Scintimammography/Breast-Specific Gamma Imaging/Molecular Breast Imaging

Medical Policy

Section
Radiology

Original Policy Date
12:2013

Last Review Status/Date
Reviewed with literature search/12:2013

Issue
12:2013

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Description

Scintimammography refers to the use of radiotracers with nuclear medicine imaging as a diagnostic tool for abnormalities of the breast. Breast-specific gamma imaging (BSGI), or molecular breast imaging (MBI), refer to specific types of imaging machines that are used in conjunction with scintimammography in order to improve diagnostic performance.

Scintimammography is a diagnostic modality using radiopharmaceuticals to detect tumors of the breast. After injection of a radiopharmaceutical, the breast is evaluated with planar imaging. Scintimammography is performed with the patient lying prone and the camera positioned laterally, which increases the distance between the breast and the camera. Scintimammography using conventional imaging modalities has relatively poor sensitivity in detecting smaller lesions (e.g., smaller than 15 mm), because of the relatively poor resolution of conventional gamma cameras in imaging the breast. Interest in this approach has increased in recent years with the development of breast-specific gamma imaging (BSGI) and, even more recently, molecular breast imaging (MBI). Breast-specific gamma cameras acquire images while the patient is seated in a position similar to that in mammography, and the breast is lightly compressed. The detector head(s) is immediately next to the breast, increasing resolution, and the images can be compared with the mammographic images. Breast-specific gamma imaging and molecular breast imaging differ primarily in the type and number of detectors used (multi-crystal arrays of cesium iodide or sodium iodide versus semiconductor materials, such as cadmium zinc telluride, respectively). In some configurations, a detector is placed on each side of the breast, and they lightly compress it. The maximum distance between the detector and the breast is therefore from the surface to the midpoint of the breast. MBI systems can achieve greater resolution and smaller pixel size. Much of the research on BSGI and MBI has been conducted at the Mayo Clinic. The radiotracer usually utilized is technetium Tc99m sestamibi. MBI imaging takes approximately 40 minutes. (1)
Breast-specific gamma imaging and molecular breast imaging have been suggested for a variety of applications. The Society for Nuclear Medicine recently released guidelines for breast scintigraphy with breast-specific gamma cameras. The potential uses they listed are as follows:

1. Among patients with recently detected breast malignancy, initial staging; detecting multicentric, multifocal, or bilateral disease; and assessing response to neoadjuvant chemotherapy.

2. Among patients at high risk for malignancy, evaluating suspected recurrence or using it when a mammogram is limited or a previous malignancy was occult on mammogram.

3. Among patients with indeterminate breast abnormalities and remaining diagnostic concerns, evaluating lesions identified by other breast imaging techniques, palpable or non-palpable, aiding in biopsy targeting, and a number of others.

4. Among patients with technically difficult breast imaging, such as radiodense breast tissue or implants, free silicone, or paraffin injections.

5. Among patients for whom breast magnetic resonance imaging (MRI) is indicated but contraindicated, e.g., patients with implanted pacemakers or pumps, or as an alternative for patients who meet MRI screening criteria, such as BRCA1, BRCA2 mutations.

6. Among patients undergoing preoperative chemotherapy, for monitoring tumor response in order to determine the impact of therapy of plan for residual disease.

The guideline also mentions other efforts, such as the American College of Radiology’s Appropriateness Criteria and the American College of Surgeons’ Consensus Conference III. (2) Less emphasis is placed on detecting positive axillary lymph nodes with BSGI or MBI than with scintimammography because with current configurations, these lymph nodes are frequently out of view. Selected studies on these modalities are discussed below.

The primary radiopharmaceutical used with BSGI or MBI is technetium Tc99m sestamibi (marketed by Draxis Specialty Pharmaceuticals Inc.; Cardinal Health 414, Dublin, Ohio; LLC, Mallinckrodt Inc., and Pharmalucence, Inc., Bedford, MA). The labeling states that technetium-99m sestamibi is “indicated for planar imaging as a second-line diagnostic drug after mammography to assist in the evaluation of breast lesions in patients with an abnormal mammogram or a palpable breast mass. Technetium Tc99m sestamibi is not indicated for breast cancer screening, to confirm the presence or absence of malignancy, and it is not an alternative to biopsy.”

