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The usefulness of addition of breast-specific gamma imaging to mammography in women with dense breast

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Abstract

Background Mammography (MG) has been adopted as a screening modality for breast cancer. However, the diagnostic yield was reported to decrease in women with dense breasts in MG. Several modalities have been introduced to improve the drawbacks. Breast-specific gamma imaging (BSGI) is a new technique in nuclear medicine imaging that could support breast cancer diagnosis. The aim of this study was to evaluate whether the addition of BSGI according to MG category could improve the accuracy of diagnosis and reduce unnecessary studies or biopsies.

Results From February 2013 to December 2018, 548 patients with 628 breast lesions were enrolled in this retrospective study. The performances of BSGI and MG were evaluated for detecting breast cancer. We classified subgroups by adding the results of BSGI for BI-RADS category 0 and 4a lesions on MG. For each subgroup, diagnostic performance was calculated in overall and dense/non-dense. Factors associated with false-negative BSGI were evaluated. The sensitivity of BSGI (88.26%) was comparable to that of MG (87.95%) ($P > 0.05$). Specificity (81.44%) and AUC (0.85) of BSGI were significantly superior to those of MG (66.83% and 0.77, respectively). In the subgroup analysis of BSGI plus MG, the sensitivity of BSGI + MG0 and BSGI + MG4a were 95.98% and 94.64%, respectively. And specificities were 69.80% and 77.23%, respectively. Sensitivity and AUC of subgroups increased significantly compared to those of MG alone in overall and dense breasts. A nodule ≤ 10 mm and a low Ki-67 showed significant association with the false negativity of BSGI.

Conclusions Applying BSGI to MG, notably for breast lesions with BI-RADS category 0 or 4a, could improve the diagnostic performance, even in dense breasts.

Keywords Breast-specific gamma imaging, Mammography, Breast density, Breast cancer, Diagnosis

Background

Mammography (MG) has been widely adopted as a screening imaging method. It has been demonstrated to upgrade outcomes for breast cancer diagnosis [1]. Breast density is an independent risk factor for the development of breast cancer, and it has been reported that the sensitivity of women with dense breasts in MG decreases to 48–68% [2]. Several modalities have been introduced, such as breast ultrasonography (US), breast magnetic resonance imaging (MRI), and tomosynthesis, for improving breast cancer detection in women with dense breasts. The sensitivity of US combined with MG was increased by approximately 91.1% [3]. The yield of whole-breast US has been reported to improve cancer detection (3.5–4.4 additional cancers per 1000 screened) in women with dense breasts. However, the disadvantages of whole-breast US are high false-positive rates and low positive predictive values [4]. Breast MRI is recommended as the first choice for supplemental screening in

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women at higher risk of breast cancer because of its high sensitivity, even in women with dense breasts. However, it causes high recall rates, increases cost and scan time, and requires the use of contrast agents [5].

Breast-specific gamma imaging (BSGI) is a new nuclear medicine technique that uses a physiological approach to detect breast lesions. Several studies have reported that BSGI improved breast cancer detection accuracy [6]. BSGI is a more comfortable and inexpensive study for patients and a less time-consuming method for physicians to interpret the results [7, 8].

This study has focused on the Breast Imaging Reporting and Data System (BI-RADS) category 0 and category 4a lesion. The lesion with BI-RADS category 0 or 4a needs additional study or a biopsy. The malignancy risk of category 0 (6.8–7.2%) and category 4a (2–10%) are relatively low [9–11]. In reality, the BIRADS category 4a lesions constitute a substantial portion of breast biopsies [12]. However, it showed poor inter-rater reliability and low positive predictive value [9].

In this retrospective study, we compared the performances of BSGI with those of MG among the overall and dense groups for malignant breast lesions. We also performed subgroup analyses through the selective application of BSGI results according to MG results.

Methods

Study population

This retrospective study was approved by the Institutional Review Board of ******, having waived written informed consent for data access. From February 2013 to December 2018, 1209 patients who performed BSGI were reviewed. BSGI was performed on the following cases: (a) patients who were diagnosed with a malignancy prior to surgery, (b) patients with suspicious lesions on other imaging modalities, and (c) patients with multiple benign looking lesions on other imaging modalities. We excluded patients who operated for malignant and high-risk lesions [atypical ductal hyperplasia (ADH), atypical lobular hyperplasia (ALH), and lobular carcinoma in situ (LCIS)] or who performed BSGI during chemotherapy due to breast cancer. Patients without follow-up were also excluded. A total of 661 patients were excluded. For multiple breast lesions, each lesion was counted as one lesion. 628 lesions of 548 patients were enrolled.

