Results of a Multi-Center Patient Registry to Determine the Clinical Impact of Breast-Specific Gamma Imaging, a Molecular Breast Imaging Technique,

Margaret Bertrand, MD, Leora Lanzkowsky, MD, Lillian Stern, MD, Dr. Jean Weigert, MD

Background:
Molecular breast imaging techniques such as BSGI are increasingly being utilized as adjunct diagnostic technologies.

Purpose:
This is a retrospective analysis to examine the impact of BSGI in clinical practice.

Methods:
BSGI was used as an adjunct diagnostic modality at four institutions. BSGI was performed as recommended by either the interpreting radiologists or referring physician. Typically, BSGI was used as a problem solving tool for patients with complex mammographic and/or sonographic findings. The interpreting radiologist had access to all studies and patient history at the time of interpretation. Biopsy was performed as determined by the radiologist. In addition, follow up imaging was conducted on an interval deemed clinically necessary. Biopsy or follow up imaging, if biopsy was not conducted, was used as the gold standard. Biopsy results were classified as positive: malignancy or high-risk lesions such as ADH, ALH and LCIS or negative: benign conditions not requiring additional intervention. Imaging studies were classified as Positive (BIRADS VI or V) negative (BIRADS I or II) or indeterminate (BIRADS 0 or III).

Results:
BSGI was utilized in a total of 2,004 patients. Pathology (N = 642) or follow up imaging (N = 400) was available for 1,042 cases resulting in 250 positive and 792 negative findings. BSGI was positive in 339 patients, negative in 634 and indeterminate in 69. BSGI had an overall sensitivity and specificity of 91% and 77% respectively.

Mammographic findings were available for 362 patients resulting in 27 negative, 206 positive and 129 indeterminate findings. BSGI detected 5 malignant and 4 high-risk lesions in patients with negative mammograms and 25 malignant and 3 high-risk lesions in patients with indeterminate mammograms. Of the patients with positive mammographic findings, BSGI was positive in 122 and negative in 12 malignant lesions and BSGI was negative in 30 and positive in 42 benign lesions.

Conclusion:
BSGI significantly contributed to the detection of malignant or high-risk lesions in patients with negative or indeterminate mammographic findings. However, BSGI should not be utilized to obviate the need for biopsy in patients with suspicious findings in mammography. BSGI is a useful diagnostic modality to augment mammography in the management of patients with difficult to diagnose breast tissue.