Several scintillation or gamma cameras have general 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA), which states that they are cleared for “use in imaging the distribution of radionuclides in the human body using planar imaging techniques.” Two examples of gamma cameras used in BSGI or molecular breast imaging are Dilon 6800® (Dilon Technologies, Newport News, VA) and LumaGEM™ (Gamma Medica Instruments, Northridge, CA).

NOTES:

The term “molecular breast imaging” is used in different ways, sometimes for any type of breast imaging involving molecular imaging, including positron emission mammography (PEM) and sometimes limited to imaging with a type of breast-specific gamma camera, as is used in this report.
Use of single positron emission computed tomography (SPECT) and positron emission tomography (PET) of the breast are not covered in this policy.

Policy

Scintimammography or breast-specific gamma imaging, and molecular breast imaging are considered investigational in all applications, including but not limited to its use as an adjunct to mammography or in staging the axillary lymph nodes.

Policy Guidelines

The most commonly used radiopharmaceutical used in for BSGI or MBI is technetium Tc 99m sestamibi (marketed by Draxis Specialty Pharmaceuticals Inc., Cardinal Health 414, LLC, Mallinckrodt Inc., and Pharmalucence, Inc.). There is a specific HCPCS code for this radiopharmaceutical:

A9500: Technetium Tc-99m sestamibi, diagnostic, per study dose, up to 40 millicuries.

Rationale

This policy was created in January 1998 and updated periodically with literature review. The most recent update covers the period of September 2010 through February 2012.

Mammography is the main screening modality for breast cancer. The clinical utility of adjunctive screening tests, such as scintimammography or magnetic resonance imaging (MRI), is primarily in the evaluation of women with inconclusive results on mammography. A biopsy will generally be performed on a breast lesion if imaging cannot rule out malignancy with certainty. Therefore, adjunctive tests will be most useful in women with inconclusive mammograms if they have a high negative predictive value, and can obviate the need for a biopsy.

The most relevant types of research studies will include populations of patients who have inconclusive mammograms, or populations that are expected to have less accurate mammograms, and that test the utility of scintimammography/BSGI in addition to mammograms for determining whether a biopsy is required. Studies that directly compare the accuracy of scintimammography/BSGI with alternatives such as MRI, also contain useful information, although with less direct clinical relevance. These types of studies will also be included in this review.

Scintimammography with conventional SPECT imaging

Interest in scintimammography using conventional imaging as an adjunct to mammography has waned over time primarily because of the difficulty in imaging small lesions. A meta-analysis
published in 2006 reviewed retrospective and prospective evidence on 2,424 patients from single-site trials and 3,049 patients from multi-site trials performed since January 1997 on the use of scintimammography for the diagnosis of primary breast cancer. (3) The studies included at least 100 patients, used pathology findings as the reference standard, included planar images, and used Tc99m-MIBI or Tc99m-tetrofosmin. The overall sensitivity and specificity were 85% and 84%, respectively, in the single-site trials and 85% and 83%, respectively, in the multi-site trials. In 2006 the federal Agency for Healthcare Research and Quality (AHRQ) published a comparative effectiveness report on the accuracy of noninvasive diagnostic tests in women presenting with breast abnormalities (either by mammography or physical examination), specifically comparing ultrasound (US), positron emission tomography (PET), scintimammography, and magnetic resonance imaging (MRI). (4) The report recommends against using scintimammography to identify women with suspicious mammograms who do not need to go on for biopsy. Considering women at an average risk of breast cancer (20%) following an abnormal mammogram, for every 1,000 women who had a negative scintimammogram, 93 cases of cancer would be missed in return for avoiding 907 unnecessary biopsies. This performance is worse (i.e., there are more missed cancers) than PET, US, or MRI. None of these tests met the suggested standard of having a less than 2% risk of having cancer among women with negative diagnostic results. Regarding the use of scintimammography to detect axillary metastases, a review of published studies between 1994 and 1998 (5) showed a sensitivity of 77% and specificity of 89%. More recent studies using different radiopharmaceuticals have shown sensitivities in the high 80–90% range. (6, 7) A meta-analysis published in 2011 (8) reviewed 45 studies of scintimammography and also reported sensitivities and specificities in this range, with summary estimates for sensitivity of 83% (95% confidence interval [CI] 82%-84%) and for specificity of 85% (95% CI 83-86%). The test is still not accurate enough to replace surgical nodal dissection. No studies have examined patient outcomes comparing the strategy of using scintimammography to aid in decision making regarding nodal dissection versus standard nodal dissection. Scintimammography with conventional SPECT imaging, therefore, will not be discussed further in this policy.