Image acquisition and interpretation

Mammography

Mammography was performed with a Senographe DS (Lorad Selenia, Hologic, Marlborough, MA, USA) in the craniocaudal and mediolateral oblique projections. Expert breast radiologists interpreted all images. Mammography was evaluated by BI-RADS [10]. Patients with predominantly fatty replaced (BI-RADS density 1) or scattered fibroglandular tissue (BI-RADS density 2) breasts were classified as non-dense, and those with heterogeneously dense (BI-RADS density 3) or extremely dense tissue (BI-RADS density 4) were classified as dense. BI-RADS Categories 0, 4 (4a, 4b, 4c), and 5 were considered positive findings. And BI-RADS category 1, 2, and 3 were considered negative findings.

Breast-specific gamma imaging

Breast-specific gamma imaging was conducted after injection with 30 mCi (1110 MBq) of technetium-99 m sestamibi (Dong-A Pharmaceutical, Seoul, Korea) into an arm vein or a dorsalis pedis vein. Craniocaudal and mediolateral views were taken on each breast with a breast-specific, high-resolution, small field-of-view gamma camera (Dilon 6800 Gamma Camera, Dilon Technologies, Newport News, VA).

One nuclear medicine specialist interpreted all BSGI images without the pathology information. BSGI images with no focal lesion or scattered physiologic uptake are regarded as a negative finding. A focal lesion with increased uptake on BSGI images was regarded as a positive finding. It was checked whether the focal uptake lesion on BSGI was consistent with the biopsy-proven lesion on other breast imaging modalities.

Histopathological evaluation

The histopathological diagnoses were retrieved from the electronic records of our institution. The final histopathological diagnoses were made based on evaluations of the surgical specimens of patients who underwent surgery after the imaging studies. Evaluation of core-needle biopsy specimens was considered representative of patients who declined surgery or were transferred to other hospitals. In the case of benign lesions, the diagnosis was performed based on the result of core needle biopsy result or follow-up imaging on other modalities at least 2 years later. For malignant lesions, we reviewed the histologic type, presence of the carcinoma in situ component or extensive intraductal component, nuclear grade, estrogen receptor (ER) status, progesterone receptor (PR) status, human epidermal growth factor receptor 2 (HER2) status, Ki-67 index, and tumour size. The Ki-67 was classified as positive if the Ki-67 positive nuclei content was 14% or more. The tumour size was determined as the largest diameter.

Statistical analysis

We compared the performances of BSGI with those of MG for malignant breast lesions in all patients and dense breast group. We performed subgroup analyses through the selective addition of BSGI results according

to the MG results: BSGI + MG, BSGI + MG0, and BSGI + MG4a. The subgroups were divided as follows (Fig. 1).

(1) *BSGI + MG group* the final assessment was considered positive if there was at least one positive result on MG or BSGI. The final assessment of BSGI + MG was considered negative only if both MG and BSGI results were negative.
(2) *BSGI + MG0 and BSGI + MG4a group* the final assessment was decided according to the BSGI results.

The receiver operating characteristic curve with the area under the curves (AUCs) were compared among those subgroups. We calculated sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) to detect malignancy in each group. The McNemar test was used to evaluate the statistical significance of any difference in sensitivities and specificities among the modalities. We analysed the factors associated with a false negative.

All statistical analyses were performed using MedCalc Software, v.19.6.4 statistical software (Mariakerke, Belgium) or SPSS 19.0 software (SPSS Inc., Chicago, IL, USA). A p value < 0.05 was considered statistically significant.

