

Preplanned Studies

Detection and BI-RADS Classification of Breast Nodules in Urban Women — China, 2021

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Summary

What is already known about this topic?

Female breast nodules represent the most frequently detected lesions during breast ultrasound screening. Notably, nodules classified as Breast Imaging Reporting and Data System (BI-RADS) 4 or 5 indicate an elevated risk of breast cancer. Nevertheless, the detection rate and BI-RADS classification of female breast nodules in China remain largely undocumented.

What is added by this report?

In 2021, breast nodules were detected in 27.9% of urban women in China. Among women with breast nodules marked with BI-RADS classification information, 95.9% were categorized as BI-RADS 2–3, while 4.0% were classified as BI-RADS 4–5. Age, geographic location, per capita gross domestic product (GDP), body mass index (BMI), high triglyceride (TG), high low-density lipoprotein cholesterol (LDL-C), and diabetes were identified as risk factors for BI-RADS 4–5.

What are the implications for public health practice?

This study highlights the importance of managing high-risk women with breast nodules through BI-RADS classification. Women with older age, high TG, high LDL-C, or diabetes demonstrate higher detection rates of BI-RADS 4–5, underscoring the need for targeted health interventions for high-risk populations while accounting for regional and socioeconomic disparities.

Methods: This study analyzed health examination data from 6,412,893 urban women across 31 provincial-level administrative divisions (PLADs). We calculated detection rates of breast nodules and their various BI-RADS classifications. Chi-square (χ^2) tests were performed to compare differences between groups. Multivariable logistic regression models were constructed to explore associations between breast nodules and BI-RADS 4–5 with demographic, socioeconomic, and metabolic indicators.

Results: The overall detection rate of breast nodules in Chinese urban women was 27.9%, with provincial rates ranging from 11.6% to 37.0%. Among women with breast nodules marked with BI-RADS classification information, 95.9% were categorized as BI-RADS 2–3, while 4.0% were classified as BI-RADS 4–5. Further analyses revealed that age, geographic region, per capita gross domestic product (GDP), body mass index (BMI), high triglyceride (TG), high low-density lipoprotein cholesterol (LDL-C), and diabetes were significant risk factors for BI-RADS 4–5 classification.

Conclusions: This study highlights the importance of managing high-risk women with breast nodules through BI-RADS classification, underscoring the need for targeted health interventions while considering regional and socioeconomic disparities.

ABSTRACT

Introduction: Female breast nodules represent the most frequently detected lesions during breast ultrasound screening. Notably, nodules classified as BI-RADS 4 or 5 indicate an elevated risk of breast cancer. Nevertheless, the detection rate and BI-RADS classification of female breast nodules across China remain largely undocumented.

Breast cancer is the most prevalent cancer among women, with a significant rise in incidence observed in China (1–2). Breast ultrasound plays a central role in the early detection of female breast cancer or lesions predisposing to female breast cancer, particularly nodules, which are the most commonly encountered abnormalities (3). The Breast Imaging Reporting and Data System (BI-RADS) provides a standardized framework for assessing and reporting the malignancy risk associated with breast nodules. Notably, nodules

classified as BI-RADS 4 or 5 indicate an elevated risk of breast cancer (4–5). This distinction is critical for risk stratification and subsequent clinical decision-making. However, there is a significant gap in nationwide research regarding the detection rate of female breast nodules in China, as well as the prevalence of nodules with malignancy risk. This paucity of data may impede timely intervention and prevention for breast cancer. Therefore, this study analyzed the health examination data of 6,412,893 urban women from 31 provincial-level administrative divisions (PLADs) across the country, aiming to comprehensively investigate the detection rate and BI-RADS classification of breast nodules in Chinese urban women, and identify factors potentially associated with the malignancy risk. Our findings demonstrated that the overall detection rate of breast nodules in Chinese urban women was 27.9%, with provincial rates ranging from 11.6% to 37.0% across 31 PLADs. Among women with breast nodules marked with BI-RADS classification information, 95.9% were categorized as BI-RADS 2–3, while 4.0% were classified as BI-RADS 4–5. Further analyses revealed that age, geographic region, per capita gross domestic product (GDP), body mass index (BMI), high triglyceride (TG), high low-density lipoprotein cholesterol (LDL-C), and diabetes were risk factors of BI-RADS 4–5. The findings of this study provide valuable evidence to guide breast cancer prevention strategies in China.

