Comparison of 99mTc-MIBI, ultrasound, and mammography for the diagnosis of BI-RADS 4 category lesions

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Abstract

Introduction: We sought to determine the diagnostic efficacy of BSGI in Chinese women with BI-RADS 4 category lesions and to compare this efficacy to that of ultrasound/mammography.

Methods: We retrospectively assessed 177 women who had undergone BSGI of BI-RADS 4 category lesions detected via ultrasound and/or mammography.

Results: Of the 177 cases, 117 (66.1%) were malignant lesions and 60 (33.9%) were benign. The sensitivity, specificity, positive, and negative predictive values of BSGI were 94.9% (111/117), 78.3% (47/60), 89.5% (111/124), and 88.7% (47/53), respectively. For mammography, the specificity and positive predictive values were 48.3% (29/60) and 77.5% (107/138), while for ultrasound they were 53.3% (32/60) and 79.6% (109/137). The sensitivity and specificity of BSGI for the detection lesions ≤ 1 cm were 90.9% (10/11) and 88.0% (22/25), while these values for breast lesions ≥ 1 cm were 94.3% (100/106) and 71.4% (25/35), and these values for dense breast tissue were 94.0% (79/84) and 78.0% (39/50), as opposed to non-dense breast values of 97.0% (32/33) and 80.0% (8/10). The sensitivity of BSGI for IDC and DCIS were 98.9% (95/96) and 75.0% (9/12). The tumor to normal tissue ratio of BSGI for malignant lesions was significantly higher than that of benign lesions (2.18 ± 1.17 vs 1.66 ± 0.40 , $t = 7.56$, $P < 0.05$).

Conclusions: These results reveal that BSGI is highly sensitive, with good positive/negative predictive values. BSGI for IDC proved to be superior to DCIS for diagnosis of BI-RADS 4 category lesions as compared with ultrasound or mammography. BSGI showed perfect results in density breasts and lesions ≤ 1 cm in size. **Keywords :** Breast cancer; BSGI; Mammography; $^{99m}\text{Tc-MIBI}$; Ultrasound

1 Background

Rates of cancer have increased by nearly 28% in the decade of 2006-2016, with breast cancer remaining the most frequent cancer causing death in women^[1]. Early stage breast cancer diagnosis can improve survival in affected patients. Herein we sought to assess Breast Imaging Reporting and Data System (BI-RADS) 4 category lesions detected via ultrasound and/or mammography in order to resolve the best approach for accurate diagnosis thereof. The BI-RADS 4 classification is intended to designate potentially suspicious masses warranting biopsy, with 3 subgroups (4a, 4b, and 4c) of increasing suspicion. These lesions by definition do not have a morphology characteristic of breast cancer, however they have a risk of malignancy that can range from 2-95% over time. This variability can lead to the unnecessary biopsy and over-treatment of benign lesions^[2]. Breast-specific gamma imaging (BSGI) is an improved means of the high-resolution radioimaging of breast tissues using a small field-of-view gamma camera confined to the breast region. In this manuscript we aimed to assess the diagnostic efficacy of using BSGI for the differential diagnosis of BI-RADS 4 lesions identified via ultrasound/mammography, and to compare this approach with those two other diagnostic methods in order to establish the clinical value of BSGI.

2 Methods

2.1 General information

The hospital ethics committee approved this retrospective study. Written informed consent was obtained from each patient. In total, we retrospectively studied 177 patients who were diagnosed and treated at the Hospital (Second Affiliated Hospital of Zhejiang University School of Medicine, Hangzhou, China) between January, 2015 and June, 2018. Each patient had been identified as having BI-RADS 4 category masses based via ultrasound and/or mammography assessments who had also undergone BSGI at the Hospital. Patients who had previously undergone surgery for breast cancer were not included in this study. After imaging examination, histopathologic confirmation was performed via surgical excision or core needle biopsy. All patients' clinical records were reviewed, while clinicopathological characteristics, including age, menstrual state, clinical stage, lesion location, tumor size and grade, and histological type were obtained from medical records at our institution.