Results

548 patients (median age, 54.6 years; range, 25–89 years) with 628 lesions were included in this study. There were 224 malignant lesions and 404 benign lesions in pathologic diagnosis and follow-up imaging studies. 468 patients had dense breasts, and 80 had non-dense breasts (patient age; dense, 52.92 ± 8.42 vs non-dense, 65.52 ± 11.13, $p < 0.05$). Malignant lesions were 165 in dense and 59 in non-dense breasts. Benign lesions were 378 in dense and 26 in non-dense breasts. Breast-specific gamma imaging showed 273 positive results and 355 negative results. Of 273 positive BSGI results, 198 lesions were confirmed to be malignant by biopsy, 75 were confirmed to be benign. Among the benign lesions, the diagnosis of 70 was confirmed by biopsy, and the remaining five were confirmed through follow-up imaging. In negative BSGI, of which 26 were confirmed malignant. Mammography showed positive results in 331 cases, 197 of which lesions were malignant and 134 benign. In negative MG, of which 27 were confirmed benign. Pathologic subtypes of breast cancers are described in Table 1.

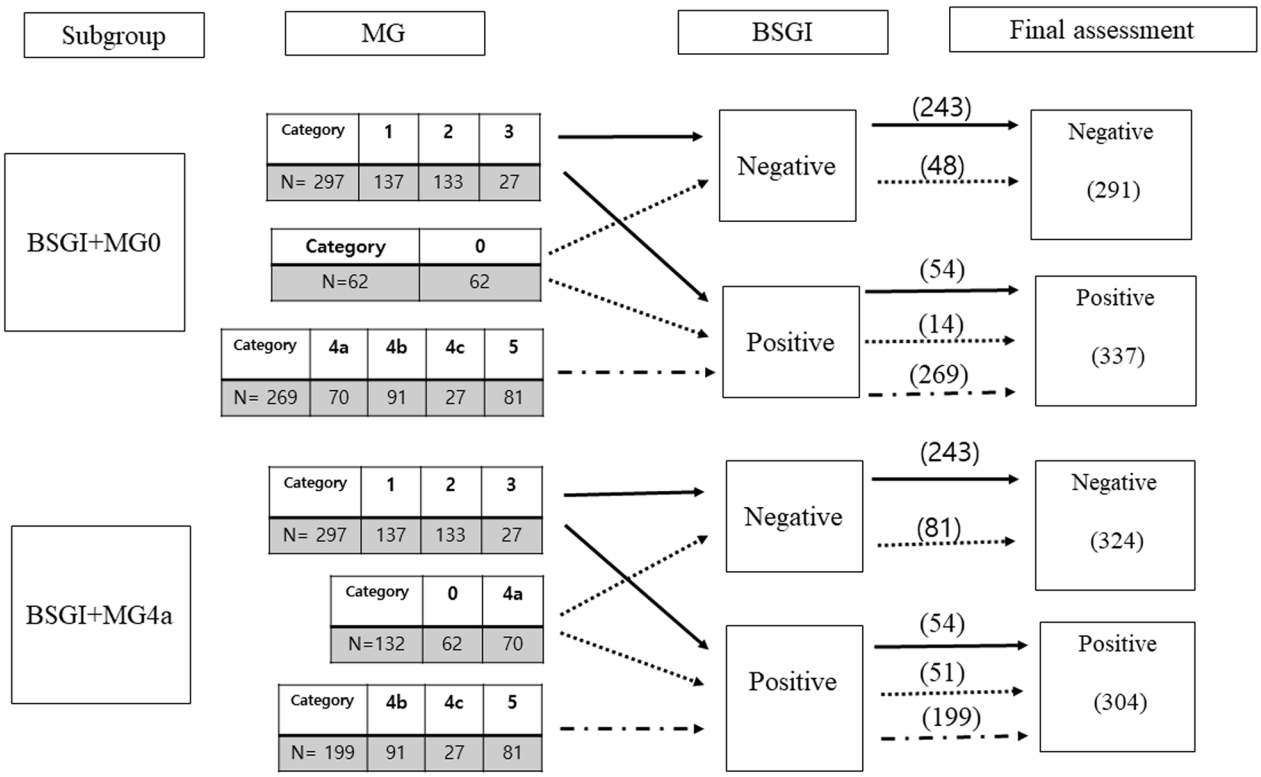

Fig. 1 The subgroups of mammography

Table 1 Pathology characteristics of breast cancers (n = 224)