Scintimammography with breast-specific gamma imaging

Use of BSGI as an adjunct to mammography

The use of dedicated gamma camera systems has renewed interest in scintimammography as a primary screening technique. Rhodes and colleagues reported on a study that used a dedicated gamma camera for breast imaging that permits cranial-caudal images with compression. (9) Scintimammography, which would now be called breast-specific gamma imaging (BSGI), was performed on 40 women with small mammographic abnormalities (less than 2 cm) scheduled to undergo biopsy. Thirty-three of the 36 malignant lesions confirmed at biopsy were identified on BSGI images. The authors conclude that this preliminary study suggests an important role for BSGI in women with dense breasts in whom the sensitivity of mammography is decreased. The high prevalence of malignant lesions suggests that this study recruited a highly selected population of patients.

Brem and colleagues also used a breast-specific gamma camera to evaluate 94 women considered at high risk of breast cancer with normal mammographic findings. (10) High risk was defined as a calculated 5-year risk of developing breast cancer of 1.66%, as determined by the Gail model. Of the 94 women in the study, 35 had a prior history of some type of breast cancer or atypical hyperplasia. The results of the scintimammography were categorized from 1 to 5, similar to the Breast Imaging Reporting and Data System (BI-RADS) scoring system.
developed for mammographic evaluation. For example, scores of 1 to 3 were considered to be without evidence of disease, while those with scores of 4 and 5 resulted in an US exam directed to the region of interest. If US identified a hypoechoic area, a biopsy was performed; if the US exam was normal, patients were followed up at 6 months with repeat scintimammography. A total of 16 of the 94 women (17%) had abnormal scintimammograms; follow-up US in 11 of these 16 identified a hypoechoic lesion that was biopsied. The 5 remaining patients had normal US results and were followed up with a repeat scintimammogram at 6 months, which was normal. Of the 11 who underwent US-guided biopsy, 2 invasive cancers (12%) were identified; the cancers measured less than 8 mm in diameter. In 1 of these patients, the identified cancer was a local recurrence after lumpectomy, and the authors suggest that the mammographic evaluation was compromised by post-therapeutic changes.

Brem and colleagues (11) examined the performance of BSGI in a retrospective study of 146 consecutive patients undergoing BSGI, who had a mixed set of indications, including palpable lesions with no mammographic correlation, diagnosis of multicentricity or multifocality in women with known breast cancer, or screening of women at high risk of breast cancer. The analysis was performed per lesion (n=167), not per patient. The overall prevalence of disease was 49.7%. The sensitivity of BSGI was 96.4% (95% CI: 92–99%), and the specificity was 59.5% (95% CI: 49–70%). The positive predictive value was 68.8% (95% CI: 60–78%), and the negative predictive value was 94.3% (95% CI: 88–99%). However, the sensitivity in detecting invasive cancer was 100% for lesions larger than 10 mm, 87.5% (95% CI: 45–99%; n=8) for lesions 6–10 mm, and 83.3% (95% CI: 35–99%; n=6) for tumors 0–5 mm; the sensitivity differed for ductal carcinoma in situ (DCIS) and the number of cases was smaller. The performance of BSGI in detecting smaller tumors in particular requires further investigation. As the authors point out, additional larger studies are needed to confirm or modify these findings.

In another study, 150 patients with BI-RADS classification 4 or 5 lesions smaller than 2 cm who were scheduled for biopsy underwent scintimammography using a dual-head, breast-specific gamma camera; the results from 3 blinded readers were averaged. (12) In 88 patients, 128 cancers were found. The per-lesion sensitivity with the dual-head camera was 90% (115/128) for all lesions and 82% (50/61) for lesions 1 cm or smaller.

In a retrospective study on BSGI, Brem et al. examined the detection of occult foci of breast cancer among 159 women with recently diagnosed breast cancer (77%) or a clinically suspicious lesion among women who were ultimately proven to have breast cancer (23%). (13) Twelve percent of the women had personal histories of breast cancer, and 43% had family histories of breast cancer. BSGI identified 56 potential, additional cancers among 46 women. “Second look” ultrasound was performed to evaluate 53 of the lesions and MRI for 14 of the lesions. Biopsies were performed on 46 of the 56 lesions, using ultrasound, stereotactic, or magnetic resonance imaging (MRI) guidance; 3 others were removed during surgery; the remaining 7 were found to be benign (5) or were lost to follow-up. (2) Biopsy or surgery revealed 14 cancerous lesions (25%) and 35 benign lesions (63%). Five lesions initially identified as benign were subsequently found to be cancerous. Of the 159 women overall, additional cancerous lesions were identified using BSGI in 9%; 3% of the 9% were in the contralateral breast. The authors noted that FDA approval of Gamma Loc will permit localization and biopsy of BSGI-located lesions.