2.2 Imaging method

A antecubital vein injection of 555-740 MBq of ^{99m}Tc -MIBI (Shanghai GMS Pharmaceutical Co., Ltd) was administered to patients. Once 10 minutes had elapsed following tracer injection, BSGI was conducted. Patients in a sitting position were imaged with a breast-specific gamma camera (Dilon 6800; Dilon Technologies Inc., USA), allowing for the high-resolution bilateral collection of craniocaudal (CC) and mediolateral oblique (MLO) images. Two physicians specializing in nuclear medicine interpreted all BSGI images according to the Society of Nuclear Medicine published BSGI operation guidelines for interpreting BSGI imaging results^[3]. Positive BSGI tumors were those which were determined to either exhibit a tumor-to-normal tissue ratio (TNR) > 2.09, or to be highly suspicious. Lesions analyzed by ultrasound were determined to be positive based on suspicious appearance suggesting the need for biopsy or removal. Two radiologists interpreted all mammography images based on BI-RADS classification.

2.3 Statistical analysis

The sensitivity, specificity, positive and negative predictive values for BSGI, ultrasound and mammography were determined. The relative efficiencies of BSGI, ultrasound, and mammography, as well as the semi-quantitative indicators thereof, were calculated and compared via χ^2 tests. SPSS v20 was used for all statistical testing, with $P < 0.05$ as the significance threshold.

3 Results

3.1 Ultrasound and mammography

Our study included 177 patients, of whom 135 (76.3%) were diagnosed with BI-RADS 4 category lesions by ultrasound, 127 (71.8%) cases were diagnosed as having BI-RADS category 4 lesions via mammography, and 87 (49.1%) were diagnosed with via both of these approaches.

3.2 Pathologic results

Of the 177 female patients, 117(66.1%) were ultimately found to be malignant. Of those with malignant lesions, the average patient age was 53.5y, with a range from 23 to 89y. Detected malignant lesions included invasive

ductal carcinomas(IDC, n=96), ductal carcinomas in situ (DCIS, n=12), invasive lobular carcinomas (n=2), malignant phyllodes tumors (n=2), and others (n=5). The remaining 60 (33.9%) cases proved to be benign. Of patients with benign lesions, the average age was 47.2y, with a range from 19 to 74y. Benign lesions included fibroadenomas (n=31), adenosis (n=18), intraductal papillomas (n=7), atypical ductal hyperplasias (n=2), and others (n=5).

3.3 Diagnosis via BSGI, ultrasound, and mammography

The TNR cut-off for sensitivity and specificity was 2.09(Se:62.4%, Sp:78.6%) (Fig 1. A). We found that there was a statistically valid correlation between lesion malignancy and TNR ratio. The TNR ratio for the malignant group was 2.18 ± 1.17 , while the TNR ratio for the benign group was 1.66 ± 0.40 ($t=7.56$, $P<0.05$). The sensitivity of BSGI, mammography, and ultrasound for malignant lesion detection reached 94.9%, 91.5%, and 93.2%, respectively. BSGI had the greatest specificity at 78.3%, compared to mammography(48.3%, $P<0.05$) and ultrasound(53.3%, $P<0.05$) (Fig 1. B). Sensitivity and specificity findings for these imaging approaches are shown in Table 1.

Malignant lesions were between 3 mm and 74 mm, with 11 lesions being smaller than 10 mm. Benign lesions were between 2 mm and 44 mm, with 25 lesions being smaller than 10 mm. The sensitivity of BSGI was similar to ultrasound for lesions ≤ 1 cm, whereas BSGI specificity was highest at 88.0%, as compared to mammography(40.0%, $P<0.05$) and ultrasound (64.0%, $P<0.05$) (Fig 1. C). For lesions ≥ 1 cm in size, the specificity of BSGI was 71.4% as compared to ultrasound at 45.7% ($P<0.05$) (Fig 1. D).

The American College of Radiology BI-RADS classifications are intended to offer a standardized means of reporting on the density of mammographic findings. Of these 177 subjects, 134 (75.7%) were shown to have dense breast tissue with a BI-RADS density category of 3 or 4 on mammography. In these women, BSGI specificity was highest at 94.0%, as compared to mammography(44.0%, $P<0.05$) and ultrasound (56.0%, $P<0.05$) (Fig 2. A). In pre- or post-menopausal women, BSGI sensitivity was not greater than that of mammography or ultrasound, nor was there a significant difference in sensitivity between the pre- and post-menopausal groups (Fig 2. B). With respect to cancer types, the sensitivity for the detection of IDC by BSGI was superior to that of DCIS ($P<0.05$). The sensitivity of BSGI was equivalent between luminal-A, luminal-B, HER2(+), and triple negative breast cancers (Fig 2. C). BSGI sensitivity for detecting ductal carcinomas in situ was similar to that of mammography or ultrasound (Fig 2. D).