Characteristic	No. of cases (%)	Characteristic	No. of cases (%)
Histologic subtype		*Estrogen receptor*	
IDC	166 (74.1%)	Positive	160
DCIS only	37 (16.5%)	Negative	64
ILC	9 (4.0%)	*Progesterone receptor*	
Papillary carcinoma	4 (1.8%)	Positive	138
Metaplastic carcinoma	2 (< 1%)	Negative	86
Mucinous carcinoma	2 (< 1%)	*HER2 status*	
ACC	1 (< 1%)	Positive	55
Others[a]	3 (1.3%)	Negative	169
Tumor size		*Ki-67 index*[b]	
< 1.0 cm	42	Low	30
≥ 1.0 cm	182	High	152
Nuclear grade			
Low	133		
High	91		

IDC invasive ductal carcinoma, *DCIS* ductal carcinoma in situ, *ILC* invasive lobular carcinoma, *ACC* adenoid cystic carcinoma

[a] Other types: Invasive carcinoma of no special type (n = 1), poorly differentiated carcinoma (n = 1), and Paget's disease (n = 1)

[b] Ki-67 index was reported in 182 cases

Overall diagnostic performance of BSGI and MG for detecting malignant lesions

The overall performance of BSGI and MG is shown in Table 2. For detecting malignant lesions, the specificity of BSGI (81.44%) was significantly higher than that of MG (66.83%) ($P < 0.001$). The AUC of BSGI (0.85) was significantly higher than that of MG (0.77) ($P < 0.001$). Table 3 shows the diagnostic performance of MG and BSGI according to breast density. There are no significant differences in sensitivity and specificity in BSGI. No significant difference was observed in the sensitivity of MG according to breast density. However, the specificity of MG was significantly higher in dense breasts (dense, 69.31% vs non-dense, 30.77%, $P < 0.001$). The NPV of BSGI was significantly higher in dense breasts (dense, 93.90% vs non-dense, 77.78%, $P = 0.009$).

Diagnostic performance of the subgroups for detecting malignant lesions

The sensitivity (96.43%, CI; 93.1–98.4%) of BSGI + MG was significantly higher than that of MG alone ($P < 0.001$) in all patients. Meanwhile, the specificity of BSGI + MG was significantly lower than that of MG alone ($P < 0.001$). There is no significant difference in AUC between

Table 2 Comparison of the overall performance of MG, BSGI and subgroups for detecting malignancy

	MG	BSGI	*P* value	BSGI_MG	*P* value[a]	BSGI_MG0	*P* value[b]	BSGI_MG4a	*P* value[c]
Sensitivity (CI)	87.95 (82.9–91.9)	88.39 (83.5–92.3)	1.000	96.43 (93.1–98.4)	< 0.001	95.98 (92.5–98.1)	< 0.001	94.64 (90.8–97.2)	0.003
Specificity (CI)	66.83 (62.0–71.4)	81.44 (77.3–85.1)	< 0.001	58.17 (53.2–63.0)	< 0.001	69.80 (65.1–74.2)	0.224	77.23 (72.8–81.2)	< 0.001
AUC (CI)	0.774 (0.739–0.806)	0.849 (0.819—0.876)	< 0.001	0.773 (0.738–0.805)	0.978	0.829 (0.797–0.858)	0.022	0.859 (0.830–0.886)	< 0.001
PPV (CI)	59.52 (54.0–64.8)	72.53 (66.8–77.7)		56.10 (51.0–61.1)		63.80 (58.4–68.9)		69.74 (64.2–74.9)	
NPV (CI)	90.91 (87.0–93.9)	92.68 (89.5–95.2)		96.71 (93.6–98.6)		96.91 (94.2–98.6)		96.30 (93.6–98.1)	

BSGI breast-specific gamma imaging, *MG* mammography, *CI* confidence interval, *PPV* positive predictive value, *NPV* negative predictive value

[a] MG versus BSGI

[b] MG versus BSGI + MG0

[c] MG versus BSGI + MG4a

Table 3 Diagnostic performance of MG and BSGI according to breast density for detecting malignancy

