

Molecular Breast Imaging: the Sensitivity of Breast-Specific Gamma Imaging (BSGI) as a diagnostic Adjunct to Mammography and Ultrasound in a Triple Assessment Protocol

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Objectives

BSGI is a diagnostic breast imaging procedure becoming more common in clinical breast practice. The goal of this work is to quantify its performance as an addition to mammography and ultrasound in detection of breast carcinoma when used in the community breast center setting.

Methods

A multi-center patient registry was maintained for all patients routinely sent to BSGI as part of their diagnostic work up. From the registry data, patients who had a mammogram followed by ultrasound and BSGI were selected for evaluation. The BIRADS rating schematic was used for mammography and sonography and a similar category system was used for the BSGI images. For each modality, the reports were classified as positive (categories 4 - 6) or Negative (categories 0 - 3). Needle and/or surgical biopsy were conducted as deemed clinically necessary and all patients who had a malignant diagnosis by pathology were entered into this analysis.

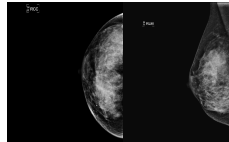
Results

731 patients had all three imaging modalities as part of their diagnostic work up resulting in 180 malignancies confirmed by pathology: 29 ductal carcinoma in-situ, 110 infiltrating ductal carcinoma, 11 infiltrating lobular carcinoma, 9 papillary carcinoma and 21 mixed component malignancies. Mammography was positive in 130 (sensitivity = 72%) while ultrasound was positive in 114 (sensitivity = 63%) and BSGI was positive in 147 (sensitivity = 82%). The combination of mammography and ultrasound was positive in 163 cases (sensitivity = 90%) while the addition of BSGI provided positive findings for 177 malignancies resulting in a sensitivity of 98%. A subsequent breast MRI detected one of the lesions missed by the three modalities while two lesions were found by pathology alone.

Example Patient History – courtesy of Legacy Good Samaritan Hospital, Portland, OR

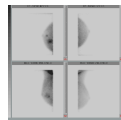
48 year old with a previous negative biopsy of the right breast noted a dimpling near the nipple of her right breast during breast self-examination.

The patient was seen for a mammogram to evaluate the area of concern. No significant change from mammogram 2 years prior. No mass or spiculated lesion noted at the sight of the subtle dimpling and stable calcifications are noted in the medial aspect.

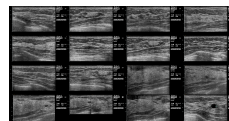


Ultrasound (not shown) shows a small cyst and a hypoechoic area likely representing scarring from the previous procedure. BIRADS 3. Patient is asked to return for additional imaging in 6 months.

8 weeks later the patient returned reporting an increase in dimpling. Clinical examination and sonographic evaluation of this area were negative leading to the suggestion of a BSGI for additional evaluation.



BSGI of the left breast has normal, uniform distribution. The right breast has a large area of increased uptake in the upper-inner quadrant, measuring approximately 2 cm. A second, smaller and more intense focus is located retroareolar, measuring about 1 cm at the 6 o'clock position. In addition, there are areas of increased activity in the right axilla.



Second look ultrasound was performed using the BSGI images as a reference and an irregular hypoechoic mass was noted in the 6 o'clock position consistent with the focal intensity noted in BSGI. Biopsy of this area was conducted resulting in a ductal carcinoma diagnosis. In the area of the larger medial focal uptake on BSGI, ultrasound demonstrated fibroglandular tissue with complex cysts, but no mass or other distortion.

The large focal intensity noted in the upper inner quadrant of the right breast on BSGI was negative in ultrasound and corresponded to a cluster of stable microcalcifications visualized in the mammogram however, this uptake was still concerning to the surgeon who decided to place a localization wire marking the site of the microcalcifications under mammographic guidance prior to surgery in order to obtain tissue from this site at the time of the lumpectomy procedure for the retroareolar cancer. Pathology of this region revealed a 2 cm ductal carcinoma in-situ.

Conclusions

Of the three imaging modalities, BSGI provided the highest independent sensitivity and when added to the diagnostic workup, BSGI detected an additional 14 malignancies, increasing the sensitivity from 90% to 98%. Although it is beyond the scope of this work, it is interesting to note that the cost of the BSGI procedure is relatively low, about \$320, and that in this population the BSGI specificity was 74%. In summary, when added to the diagnostic work up of patients in the community breast cancer, BSGI can improve the detection of breast malignancy when compared to mammography and ultrasound alone.

Radiation Dose

The main benefits of sonography is that it does not use ionizing radiation and it is readily available at most breast centers. For these reasons, it should be considered the primary diagnostic tool. However, as these results demonstrate, its sensitivity for detecting breast malignancies is significantly lower than that of MBI/BSGI. Therefore BSGI/MBI should be considered when sonography is negative or indeterminate and it has not fully addressed the diagnostic concern.

Nearly all of the peer-reviewed clinical literature published on BSGI/MBI has utilized the dosage recommended on the Sestamibi drug insert package, 20 – 30 mCi. However there has been a concentrated effort to reduce the dose associated with this imaging procedure and recent data suggests that all of the commercial MBI/BSGI systems are likely capable of imaging using doses of less than 10 mCi (Böhm-Vélez et al. Chicago International Breast Conference, October 18-21, 2012).

Risk estimates based on BEIR VII age-dependent organ risks for female patients indicate that an administered dose of 20 mCi (740 MBq) of Tc-99m-MIBI is associated with an LAR of induced fatal cancer of 26 cases in 100000 women aged 40 years at exposure (0.026%). Based on the results of our study, this theoretical risk is substantially outweighed by the benefit patients received in this study, 24 of 188 (13%) having a malignancy detected by BSGI/MBI after a negative or indeterminate mammogram. The benefit outweighed the risk by 500 to 1. This benefit-to-risk ratio is appropriate for the diagnostic population and will be further improved by dose-reduction.