3.4 False-positive and -negative BSGI findings

This study revealed 13 false-positive and 6 false-negative BSGI findings, the pathology findings of which are shown in Table 2.

4 Discussion

We believe this to be the first study exploring the diagnostic efficacy of BSGI for differentiating between malignant and benign BI-RADS 4 lesions as compared to that of ultrasound or mammography in Chinese women. Our results demonstrate that BSGI is well-suited to the diagnosis of suspicious lesions. Generally, screening-based mammography is one of the primary approaches to breast cancer screening. Mammography has a high degree of sensitivity for the detection of breast cancer in most patients, and it has been widely implemented clinically, leading to a decline in breast cancer death rates^[4]. While mammography has become the standard means of breast cancer screening, it is influenced by breast density and the presence of scar tissue, with the degree of density leading to sensitivity values ranging from 85% to 68%. Breast density is also strongly correlated with the risk of breast cancer^[5-7]. Among Chinese populations, approximately 75% of women have heterogeneously or extremely dense breasts, limiting the utility of mammography-based screening. This is particularly true in young populations, where there is a trend towards increased breast cancer incidence, and as such an alternative method of breast cancer detection is needed for this population. Unlike mammography, the sensitivity of the BSGI is not affected by breast tissue density, prosthesis implantation, structural deformation, scarring, or radiation therapy. Yu et al.^[8] reported that the diagnostic specificity of BSGI for breast cancer was high (83.2%), and BSGI in women with dense breast tissue was superior to mammography. Kessler et al.^[9] reported on 93 cases of BI-RADS 4 breast lesions detected via mammography, with a positive rate of biopsy of 14%. Some special pathological types of breast cancer, such as invasive lobular carcinomas in the early stage of disease, are difficult to detect by conventional imaging, while the detection rates for such carcinomas by BSGI are over 90%^[10]. Consistent with this, in this study 2 lesions of invasive lobular carcinoma were correctly diagnosed by BSGI.

Ultrasound, as a first-line examination to differentiate between benign and malignant breast lesions, offers the advantages of being non-invasive, convenient, and requiring little time. It has been widely used for the BI-RADS classification of breast lesions in the clinic. However, the utility of ultrasound for breast lesions has been varied for some types of lesions, with a lack of specificity for some, or overlap of benign and malignant signals^[11]. Patients with mammary intraductal papillomas typically present with nipple discharge and lumps in the cancer area, which are characterized by catheter expansion and a hypoechoic lesion upon ultrasound. Tadvalkar et al.^[12] retrospectively analyzed BSGI findings for 139 females with invasive carcinoma. The efficiency of BSGI-mediated diagnosis of breast cancer is related to tumor differentiation and size. In this study, for lesions ≤ 1 cm, the sensitivity of BSGI was similar to that of ultrasound, while the specificity of BSGI was superior to ultrasound. In addition, 4 intraductal papillomas were misdiagnosed by ultrasound, yet were correctly diagnosed via BSGI.

Ultrasound and mammography are anatomical methods for detecting breast cancer. Nuclear medicine approaches that rely on the physiological characteristics of tumors are increasingly common. The detection of breast cancer can be improved by using physiological imaging as an auxiliary imaging method. BSGI, as a functional imaging test, compared with the traditional planar scintigraphy, BSGI has

better sensitivity, especially in patients with dense breasts, and it is also better for detecting subcentimeter (≤ 1 cm) lesions^[8]. The radioactive tracer $^{99m}\text{Tc-MIBI}$, after injection into the human body, enters into mitochondria. The number of mitochondria in cells is closely related to cell activity, and as malignant cells have a higher metabolic rate they have more mitochondria. As a result, the uptake of $^{99m}\text{Tc-MIBI}$ in cancer cells is greater than in surrounding normal tissues. In vitro experiments show that tumor cells absorb $^{99m}\text{Tc-MIBI}$ at a rate more than 50% higher than do normal cells^[13]. Kim et al.^[14] conducted a retrospective analysis of 520 suspected breast cancer patients. When using $^{99m}\text{Tc-MIBI}$ imaging, the malignant group TNR was 2.00 ± 1.88 , and this was significantly higher than in the benign group (0.60 ± 0.70). In our study, the TNR in the malignant group was 2.18 ± 1.17 , significantly higher than the benign group (1.66 ± 0.40).