	MG			BSGI		
	Nondense	**Dense**	***P* value**	**Nondense**	**Dense**	***P* value**
Sensitivity (CI)	94.92 (85.9–98.9)	85.45 (79.1–90.5)	0.55	89.83 (79.2–96.2)	87.88 (81.9–92.4)	0.688
Specificity (CI)	30.77 (14.3–51.8)	69.31 (64.4–73.9)	0.000	80.77 (60.6–93.4)	81.48 (77.2–85.3)	0.928
PPV (CI)	75.68 (64.3–84.9)	54.86 (48.6–61.1)	0.001	91.38 (81.0–97.1)	67.44 (60.7–73.7)	0.000
NPV (CI)	72.73 (39.0–94.0)	91.61 (87.8–94.5)	0.068	77.78 (57.7–91.4)	93.90 (90.7–96.2)	0.009
AUC (CI)	0.628 (0.517–0.731)	0.774 (0.736–0.808)		0.853 (0.760–0.920)	0.847 (0.814–0.876)	

MG mammography, *BSGI* breast-specific gamma imaging, *CI* confidence interval, *PPV* positive predictive value, *NPV* negative predictive value

BSGI + MG (0.77, CI 0.74–0.81) and MG alone ($P > 0.05$) (Table 2). In BSGI + MG0 groups, sensitivity (95.98, CI 92.5–98.1) and AUC (0.83, CI 0.80—0.86) were significantly higher than those of MG alone in all patient. The specificity showed no significant difference (69.80, CI 65.1–74.2). In BSGI + MG4a groups, sensitivity (94.64%, CI 90.8–97.2%), specificity (77.23%, CI 72.8–81.2%) and AUC (0.86, CI 0.83–0.89) were significantly higher than those of MG alone (Table 2).

In patients with dense breasts, the sensitivities of BSGI + MG, BSGI + MG0, and BSGI + MG4a were significantly higher than that of MG alone (Table 4). The specificity of BSGI + MG4a was significantly higher than that of MG alone. The AUCs of BSGI + MG0 and BSGI + MG4a were significantly higher than that of MG alone.

Analysis of false-positive and false-negative findings of BSGI

False-positive lesions were defined as having a positive result on BSGI, but no cancer was detected on pathology or follow-up images. We had 75 cases of false-positive BSGI findings; the diagnosis in 72 cases was confirmed by the results of trucut biopsy or surgical biopsy. The remaining three cases, which refused biopsy, were confirmed by follow-up images. Common pathologic diagnoses were fibrocystic changes, fibroadenomas, and intraductal papillomas. False-negative lesions were defined as lesions with negative results on BSGI; however, cancer was detected in pathology. There were 26 cases of false-negative BSGI findings.

We analysed factors associated with the false-negative lesions on BSGI, such as tumour size, breast density, nuclear grade, ER status, PR status, HER2 status, and Ki-67 index. To evaluate tumour size, we divided the lesions into groups: those less than or equal to 1.0 cm in diameter and those greater than 1.0 cm in diameter. False negative rate of BSGI was significantly higher in lesions ≤ 10 mm (13/42, 30.9%) than lesions > 10 mm (13/182, 7.1%) ($P < 0.001$). For the Ki-67 index, lesions with low Ki-67 resulted in a significantly higher proportion of false-negative (5/30, 16.7%) than those with a high Ki-67 (6/152, 3.9%) ($P = 0.008$). However, other factors had no association with false-negative findings on BSGI in this study (i.e., breast density, $P = 0.146$;

Table 4 Diagnostic performances of subgroups in dense breast

	MG	BSGI	*P* value	BSGI_MG	*P* value[a]	BSGI_MG0	*P* value[b]	BSGI_MG4a	*P* value[c]
Dense breast									
Sensitivity (CI)	85.45% (79.1–90.5)	87.88% (81.9–92.4)	0.585	95.76 (91.5–98.3)	< 0.001	95.15 (90.7–97.9)	< 0.001	93.94 (89.1–97.1)	0.003
Specificity (CI)	69.31% (64.4–73.9)	81.48% (77.2–85.3)	< 0.001	60.32 (55.2–65.3)	< 0.001	71.16 (66.3–75.7)	0.489	77.78 (73.2–81.9)	0.002
AUC (CI)	0.774 (0.732–0.816)	0.847 (0.810–0.884)	< 0.001	0.780 (0.742–0.819)	0.640	0.832 (0.797–0.866)	< 0.001	0.859 (0.825–0.892)	< 0.001

MG mammography, *BSGI* breast-specific gamma imaging, *CI* confidence interval

[a] MG versus BSGI

[b] MG versus BSGI + MG0

[c] MG versus BSGI + MG4a

nuclear grade, $P=0.478$; ER status, $P=0.737$; PR status, $P=0.758$; and HER2 status, $P=0.704$).