This study utilized data from the Meinian Healthcare Group system, the largest health examination chain in China, with coverage across 231 prefecture-level cities spanning 31 PLADs. The Meinian Healthcare Group implements a comprehensive quality control system encompassing standardized operational protocols, unified staff training programs, and regular quality assessments for imaging and laboratory testing. Study participants primarily comprised employees and urban residents who underwent physical examinations, laboratory tests, and imaging assessments, as detailed in a previous publication (6). From January 1, 2021, to December 31, 2021, a total of 6,412,893 women were included in the analysis. Exclusion criteria encompassed: male sex; age under 18 years; pregnancy; absence of breast ultrasound information; and history of bilateral breast cancer surgery.

The detection rate of breast nodules was defined as the proportion of women with clearly documented breast nodules in their ultrasound examination reports relative to the total number of women examined. In

accordance with the BI-RADS guidelines, breast nodules were stratified into three categories: BI-RADS 0–1 (lesions requiring further imaging or negative findings), BI-RADS 2–3 (benign lesions), and BI-RADS 4–5 (malignant lesions). The detection rate for each BI-RADS classification group was calculated as the proportion of samples assigned to that particular classification relative to the total number of samples labeled with any BI-RADS classification. Explanatory variables included age, geographic region (east, central, west, and northeast), city-level per capita GDP, BMI (kg/m^2), high TG (defined as $\text{TG} \geq 1.7 \text{ mmol}/\text{L}$), high LDL-C (defined as $\text{LDL-C} \geq 3.4 \text{ mmol}/\text{L}$), and diabetes (defined as fasting glucose $\geq 7.0 \text{ mmol}/\text{L}$).

We calculated the detection rate of female breast nodules and various BI-RADS classifications, along with their 95% confidence intervals (CIs). Chi-square (χ^2) tests were performed to compare differences between groups. Multivariable logistic regression models were constructed to examine the associations between female breast nodules and BI-RADS 4–5 with demographic, socioeconomic, and metabolic indicators, adjusting for all explanatory variables. Statistical analyses were conducted using SAS software (version 9.4, SAS Institute Inc., Cary, NC, USA). A two-tailed $P < 0.05$ was considered statistically significant.

Among the 6,412,893 eligible women, 30.1% were aged 30–39 years, 47.9% resided in eastern China, and 28.2% were overweight. Overall, 27.9% (95% CI: 27.8%, 27.9%) of urban women in China were detected with breast nodules. The detection rate varied significantly by age, region, and per capita GDP, with the highest rates observed among women aged 40–49 years (37.0%, 95% CI: 36.9%, 37.1%), those residing in northeastern China (31.2%, 95% CI: 31.1%, 31.3%), and those living in areas with the highest per capita GDP (29.8%, 95% CI: 29.7%, 29.9%). Multivariable logistic regression analysis revealed that women aged 40–49 years demonstrated the highest risk of having breast nodules [odds ratio (OR)=2.10, 95% CI: 2.09, 2.11]. Women living in areas with the lowest per capita GDP had the lowest risk of breast nodules. Regarding BMI, underweight women were more susceptible to developing breast nodules (Table 1).

Women residing in western China demonstrated a significantly lower risk of breast nodules compared to their counterparts in eastern regions (OR=0.68, 95% CI: 0.68, 0.68). Figure 1 further illustrates the regional disparity in the detection rate of female breast nodules. Overall, PLADs in the eastern and northeastern regions

TABLE 1. Detection rate and associated factors of breast nodules in urban women in China, 2021.

