483	223	1706
MG−, US+	38	330	368	296	664
MG−, US−	9	31	40	270	310
Total MG+	133	1394	1527	343	1870
Total MG−	47	361	408	566	974
Total US+	155	1696	1851	519	2370
Total US−	25	59	84	390	474
Any positive	171	1724	1895	639	2534

Abbreviations: MG, mammography; US, ultrasound; +, positive; −, negative.

TABLE 3 Diagnostic performance of mammography versus ultrasound

	Mammography	**Ultrasound**	***p*-value**
Sensitivity			<0.001
No./total	1527/1935	1851/1935	
% (95% CI)	78.9 (77.0–80.7)	95.7 (94.6–96.5)	
Specificity			<0.001
No./total	566/909	390/909	
% (95% CI)	62.3 (59.0–65.4)	42.9 (39.7–46.2)	
Diagnostic accuracy (AUC)			<0.001
Value	0.713	0.768	
% (95% CI)	71.3(69.6–72.9)	76.8(75.2–78.4)	

Abbreviations: AUC, area under the receiver operating characteristic curve; CI, confidence interval.

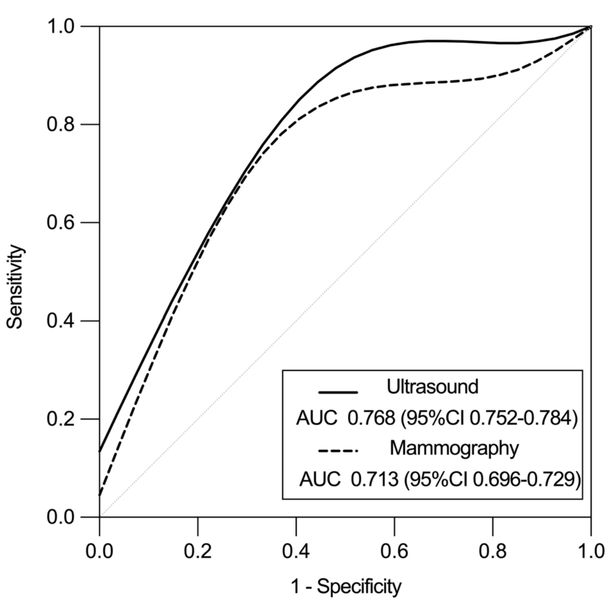

FIGURE 1 The receiver operating characteristic (ROC) curves were calculated according to DeLong et al.[22] The area under the ROC curve (AUC) was 0.713 (95% CI: 0.696–0.729) for mammography and 0.768 (95% CI: 0.752–0.784) for ultrasound, with a comparison of $p < 0.001$

Effect of age, BMI, and breast density on the performance of ultrasound and mammography

We investigated whether age, BMI, and breast density influenced the diagnostic performance of each modality (Table 4). The sensitivity of ultrasound was significantly higher than that of mammography in all subgroups ($p < 0.05$ in all subgroups). In the subgroups divided by age and BMI, the specificity of ultrasound was significantly lower than that of mammography ($p < 0.05$), whereas, in the nondense breast group, there was no significant difference in the specificity of the two diagnosis modalities. Moreover, ultrasound was significantly more accurate than mammography in those groups ($p < 0.05$), except among women in the subgroups aged 61 to 70 years and with BMI ≥23 kg/m^2 and nondense glands, in whom no significant difference was detected.

By comparing the confidence intervals of the diagnostic performance parameters in different subgroups, we revealed that the sensitivity of mammography increases gradually with increasing age ($p < 0.05$) and BMI ($p < 0.05$) but decreases as gland density increases ($p < 0.05$) (Table 4). In addition, we found that the sensitivity and accuracy of

TABLE 4 Effect of age, body mass index, and breast density on the diagnostic performance of mammography and ultrasound