Discussion

Women with extremely dense breasts have an increased risk of a late breast cancer diagnosis. Asian women, including Korean, have a relatively higher incidence of dense breast tissue than western women [13]. Breast-specific gamma imaging was known to be unaffected by breast density [6]. Yu et al. reported that BSGI showed a superior result to breast US and MG in Chinese women [14]. Several studies reported that BSGI combined with MG increased breast cancer detection in dense breast women [15–17]. In this study, the sensitivity of BSGI combined with MG was significantly higher than that of MG alone in overall and dense breasts (Fig. 2). And this is in line with the previous study, reporting sensitivity of BSGI combined with MG (91%). Also, the sensitivities of subgroups were higher than that of MG alone. However, the specificity of BSGI combined with MG is lower than that of MG alone. In subgroups, the specificities did not show superior results than that of MG alone.

In this study, we applied selective addition of BSGI depending on MG category. And subgroup analyses were performed for BI-RADS category 0 and 4a lesions. For BI-RADS 0 or 4a lesions, additional studies or biopsy is required. The malignancy risk of category 0 (6.8–7.2%) and category 4a (2–10%) are relatively low compared with those of category 4b (10–50%) and category 4c (50–95%) [10, 11]. For BI-RADS category 0 lesion, which means undetermined assessment, BSGI could help to categorize the lesion more correctly. If the lesion showed a positive result on BSGI, it could be considered as requiring a biopsy. In the study by Weigert et al. [18], 119 patients were BI-RADS category 0 on mammography. Of these, 90 were correctly categorized by BSGI (90/119, 75.6%). They reported that 34 patients showed positive BSGI, of them, 15 were malignant. And 75 had negative BSGI, all benign. Our study showed 62 mammographies in patients with BI-RADS category 0. Among them, 14 lesions showed positive on BSGI, and of these, seven lesions were confirmed malignant. And in 48 lesions with BI-RADS category 0 and negative BSGI, 47 were benign and only one lesion was confirmed lobular carcinoma. In patients with BI-RADS category 0, 54 were more determinately categorized by BSGI.

For BI-RADS category 4a lesion requiring a biopsy, BSGI could reduce unnecessary biopsies. If BI-RADS category 4a lesion showed a negative result on BSGI, it could be excluded from biopsies. In our study, there were 70 mammographies in patients with BI-RADS category 4a. Thirty-two lesions showed negative on BSGI, and of these, three lesions were confirmed malignancy. Two of them were subcentimeter in size. Kessler et al.