In a study of 145 consecutive patients scheduled for breast biopsy with an 86% prevalence of disease, the sensitivity of BSGI was 97.6% per patient (100% for tumors larger than 10 mm and 91.1% for tumors 10 mm or smaller). (14) The per-lesion specificity was 86.4% (4 cancers were
missed, 3 of which were detected by mammography). The authors suggest using BSGI for surgical planning or to avoid biopsy, but the negative predictive value, calculated to be 83%, is not high enough to forgo biopsy. Given the relative ease and diagnostic accuracy of the gold standard of biopsy coupled with the adverse consequences of missing breast cancer, the negative predictive value of BSGI would have to be extremely high to influence treatment decisions. The negative predictive value is determined by the sensitivity of the test, as well as the prevalence of disease. Among a population of patients with mammographic abnormalities highly suggestive of breast cancer, the negative predictive value will be lower than in a population of patients with mammographic abnormalities not suggestive of breast cancer. Therefore, the clinical utility of BSGI as an adjunct to mammography may vary according to the type of mammographic abnormalities included in the studies.

Weigert et al. reported data from a multicenter patient registry in 2012. (15) This retrospective study analyzed 1,042 patients who had BSGI imaging, pathological diagnosis by biopsy, and at least 6 months follow-up, drawn from a total of 2,004 patients in the registry. From this population, BSGI had a reported sensitivity of 91%, a specificity of 77%, a positive predictive value of 57%, and a negative predictive value of 96%. There were a total of 329 patients that had complete information from mammography and ultrasound, thus allowing direct comparison of diagnostic accuracy among these 3 modalities. In this subset of patients, BSGI had a sensitivity of 92%, compared to 74% for mammography and 84% for ultrasound, and a negative predictive value of 93%, compared to 82% for mammography and 85% for ultrasound. In 139 patients with a suspicious lesion on mammography, BSGI imaging was negative in 21 cases, 13 of which were true-negatives and 8 of which were false-negatives.

Conclusions. Evidence on the utility of BSGI as an adjunct to mammography is insufficient to permit conclusions on its clinical utility. Available studies are relatively small, mainly retrospective, and do not provide adequate comparison to relevant alternatives such as MRI. Although the evidence suggests that BSGI has reasonably high overall accuracy, the negative predictive value of BSGI has not been demonstrated to be high enough to forego biopsy. As a result, the use of BSGI to change management is not supported by the evidence and the clinical utility of BSGI has not been demonstrated. There are no studies that demonstrate that BSGI can change management in ways that improve outcomes, in particular, there is insufficient evidence to determine whether BSGI can be used as an adjunct to mammography to reduce unnecessary biopsies.

**Diagnostic accuracy of BSGI compared to alternatives**

To evaluate how BSGI might be used in diagnosis of breast cancer, it must be compared to other breast-imaging modalities, such as traditional mammography, US, or MRI. Although some comparative studies have been published, they are limited by the retrospective nature of most study designs, small sample sizes, patient populations with mixed indications for imaging, and a high prevalence of cancer. For example, Brem and another set of coauthors (16) compared the performance of BSGI, mammography, and MRI in 20 of 290 women undergoing BSGI who had pathologically confirmed DCIS. In this retrospective review, MRI was performed on only 7 patients. Because the study design excluded women without DCIS, it could only address the sensitivity of these tests. It reported the sensitivity of BSGI to be 91%; for MRI, 88%; and for mammography, 82%. The difference was not statistically significant and presumably did not include the same patients (since MRI results were only available for a subset). Spanu et al. compared BSGI with mammography in the detection of multifocal/multicentric disease in breast cancer patients; they found that BSGI was more sensitive than mammography for this purpose.
However, the relevant comparison in this context would probably be between BSGI and another modality such as MRI.

