

A SUMMARY OF CLINICAL STUDIES ON BREAST-SPECIFIC GAMMA IMAGING (BSGI)

There have been several clinical studies evaluating the impact of BSGI in breast cancer detection and the results have been summarized in several peer reviewed publications and presentations. One of the most comprehensive analysis done on the sensitivity of BSGI was presented by the group from George Washington Medical Center at the 2007 American Roentgen Ray Society meeting (1). In this work, the authors sub-categorized the BSGI findings of 83 malignancies into subgroups for sensitivity analysis (see table 6). They noted an overall sensitivity of 96% for all lesions and 97% for invasive cancers. In addition, the sensitivity of BSGI for DCIS was 94% and the median size of DCIS detected was 7mm. In their analysis of sensitivity relation to size, of the 16 malignancies smaller than 1 centimeter, 8 were smaller than 5 millimeters (including one 4 mm lesion missed by MRI). BSGI had a sensitivity of 89% in this subgroup and detected 2 lesions (1- DCIS and 1 – IDC) measuring 1mm at pathology.

Overall	96%
Invasive Cancers	97%
Sub-centimeter lesions	89%
DCIS	94%

Table 6: the sensitivity of BSGI in various subgroups.

These findings are confirmed by another recent study evaluating the effectiveness of BSGI in 146 women with one of the following indications: palpable masses negative on mammogram, patients with biopsy proven cancer, areas of concern noted on mammography, but negative on ultrasound, MRI and clinical examination and high Risk patients (greater than a 1.66% of breast cancer in the next 5 years). This study found an overall sensitivity of 96.4%, with a 89% sensitivity for lesions smaller than 5 mm. The negative and positive predictive values were 94% and 68.8% respectively (2).

Other studies, some exceeding 500 patients have provided evidence of BSGI sensitivity, specificity and perhaps most importantly negative predictive value (see Table 7) (3,4,5,6). Since BSGI is used as molecular imaging compliment to mammography, it is important that it provides a positive clinical impact without introducing significant risk of missed cancer diagnosis. The high negative predictive value indicates that there is a low risk of a missed cancer diagnosis using BSGI.

	BSGI 1	BSGI 2	BSGI 3	BSGI 4
Total Patients	164	163	773	512
Sensitivity	96	89	95	89
Specificity	92	86	95	90
NPV	99	95	100	98

Table 7: the clinical performance of BSGI from several studies.

Studies on the integration of BSGI into clinical practice also have shown significant results. One particularly interesting work was presented at the 2008 Miami Breast Conference (7). The authors evaluated the impact of ultrasound, BSGI and breast MRI as adjunctive imaging techniques to mammography in the diagnosis of breast cancer. For this evaluation, all three adjunctive imaging studies were performed on all patients and the results were recorded as positive (BIRADS IV or V), Negative (BIRADS I or II) or indeterminate (BIRADS 0 or III). Using these findings, the author then evaluated the sensitivity of breast cancer resulting by combining the mammogram and each of the modalities. The combination of mammography and ultrasound alone would have missed 2 cancers while the combination of mammography and MRI would have missed 4 cancers. There were 4 women who had negative or

indeterminate mammogram and were unable to undergo breast MRI (2 had ferromagnetic implants and 2 suffered acute claustrophobia). The combination of mammography and BSGI detected all cancers.

There are at least three additional studies evaluating the impact of BSGI in surgical planning finding that BSGI changed patient treatment planning in 15 – 19% of patients. In addition, BSGI detected secondary, occult cancers in patients with known primaries in approximately 10 - 14% of patients with a false positive rate as low as 6.3% (8,9,10).

In other studies, BSGI has demonstrated higher sensitivity for lobular carcinoma and DCIS than mammography, ultrasound and in at least one study, breast MRI (11,12,13,14) (see Table 8). These findings indicate that BSGI is an excellent adjunctive procedure for the detection of breast carcinoma in patients with dense breast, especially those of high risk, patients with indeterminate findings on mammography and ultrasound and patients with known breast cancer diagnoses.

Sensitivity	DCIS	ILC
BSGI	91%	93%
MRI	88%	83%
Mammo	82%	79%
Ultrasound	NR	68%

Table 8: Comparison of several modalities in the sensitivity of lobular carcinoma and Ductal carcinoma in-situ. NR = not reported.

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- ³ Kieper D, Brem R, Keppel C, Majewski S, Weisenberger A, Welch B. An Introduction to Breast Specific Gamma Imaging. NCBC Annual Conference, Las Vegas Nevada, Feb 28 – Mar 3, 2003.
- ⁴ Cocilovo C, Greene T, Gross J, Whelan D, Valdes E, Boolbol S, Feldman S. Breast Specific Gamma Imaging: A Clinical Pilot Study. ASBD Annual Conference, Las Vegas Nevada, April 28th 2006.
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- ¹³ Coover LR, Caravaglia G, Kuhn P. Scintimammography with dedicated breast camera detects and localizes occult carcinoma. *J Nucl Med*. 2004 Apr;45(4):553-8.
- ¹⁴ Brem R. Et al. Northwestern University Breast Conference. Chicago IL. October 2007.