Other modes of examination such as shear-wave elastography (SWE) and breast MRI have also been used to try and improve diagnostic accuracy for breast cancer. SWE, a quantitative imaging technique, is widely used during breast imaging. Because breast malignant tissues are harder than normal tissues, SWE not only can locally quantify tissue hardness but also provide histological information. Yoon et al.^[15] conducted an analysis of 199 consecutive women, demonstrating that the false-positive rates of SWE were significantly higher than the false-negative rates of SWE. Size, breast thickness, and depth all influenced SWE findings. Bilimoria et al.^[16] reported that breast MRI is the most sensitive imaging modality for detecting breast cancer, and it may reveal breast cancers which are hidden to physical examination and assessment via mammography and ultrasound. Breast MRI not only has a considerable false-positive rate but also has the potential to enlarge the extent of the tumor in question. As a result, women assessed in this manner may undergo an unnecessary mastectomy. Finally, the conventional use of breast MRI is limited by the cost of magnetic resonance imaging. In addition, the continued development of digital x-ray systems has enabled further techniques such as contrast mammography to overcome the limitations of mammography, and similar novel approaches are now being investigated. Fallenberg^[17] et al. reported that contrast mammography is as accurate as MRI, however this is an invasive technique, and the injection of contrast agents is not acceptable or suitable for breast cancer screening efforts.

$^{99m}\text{Tc-MIBI}$, as a non-specific tumor imaging agent, can lead some benign lesions undergoing active hyperplasia can give false-positive results, decreasing diagnostic performance. Fibrocystic breast disease, fibroadenomas, and breast benign hyperplasias were the most common types of false positive lesions detected by BSGI^[18]. Malignant breast tumors can promote local angiogenesis, and some benign growths may mimic this activity, although in a manner not equivalent to that of malignant lesions. For example, some intraductal papilloma, inflammatory lesions, fibroadenomas, or adenopathies have abundant blood supplies. Inflammatory lesions also have the characteristics of inflammatory cells, with peripheral irregular infiltration of surrounding tissues. Weight et al.^[19] reported that BSGI provided a higher rate of change in management of patients (109/119) as compared with ultrasound (71/119), which positive findings, BSGI performed better than ultrasound in terms of a positive predictive values and accuracy. In total this study identified a total of 13 lesions with a false-positive findings on BSGI.

Limitations of BSGI

There are certain limitations to the use of BSGI for breast imaging. First, during BSGI, patients were injected of ^{99m}Tc -MIBI, a radiopharmaceutical, 555-740MBq. Patients are exposed to 6.29–9.44 mSv of radiation on average^[14,20]. Patients who have suspicious lesions or dense breast tissue may be recommended for BSGI, necessitating a longer acquisition time and a lower doses. Second, as this is a planar test there is a risk of improper positioning.^[12,21] Finally, BSGI was also a relatively insensitive approach for axillary lymph node detection.

Conclusion

In summary, for Chinese women, BSGI has a good diagnostic efficacy for the differential diagnosis of the breast tumor BI-RADS 4 category on ultrasound and/or mammography. Likewise, BSGI achieved perfect efficacy for detecting breast lesions in dense breast tissues and lesions ≤ 1 cm in size. These results demonstrated that BSGI may be useful as an auxiliary imaging modality for detecting suspicious lesions, and can reduce the need for unnecessary biopsy and surgical procedures, further reducing rates of misdiagnosis, and can further improve the diagnosis of breast cancer.

Abbreviations

BSGI, breast specific gamma imaging; BI-RADS, breast imaging reporting and data system; IDC, invasive ductal carcinomas; DCIS, ductal carcinomas in situ; TNR, tumor-to-normal tissue ratio; PPV, positive predictive value; NPV, negative predictive value; SWE, shear-wave elastography.