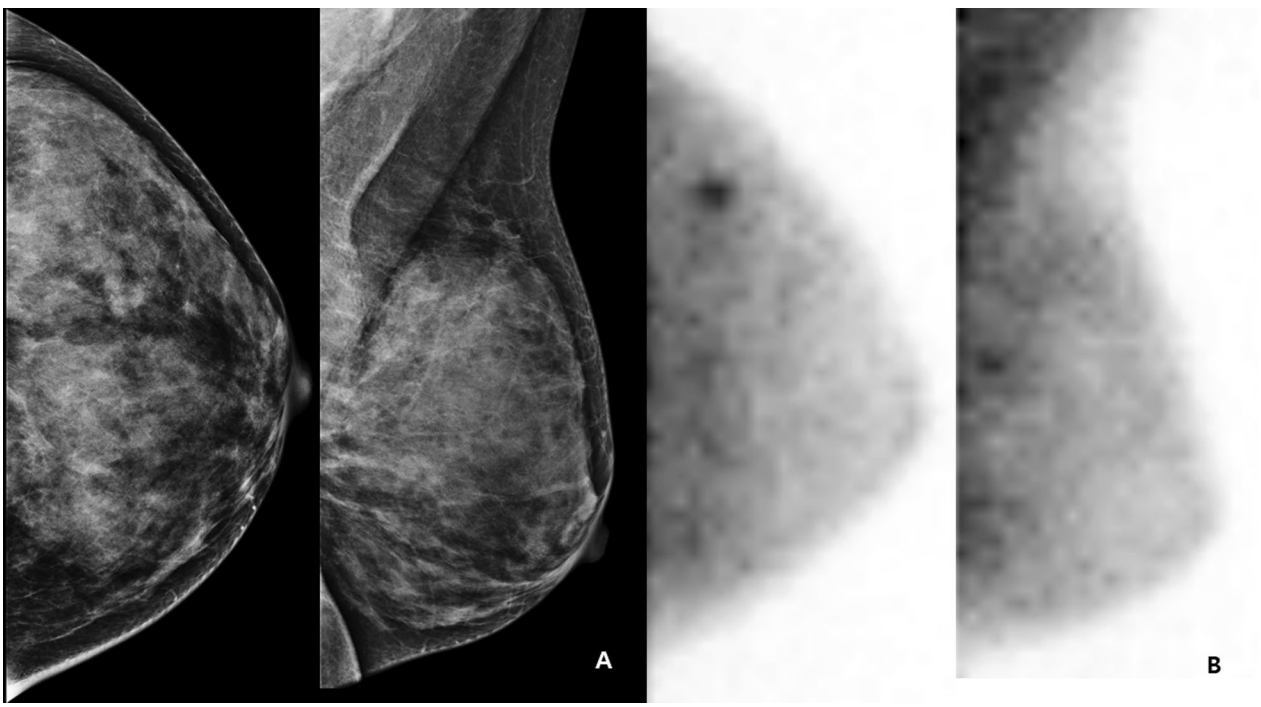

Fig. 2 There is no remarkable finding on left mammography in a woman aged 45 years with dense breast (**A**). Breast specific gamma imaging showed intense uptake in the left lateral breast (**B**). It was confirmed ductal carcinoma in situ after surgery

[12] reported that BSGI for BI-RADS category 4a lesions demonstrated an overall sensitivity of 100%, specificity of 77%, and NPV of 100%. They suggested that if BI-RADS category 4a lesions with negative BSGI findings were excluded from the biopsy, the positive biopsy rate would increase from 20 to 34%, achieving the ACR goal of 25–40% positive biopsy rate. In our study, the PPVs of BSGI_MG0 and BSGI_MG4a were 63.80% and 69.74%. The NPVs were 96.91% and 96.30%, respectively. The AUC was significantly improved by the selective addition of BSGI result to category 0 or 4a on MG. In contrast, there was no significant difference between the AUC of BSGI + MG (not selective addition of BSGI) and that of MG alone.

In dense breasts, the selective application of BSGI to MG significantly improved diagnostic yields. In dense breast, 12 lesions were BI-RADS category 0 with positive BSGI findings. Of these, six lesions were confirmed malignant. Forty-two lesions with BI-RADS category 0 had negative BSGI. Of them, 41 were benign (Fig. 3). In 58 lesions with BI-RADS category 4a, 27 lesions had negative BSGI finding. Of them, 25 lesions were benign. Thirty-one lesions had positive BSGI findings, and 15 were malignant. The selective application of BSGI to BI-RADS 0 and 4a lesions on MG, even in dense breasts, may reduce unnecessary follow-up examinations or biopsies.

Several studies have reported that a false-negative on BSGI is associated with a lesion diameter of less than 1.0 cm. It may be caused to the low cellularity, hypovascularity, and absence of inflammation in carcinomas [19, 20]. This present study is in line with those studies. A lower Ki-67 index was also significantly associated with a false-negative of BSGI in this study. Ki-67 index is known to be a protein found in all proliferating cells. A malignant lesion with low cell proliferation showed a lower Ki-67 index [21]. The others, such as nuclear grade, ER status, PR status, and HER2 expression, showed no significant association with the false-negative of BSGI.

There were some limitations in this study. First, it is a retrospective study that may occur selection biases. Second, it is hard to generalise the results of this study considering involving a single institution. Further multicenter and prospective studies are needed. Third, since some of the benign lesions did not take pathologic confirmation, there has a possibility to be proven malignant in further follow-ups of some of these lesions.