Variables	Number (n, %)	Nodules (%; 95% CI)	Nodules	
			OR (95% CI)	P
Overall	6,412,893 (100.0)	27.9 (27.8, 27.9)	–	–
Age group (years)				
18–29	984,606 (15.3)	22.9 (22.8, 23.0)	Reference	–
30–39	1,930,638 (30.1)	28.2 (28.2, 28.3)	1.34 (1.33, 1.35)	<0.0001
40–49	1,443,857 (22.5)	37.0 (36.9, 37.1)	2.10 (2.09, 2.11)	<0.0001
50–59	1,369,632 (21.4)	27.1 (27.0, 27.1)	1.37 (1.36, 1.38)	<0.0001
60–69	526,369 (8.2)	17.2 (17.1, 17.3)	0.76 (0.75, 0.76)	<0.0001
70+	157,791 (2.5)	13.7 (13.6, 13.9)*	0.59 (0.58, 0.60)	<0.0001
Geographic region				
Eastern	3,074,829 (47.9)	29.8 (29.8, 29.9)	Reference	–
Central	1,499,099 (23.4)	27.1 (27.0, 27.2)	0.89 (0.88, 0.89)	<0.0001
Western	1,222,489 (19.1)	22.3 (22.2, 22.3)	0.68 (0.68, 0.68)	<0.0001
Northeastern	616,476 (9.6)	31.2 (31.1, 31.3)*	1.12 (1.11, 1.13)	<0.0001
Per capita GDP				
Lowest	1,625,373 (25.3)	25.8 (25.7, 25.9)	Reference	–
Up to median	1,613,646 (25.2)	26.8 (26.8, 26.9)	1.08 (1.08, 1.09)	<0.0001
Above median	1,514,973 (23.6)	29.1 (29.0, 29.1)	1.12 (1.12, 1.13)	<0.0001
Highest	1,658,901 (25.9)	29.8 (29.7, 29.9)*	1.11 (1.10, 1.11)	<0.0001
BMI				
Underweight	340,926 (5.3)	27.9 (27.8, 28.1)	1.04 (1.03, 1.04)	<0.0001
Normal	3,650,339 (56.9)	29.5 (29.4, 29.5)	Reference	–
Overweight	1,808,859 (28.2)	26.5 (26.4, 26.5)	0.86 (0.86, 0.87)	<0.0001
Obesity	612,769 (9.6)	22.6 (22.5, 22.7)*	0.72 (0.71, 0.72)	<0.0001
High TG				
No	5,220,433 (81.4)	28.4 (28.4, 28.4)	Reference	–
Yes	1,192,460 (18.6)	25.6 (25.5, 25.6)*	0.98 (0.98, 0.99)	<0.0001
High LDL-C				
No	5,144,749 (80.2)	28.2 (28.2, 28.2)	Reference	–
Yes	1,268,144 (19.8)	26.6 (26.5, 26.6)*	0.99 (0.98, 0.99)	<0.0001
Diabetes				
No	6,195,661 (96.6)	28.1 (28.0, 28.1)	Reference	–
Yes	217,232 (3.4)	22.7 (22.6, 22.9)*	0.96 (0.95, 0.97)	<0.0001

Note: “–” means that data are not applicable.

Abbreviation: OR=odds ratio; CI=confidence interval; GDP=gross domestic product; LDL-C=low-density lipoprotein cholesterol.

* $P<0.05$.

exhibited higher detection rates of breast nodules, while relatively lower rates were observed in the western region. At the provincial level, the detection rates of female breast nodules ranged from 11.6% to 37.0%, with the lowest detection rates observed in Xizang, Guizhou, and Chongqing, and the highest in Zhejiang, Liaoning, and Tianjin PLADs.