Declarations

Competing interests

The authors declare that they have no competing interests.

Ethics approval and consent to participate

This study was approved by Second Affiliated Hospital of Zhejiang University School of Medicine ethics committee and all the patients had given written informed consent.

Authors' contributions:

HBL participated in its design and prepared the figures, performed patient follow-up, analysed and interpreted the data. SD participated in the design of the study and drafted the manuscript. HWZ conceived of the study and contributed to the critical revision of the manuscript. All authors read and approved the final manuscript.

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Tables

Table 1.Comparison of BSGI, mammography, and ultrasound sensitivity and specificity for BI-RADS 4 lesions

Approach	Sensitivity	Specificity	PPV	NPV
BSGI	94.9(111/117)	78.3(47/60)	89.5(111/124)	88.7(47/53)
Mammography	91.5(107/117)	48.3(29/60) ^{*a}	77.5(107/138) ^{*b}	74.4(29/39)
Ultrasound	93.2(109/117)	53.3(32/60) ^{*a}	79.6(109/137) ^{*b}	80.0(32/40)

(PPV, positive predictive value; NPV, negative predictive value.)

^{*a})BSGI to Mammography, *P*< 0.05, to Ultrasound, *P*< 0.05.

^{*b}) BSGI to Mammography, *P*< 0.05, to Ultrasound, *P*< 0.05.

Table 2 Analysis of BSGI false-positive and false-negative in diagnostic of BI-RADS 4 category lesions

False-positive		False-negative	
Classification	Number	Classification	Number
Sclerosing Adenosis	6	Ductal carcinomas in situ	3
Fibroadenoma	3	Invasive ductal carcinomas	1
Usual ductal hyperplasia	2	Tubular carcinoma	1
Intraductal papilloma	1	Mucinous carcinoma	1
Chronic inflammation	1		

Figures

Figure 1

Diagnostic of BSGI, MMG, and US for breast lesions. A. A ROC analysis determining cut-off value of TNR in detection of breast cancer. B. Sensitivity of BSGI, MMG and US for detecting breast cancer on BI-RADS 4 category lesions. C. Sensitivity of BSGI, MMG and US for detecting breast cancer ≤ 1 cm. D. Sensitivity of BSGI, MMG and US for detecting breast cancer > 1 cm.

Figure 2

Sensitivity of BSGI, MMG, and US in different trails of breast cancer. A. Sensitivity and specificity of BSGI, MMG and US for detecting breast cancer within dense tissue. B. Sensitivity of BSGI, MMG and US for detecting breast cancer for premenopausal and postmenopausal women. C. Sensitivity of BSGI, MMG and US for detecting different breast cancer molecular subtypes. D. Sensitivity of BSGI, MMG and US for detecting DCIS.

Figure 3

Breast image of a 57-year-old woman. (1) Mammography (LCC, LMLO) demonstrated a cluster of amorphous micro calcifications in the upper outer quadrant area, BI-RADS 4B; (2) Ultrasound demonstrated an hypoechoic lesion at 2 o'clock of the left breast, 0.6 cm*0.4 cm BI-RADS 4A; (3) BSGI was negative and was shown to be normal; Pathology demonstrated a usual ductal hyperplasia.

Figure 4

Breast image of an 89-year-old woman. (1) Ultrasound demonstrated a cystic solid mass at the upper outer region of the right breast, 4.4cm*3.5cm; (2) Mammography demonstrated a high density shadow at the upper outer region of the right breast, 44mm*46mm, BI-RADS 4B; (3) BSGI revealed focal increased radiotracer uptake in the right breast TNR=3.59; Pathology identified a 74-mm invasive ductal carcinoma.

Figure 5

Breast image of a 66 -year--old woman. (1) No mammographic evidence of dense breast abnormalities; (2) An ill--defined hypoechoic nodule was detected via ultrasound at 8 h of the left breast $0.6\text{cm} \times 0.5\text{cm}$ BI-RADS 4B (3) BSGI revealed focal increased radiotracer uptake in the left breast, $\text{TNR}=3.21$ Pathology confirmed a 7-mm invasive ductal carcinoma.