Conclusions

In this study, the addition of BSGI to MG showed higher sensitivity and AUC than the only MG group. Particularly, the selective addition of BSGI to MG category 0 or 4a lesions in dense breast improved the diagnostic accuracy. Breast-specific gamma imaging could be helpful as

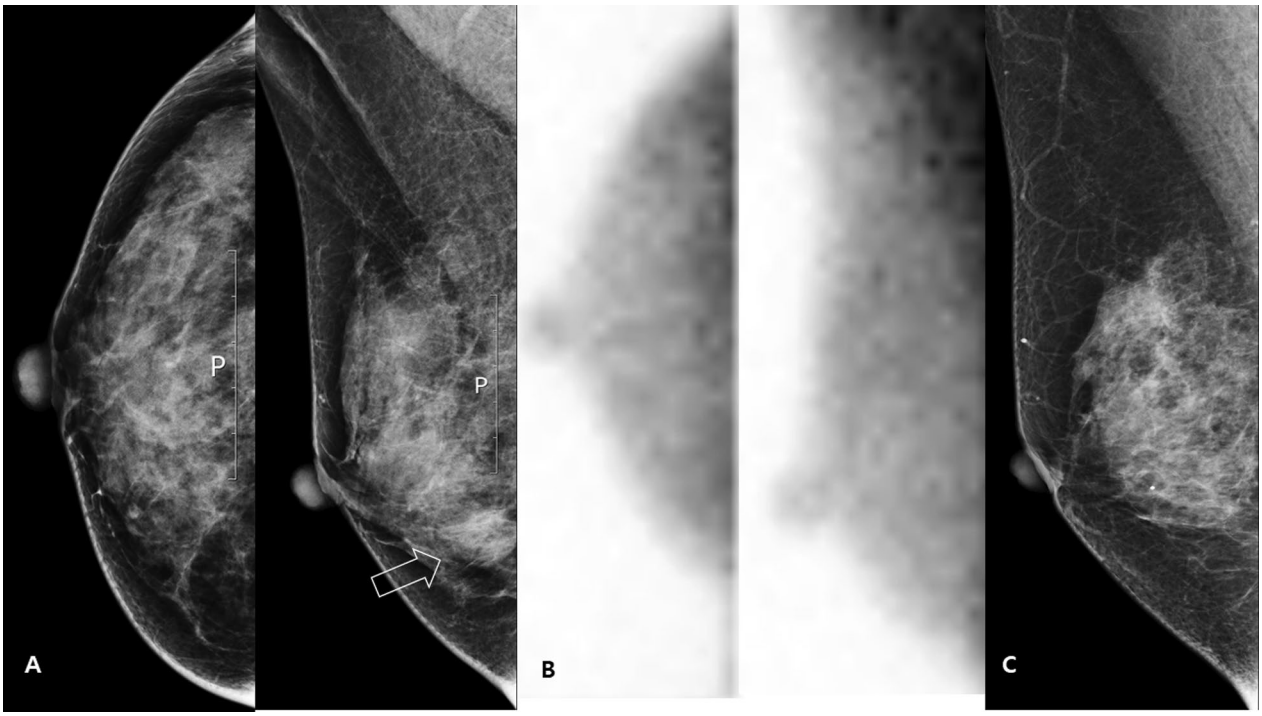

Fig. 3 In 48 years-old woman, an asymmetry in the right lower breast on mammography was assessed as category 0 (**A**). Breast-specific gamma imaging showed no uptake in the right breast (**B**). After 5 years, the asymmetry was not evident (**C**). It was a normal glandular tissue

a supportive tool for MG to detect breast cancer, even in dense breasts.

Abbreviations

MG	Mammography
BSGI	Breast-specific gamma imaging
US	Ultrasonography
MRI	Breast magnetic resonance imaging
ADH	Atypical ductal hyperplasia
ALH	Atypical lobular hyperplasia
LCIS	Lobular carcinoma in situ
BI-RADS	Breast imaging reporting and data system
ER	Estrogen receptor
PR	Progesterone receptor
HER2	Human epidermal growth factor receptor 2
AUCs	Areas under the curves
PPV	Positive predictive value
NPV	Negative predictive value

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Author contributions
YJK, JYS, and KWK analyzed and interpreted the patient data. YJK was a major contributor in writing the manuscript. CMH, HCK, DHO perforemed statistical analysis. All authors read and approved the final manuscript.

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Availability of data and materials
The datasets generated and/or analysed during the current study are not publicly available according to the hospital policy.

Declarations

Ethics approval and consent to participate
KYUH 2022-08-020 (Konyang Univ. Hospital IRB).

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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