Among women with breast nodules marked with BI-RADS classification information, 95.9% (95% CI: 95.9%, 96.0%) were classified as BI-RADS 2–3, and 4.0% (95% CI: 4.0%, 4.0%) were classified as BI-RADS 4–5. The highest detection rate of BI-RADS 4–5 was observed in women aged over 70 years (11.6%, 95% CI: 10.8%, 12.3%). Multivariable

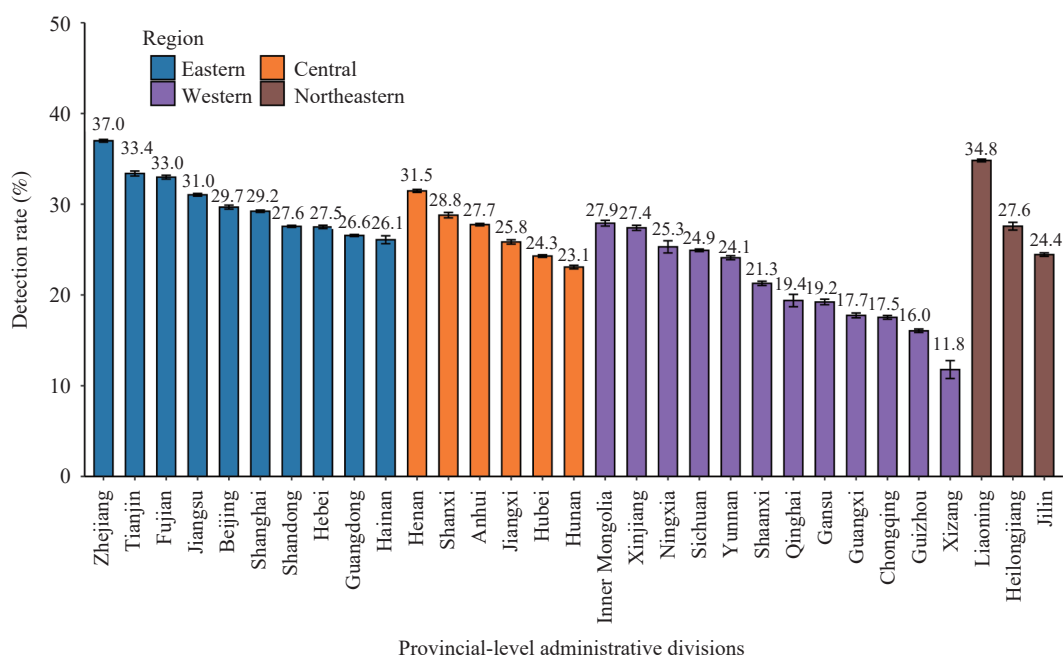


FIGURE 1. Regional disparities in the detection rate of breast nodules in Chinese urban women, 2021.

logistic regression revealed that the risk of BI-RADS 4–5 increased with age, with women aged 50 and above exhibiting odds ratios exceeding 2. Notably, women aged 70 or older demonstrated the highest risk ($OR=5.41$, 95% CI : 4.97, 5.90). Unlike the pattern observed for breast nodules, women in western regions had the highest risk of BI-RADS 4–5, and overweight or obese women exhibited a higher risk of BI-RADS 4–5. Women with metabolic abnormalities, including high TG, high LDL-C, and diabetes, faced an elevated risk of BI-RADS 4–5. Additionally, women residing in areas with higher per capita GDP demonstrated a higher risk of BI-RADS 4–5 (Table 2).

DISCUSSION

The World Health Organization emphasizes that early identification of individuals with subtle symptoms, signs, or both of possible breast malignancies is fundamentally important for breast cancer prevention and control (7). Breast nodules represent the most common lesions detected during breast ultrasound screening. Identifying women with breast nodules and assessing their malignancy risk according to BI-RADS classification constitutes an effective strategy to promote early detection and diagnosis of breast cancer. For improved policy formulation and implementation, comprehensive data are essential to understand the epidemiological profile

of female breast nodules and their associated malignancy risk in China.