	Sensitivity % (95% CI) No./total			Specificity % (95% CI) No./total			AUC value (95% CI)		
	MG	US	*p*-value	MG	US	*p*-value	MG	US	*p*-value
Age range, years									
35–40	75.1 (69.1–80.3) 184/245	95.9 (92.4–97.9) 235/245	<0.001	61.9 (55.8–67.7) 166/268	47.8 (41.7–53.9) 128/268	0.001	0.692 (0.650–0.732)	0.778 (0.739–0.813)	<0.001
41–50	76.1 (72.7–79.2) 519/682	94.3 (92.2–95.6) 643/682	<0.001	64.4 (59.5–69.0) 262/407	40.3 (35.5–45.3) 164/407	<0.001	0.705 (0.677–0.732)	0.742 (0.715–0.768)	0.034
51–60	79.5 (75.9–82.7) 454/571	96.5 (94.5–97.8) 551/571	<0.001	62.5 (54.7–69.7) 105/168	45.8 (38.2–53.7) 77/168	0.001	0.718 (0.684–0.750)	0.793 (0.762–0.822)	<0.001
61–70	84.7 (80.9–87.8) 370/437	96.6 (94.3–98.0) 422/437	<0.001	50.0 (37.6–62.4) 33/66	31.8 (21.2–44.6) 21/66	0.017	0.693 (0.651–0.733)	0.728 (0.687–0.767)	0.310
Body mass index, kg/m^2									
<23	76.5 (73.5–79.3) 643/840	95.0 (93.2–96.3) 798/840	<0.001	61.4 (57.0–65.7) 303/495	50.5 (46.0–55.0) 250/495	<0.001	0.697 (0.672–0.722)	0.782 (0.759–0.804)	<0.001
23 to <25	78.3 (74.4–81.8) 394/503	95.0 (92.6–96.7) 478/503	<0.001	65.6 (58.8–71.8) 143/218	38.1 (31.7–44.9) 83/218	<0.001	0.710 (0.676–0.743)	0.753 (0.720–0.784)	0.056
≥25	82.8 (79.4–85.7) 490/592	97.1 (95.3–98.3) 575/592	<0.001	60.7 (53.5–67.5) 119/196	29.1 (22.9–36.1) 57/196	<0.001	0.736 (0.704–0.767)	0.737 (0.704–0.767)	0.977
Breast density									
Nondense breast (a, b)	87.4 (81.7–91.5) 173/198	94.4 (90.0–97.1) 187/198	0.016	56.6 (42.4–69.9) 23/53	41.5 (28.4–55.8) 31/53	0.169	0.739 (0.680–0.792)	0.751 (0.692–0.803)	0.792
Dense breast (c, d)	78.2 (76.1–80.1) 1358/1737	95.8 (94.7–96.7) 1664/1737	<0.001	62.6 (59.3–65.9) 536/856	43.0 (39.7–46.4) 368/856	<0.001	0.709 (0.692–0.727)	0.764 (0.752–0.785)	<0.001

Note: *p*-values are for the comparison between ultrasound and mammography in different subgroups.
Abbreviation: AUC, area under the receiver operating characteristic curve.

ultrasound did not change with age, BMI, or breast density. The specificity of ultrasound decreased with increasing BMI ($p < 0.05$). However, the specificity of both ultrasound and mammography did not differ significantly in different breast densities.

DISCUSSION

To our knowledge, this is the largest prospective, head-to-head pairwise comparison of ultrasound and mammography in the early diagnosis of breast cancer. Based on our findings, ultrasound was more sensitive and accurate than mammography in detecting breast cancer in Chinese women, with a lower specificity.

The results of this study are consistent with other study results from China.[15] One of our previous studies found that breast ultrasound among women aged 30 to 65 years at high risk for breast cancer had greater sensitivity and higher accuracy than mammography.[15] Other studies from Asian women also showed that ultrasound was more sensitive and accurate than mammography. In the Japan Strategic Anti-cancer Randomized Trial, 184 breast cancers were detected in 36 859 participants by ultrasound combined with mammography, of whom 41 were positive in mammography only and 67 were positive in ultrasound only, with the diagnosis rate of breast cancer, therefore being higher for ultrasound than that for mammography.[14] A study from Thailand included 3129 symptomatic women and found that the AUC for ultrasound was 0.962, which was superior to that of mammography at 0.954 ($p = 0.015$), implying that ultrasound is more accurate than mammography.[27] An international meta-analysis showed that when looking at data from low- and middle-income countries alone, breast ultrasound did not have lesser sensitivity and specificity than those of mammography.[28] Even in Western countries, ultrasound is no less sensitive and accurate than mammography.[5] Nevertheless, few studies have compared the advantages and disadvantages of ultrasound and mammography for breast cancer early diagnosis because of the widespread acceptance of mammography in Europe and the United States and because insurance for breast cancer early diagnosis usually reimburses only for mammography. Kuhl et al. found that the diagnostic sensitivity of ultrasound was higher than that of mammography in women with high familial risk for breast cancer.[29]