A retrospective study compared BSGI, mammography, US, and MRI among 21 women with histologically confirmed lobular cancer, which can be more difficult to detect early than other breast cancers. No statistically significant difference was found between the sensitivity of BSGI (93%; n=26) and mammography (79%; n=26), US (68%, n=25), or MRI (83%; n=12). However, only some women received ultrasound or MRI, as clinically indicated, so sensitivity was being compared for different subsets of patients. In a small study (n=23) comparing BSGI and MRI in women with indeterminate lesions, there was no difference between the 2 modalities in sensitivity; the specificity of BSGI was greater than for MRI. Another study prospectively compared BSGI using technetium Tc99m tetrofosmin and SPECT/CT among 157 women with suspicious breast lesion on clinical examination, mammography, or ultrasonography. Using surgery or biopsy, 127 women were found to have cancer (140 carcinomas), and 30 women had 33 benign lesions. BSGI identified 95.7% of the carcinomas; SPECT/CT identified 90.7% (p less than 0.01). The specificity for both was 87.9%. Among cancerous lesions at or less than 10 mm, BSGI was more sensitive than SPECT/CT (89.1% vs. 78.3%, respectively; p less than 0.05). On the other hand, SPECT/CT identified 36 of 46 axillary lymph node metastases (specificity 96.4% but not high enough to preclude radio-guided sentinel lymph node biopsy, according to the authors), while BSGI detected only 4 cases. At the time this article was written, the author noted only one other study on the use of SPECT/CT to detect primary breast cancer.

Kim reported on 97 biopsies in 66 women with dense breasts and compared the accuracy of BSGI with MRI. There were 26 biopsy-proven malignancies. BSGI had a sensitivity of 88.8% (95% CI 69.8-97.6%), which was similar to the sensitivity for MRI (92.3%, 95% CI 74.9-99.1%). However, the specificity of BSGI was 90.1% (95% CI 80.7-95.9%) which was higher than MRI (39.4%, 95% CI 28.0-51.7%, p<0.0001).

Keto et al. compared BSGI to MRI for the diagnosis of ductal carcinoma in situ (DCIS) in 18 patients with newly diagnosed DCIS. All patients received both an MRI and a BSGI and images were read independently by dedicated breast radiologists. The sensitivity of BSGI was 89% compared to 94% for MRI, a difference that was not statistically different.

Conclusions. Direct comparisons of BSGI with alternative imaging modalities, mainly MRI, are limited. These studies are small, retrospective, and do not enroll the most clinically relevant populations. The limited evidence suggests that the sensitivity of BSGI is similar to MRI and that the specificity of BSGI may be higher than MRI. The evidence is not sufficient to conclude that the negative predictive value for BSGI is higher than for MRI. In addition, it is not clear how the increased specificity will lead to any changes in management that will improve outcomes.

Radiation exposure with BSGI

Another factor that should be taken into account is the radiation dose associated with this test. According to one study, the radiation dose to the breast from the 20 mCi (740 MBq) technetium Tc99m sestamibi used for BSGI at this center is 0.13 rad or 1.3 mGy, less than the 0.75 rad the authors report for mammography, except that the dose is given to the entire body. The authors assert that this dose poses an “extremely low risk of harmful effects to the patient” but that it should be reduced by a factor of 5 to 10 if BSGI were to be used as a regular screening technique. The authors also estimate that the cost of BSGI is 3-4 times that of mammography.
An article published online in August 2010 calculated mean glandular doses, and from those, lifetime attributable risk of cancer (LAR) for film mammography, digital mammography, BSGI, and positron emission mammography (PEM). (24) The author, who is a consultant to GE Healthcare and a member of the medical advisory boards of Koning (which are working on dedicated breast computed tomography [CT]) and Bracco (MR contrast agents), used BEIR VII Group risk estimates (25) to gauge the risks of radiation-induced cancer incidence and mortality from breast imaging studies. The estimated lifetime attributable risk of cancer for a patient with the average-sized compressed breast during mammography of 5.3 cm (it would be higher for larger breasts) for a single breast procedure at age 40 is

- 5 per 100,000 for digital mammography (breast cancer only),
- 7 per 100,000 for screen film mammography (breast cancer only),
- 55-82 per 100,000 for BSGI (depending on the dose of technetium Tc99m sestamibi), and
- 75 for 100,000 for PEM.

The corresponding lifetime attributable risk of cancer mortality at age 40 is

- 1.3 per 100,000 for digital mammography (breast cancer only),
- 1.7 per 100,000 for screen film mammography (breast cancer only),
- 26-39 per 100,000 for BSGI, and
- 31 for 100,000 for PEM.