This study represents the first nationwide analysis of the detection rate and BI-RADS classification of breast nodules in Chinese urban women using comprehensive health examination data. We found that 27.9% of eligible women presented with breast nodules. Compared with previous studies that relied on smaller samples or focused on specific PLADs or medical institutions, our detection rate falls within a moderate range (8–11). Given that our sample encompassed 31 PLADs and all adult age groups in China, these findings likely provide a more accurate reflection of the overall prevalence of breast nodules among Chinese urban women. Furthermore, this study determined that the detection rate of BI-RADS 4–5 was 4.0%, with this proportion increasing progressively with age, consistent with findings from previous research.

Our analysis revealed that women aged 40–49 years exhibited the highest risk of breast nodules, consistent with findings from previous studies (9–10). Notably, our novel findings demonstrated that women aged ≥ 70 years and those aged 50–69 years presented significantly higher risks of BI-RADS 4–5 classification. Given China's rapidly aging population and increasing life expectancy, the elevated malignancy risk observed among elderly women warrants particular attention. These findings collectively emphasize that women aged ≥ 40 years face an increased risk for both breast nodules and BI-RADS 4–5 classifications, with

TABLE 2. Detection rates of various BI-RADS classifications and associated factors of BI-RADS 4–5 in urban women, China, 2021.

Variables	Number (n, %)	BI-RADS (%; 95% CI)		BI-RADS 4–5	
		2–3	4–5	OR (95% CI)	P
Overall	788,367 (100.0)	95.9 (95.9, 96.0)	4.0 (4.0, 4.0)	–	–
Age group, years					
18–29	112,893 (14.3)	97.8 (97.7, 97.9)	2.2 (2.1, 2.3)	Reference	–
30–39	243,082 (30.8)	97.3 (97.2, 97.4)	2.7 (2.6, 2.7)	1.22 (1.16, 1.28)	<0.0001
40–49	231,893 (29.4)	95.8 (95.8, 95.9)	4.1 (4.0, 4.2)	1.86 (1.77, 1.94)	<0.0001
50–59	158,946 (20.2)	94.1 (94.0, 94.2)	5.9 (5.8, 6.0)	2.62 (2.50, 2.75)	<0.0001
60–69	34,294 (4.4)	91.4 (91.1, 91.7)	8.6 (8.3, 8.9)	3.95 (3.73, 4.19)	<0.0001
70+	7,259 (0.9)	88.3 (87.6, 89.1)*	11.6 (10.8, 12.3)*	5.41 (4.97, 5.90)	<0.0001
Geographic region					
Eastern	425,123 (53.9)	96.6 (96.6, 96.7)	3.3 (3.3, 3.4)	Reference	–
Central	161,651 (20.5)	96.1 (96.0, 96.2)	3.9 (3.8, 4.0)	1.12 (1.08, 1.15)	<0.0001
Western	133,538 (16.9)	93.8 (93.7, 94.0)	6.0 (5.9, 6.2)	1.89 (1.83, 1.95)	<0.0001
Northeastern	68,055 (8.7)	95.4 (95.3, 95.6)*	4.6 (4.4, 4.7)*	1.19 (1.14, 1.25)	<0.0001
Per capita GDP					
Lowest	196,744 (25.0)	95.6 (95.5, 95.7)	4.4 (4.3, 4.5)	Reference	–
Up to median	230,338 (29.2)	95.5 (95.4, 95.6)	4.5 (4.4, 4.6)	1.05 (1.02, 1.08)	0.0012
Above median	181,244 (23.0)	96.0 (96.0, 96.1)	3.9 (3.8, 4.0)	1.13 (1.09, 1.17)	<0.0001
Highest	180,041 (22.8)	96.9 (96.8, 96.9)*	3.1 (3.0, 3.2)*	1.08 (1.03, 1.12)	0.0004
BMI					
Underweight	47,256 (6.0)	97.3 (97.2, 97.5)	2.6 (2.5, 2.7)	0.93 (0.87, 0.98)	0.0108
Normal	487,221 (61.8)	96.3 (96.2, 96.3)	3.7 (3.6, 3.7)	Reference	–
Overweight	200,719 (25.5)	95.1 (95.0, 95.2)	4.8 (4.7, 4.9)	1.06 (1.03, 1.09)	<0.0001
Obesity	53,171 (6.7)	94.9 (94.7, 95.0)*	5.1 (4.9, 5.3)*	1.07 (1.02, 1.11)	0.0034
High TG					
No	658,122 (83.5)	96.2 (96.2, 96.3)	3.7 (3.7, 3.8)	Reference	–
Yes	130,245 (16.5)	94.5 (94.4, 94.6)*	5.4 (5.3, 5.6)*	1.06 (1.03, 1.10)	<0.0001
High LDL-C					
No	637,905 (80.9)	96.2 (96.2, 96.3)	3.7 (3.7, 3.8)	Reference	–
Yes	150,462 (19.1)	94.7 (94.6, 94.8)*	5.3 (5.1, 5.4)*	1.09 (1.06, 1.13)	<0.0001
Diabetes					
No	768,214 (97.4)	96.0 (96.0, 96.1)	3.9 (3.9, 4.0)	Reference	–
Yes	120,153 (2.6)	93.2 (93.0, 93.6)*	6.7 (6.4, 7.1)*	1.08 (1.01, 1.14)	0.0149