The American College of Radiology Imaging Network 6666 multicenter clinical study is currently the largest prospective study of ultrasound as an early detection method in the Americas and found no significant difference in detection rates between breast ultrasound and mammography among women with dense breast tissue.[16,20,30] In contrast, in our study, ultrasound was a more sensitive diagnosis modality than that of mammography in all age, BMI, and breast density subgroups. Most breast cancers, especially invasive cancers, present as a mass, and the ability of ultrasound to detect a mass is superior to that of mammography, which is the main reason why ultrasound is more sensitive than mammography. In addition, we found that ultrasound had a more accurate performance than mammography in most cases, except in women who were older, overweight (BMI ≥ 23 kg/m^2), or had no dense breast tissue.

However, the specificity decreases as the sensitivity increases. The specificity of ultrasound was significantly lower than that of mammography (43.5% vs. 62.6%), implying that ultrasound may have increased the rate of false positives more often, bringing about unnecessary biopsies and, to some extent, possibly increasing patient anxiety. To avoid this problem, we recommend that mammography be used as a complementary diagnosis tool for ultrasound-positive breast lesions to determine if a biopsy needs to be performed.

In the present study, 330 (89.7%) breast cancers detected by ultrasound only were invasive cancers, whereas only 28 (63.6%) of the cancers detected by mammography alone were invasive. More invasive cancers were missed by mammography than that by ultrasound, which was consistent with the results of the American College of Radiology Imaging Network 6666 study.[16,31] The high percentage of in situ cancers diagnosed on mammography is one of the concerns that breast cancer screening makes overdiagnosis and overtreatment because many in situ cancers may not develop into invasive cancers or become symptomatic throughout life. Ultrasound diagnoses more life-threatening invasive cancers than that of mammography.[31]

We compared the overlap of confidence intervals for diagnostic performance tests within different subgroups for a single examination modality. We found that the sensitivity of mammography increased with age, possibly because the density of the breast decreases with age, thus making mammography more sensitive, suggesting that older women may be more suitable for mammography. The specificity of ultrasound sharply decreases in more obese women, which may be due to the increased tissue thickness and fat attenuation reducing the quality of ultrasound-guided images.[32] This seems to be echoed in the trend of ultrasound accuracy being negatively correlated with BMI. However, we found that different breast densities do not seem to have a significant effect on the sensitivity and specificity of ultrasound, similar to the results of another study from Austria.[26]

This study has noteworthy limitations. Because of the lack of long-term follow-up, we could not rigorously assess whether ultrasound reduces breast cancer mortality. However, ultrasound detects more life-threatening invasive breast cancers than mammography. As more early invasive cancers can be detected by ultrasound, breast cancer survival rates may also improve.

In conclusion, breast ultrasound is a more sensitive and accurate modality than mammography for the early diagnosis of breast cancer in Chinese women with suspected breast lesions. It might also be true for all women with dense breasts worldwide. For older or obese women, mammography can be used to supplement ultrasound to increase sensitivity, specificity, and accuracy. However, long-term follow-up is still needed to assess whether ultrasound reduces breast cancer mortality.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

CLINICAL TRIAL REGISTRATION

This study was registered at ClinicalTrials.gov (identifier: NCT04429269).

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How to cite this article: Wang Y, Li Y, Song Y, Chen C, Wang Z, Li L, et al. Comparison of ultrasound and mammography for early diagnosis of breast cancer among Chinese women with suspected breast lesions: A prospective trial. Thorac Cancer. 2022;13(22):3145–51. https://doi.org/10.1111/1759-7714.14666