Note: Due to the extremely small sample size, the detection rate of BI-RADS 0–1 is 0.0%; therefore, these data are not displayed in the table. “–” means that data are not applicable.

Abbreviation: OR=odds ratio; BMI=body mass index; CI=confidence interval; GDP=gross domestic product; LDL-C=low-density lipoprotein cholesterol.

* $P<0.05$.

special vigilance required for potentially malignant breast disease in women aged ≥ 70 years.

BI-RADS 4–5 classification indicates a high risk of breast cancer. Our geographic distribution analysis revealed that the highest risk of BI-RADS 4–5 was observed in western regions of China. Regarding

socioeconomic indicators, regions with higher per capita GDP demonstrated a significant positive correlation with increased risk of BI-RADS 4–5 classification. Additionally, this study identified several metabolic and anthropometric risk factors associated with BI-RADS 4–5, including BMI and various

metabolic indicators. These findings underscore the importance of developing tailored prevention strategies for populations with these high-risk factors, while simultaneously accounting for regional and socioeconomic disparities.

This study has several limitations. First, as the data were derived exclusively from health examination centers in urban areas, rural populations may be inadequately represented. Further research incorporating rural residents is necessary to provide a more comprehensive epidemiological profile of breast nodules across China. Second, the cross-sectional design inherently limits our ability to establish definitive causal relationships between breast nodules, BI-RADS 4–5 classification, and the associated factors identified. Finally, since our detection rates were based solely on ultrasound examination results — while breast nodule detection methods also include physical examination and mammography — there exists a potential risk of underestimation in our reported prevalence.

This study represents the first nationwide, big data-based analysis of the detection rate and BI-RADS classification of breast nodules in Chinese urban women, alongside an exploration of factors associated with BI-RADS 4–5. The findings underscore the pressing need for greater attention to female breast nodules and provide valuable foundational data for optimizing high-risk management in China's urban female population.

Conflicts of interest: No conflicts of interest

Ethical statement: Granted by the Peking University Institution Review Board (IRB-0000152-19077).

Funding: Strategic Research and Consultancy Project of the Chinese Academy of Engineering (2023-JB-11).

doi: 10.46234/ccdcw2025.056

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Submitted: February 10, 2025

Accepted: February 26, 2025

Issued: March 07, 2025

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