The risk is higher for younger patients, so for example, the lifetime attributable risk of cancer mortality at age 20 is

- 4 per 100,000 for digital mammography (breast cancer only),
- 5 per 100,000 for screen film mammography (breast cancer only),
- 37-56 per 100,000 for BSGI, and
- 44 for 100,000 for PEM.

A major difference in the impact of radiation between mammography, on the one hand, and BSGI or PEM, on the other, is that for mammography, the substantial radiation dose is limited to the breast. With BSGI and PEM, all organs are irradiated. Furthermore, as one ages, the risk of cancer induction from radiation exposure decreases more rapidly for the breast than for other radiosensitive organs. The organ at highest risk for cancer is the colon with BSGI and the bladder with PEM; these cancers, along with lung cancer, are also less curable than breast cancer. Thus, the distribution of radiation throughout the body adds to the risks associated with BSGI and PEM. Hendrick concludes that “The results reported herein indicate the BSGI and PEM are not good candidate procedures for breast cancer screening because of the associated higher risks for cancer induction per study compared with the risks associated with existing modalities such as mammography, breast US, and breast MR imaging. The benefit-to-risk ratio for BSCI and PEM may be different in women known to have breast cancer, in whom additional information about the extent of disease may better guide treatment.”
Hendrick estimates that the breast radiation dose for digital breast tomosynthesis is one to two times that for 2-view mammography (depending on whether it is 1- or 2-view tomosynthesis), while dedicated breast CT doses aim to be close to 2-view mammography; neither of these tests have received FDA approval yet. A lower dose version of molecular breast imaging (MBI) has been developed and is currently being tested at the Mayo Clinic among 1,000 women with dense breast tissue on mammography who are at increased risk of cancer. (1) According to the authors, all of whom are from the Mayo Clinic, this new approach will “make MBI comparable with screening mammography in terms of radiation exposure.” It is not clear whether this statement refers to breast exposure or whole body exposure.

Since the use of BSGI or MBI has been proposed for women at high risk of breast cancer, it should be mentioned that there is controversy and speculation over whether some women, such as those with BRCA mutations, have a heightened radiosensitivity. (26, 27) Of course, if women with BRCA mutations are more radiosensitive than the population as a whole, the above estimates may underestimate the risks they face from breast imaging with ionizing radiation (i.e., mammography, BSGI, MBI, PEM, SPECT/CT, breast-specific CT, and tomosynthesis; ultrasound and MRI do not involve the use of radiation). More research will be needed to resolve this issue. Also, the risk associated with radiation exposure will be greater for women at high risk of breast cancer, whether or not they are more radiosensitive, because they start screening at a younger age when the risks associated with radiation exposure are larger.

Several uses have been currently proposed for BSGI: to screen or diagnose women with dense breasts (e.g., 19); to identify women with suspicious findings suggestive of possible breast cancer who could avoid biopsy (13); to evaluate the extent of disease in a newly diagnosed patient (28, 29); to gauge the effectiveness of neoadjuvant therapy (30); and to identify possible spread of cancer to lymph nodes (the current research focuses on technical issues (e.g., (31, 32)). The relevant population (e.g., prevalence of cancer), comparator imaging (e.g., mammography or MRI), and diagnostic metric (e.g., sensitivity or negative predictive value) vary across these different uses.

Conclusions. The use of BSGI results in additional radiation exposure for women being screened for breast cancer. This radiation exposure is distributed throughout the body, as opposed to mammography where it is concentrated to the breast. The clinical importance of this additional exposure is uncertain, and efforts are ongoing to minimize the radiation dose.

Summary

The evidence to date does not provide sufficient support for any of the uses discussed. Limited evidence on the diagnostic accuracy of BSGI reports that the test has a relatively high sensitivity and specificity for detecting malignancy. However, the evidence does not establish that BSGI improves outcomes when used as an adjunct to mammography for breast cancer screening. In the available studies, the negative predictive value of BSGI has not been high enough to preclude biopsy in patients with inconclusive mammograms. In addition, the evidence is not sufficient to conclude that BSGI is better than MRI for this purpose. Larger, higher-quality studies are required to determine whether BSGI has a useful role as an adjunct to mammography.

Clinical Trials

According to online site clinicaltrials.gov, about 17 trials are currently underway on BSGI or MBI, and many of them are being conducted at the Mayo Clinic. They include the following:
Practice Guidelines and Position Statements

As noted in the Description section, the Society for Nuclear Medicine released a procedure guideline on breast scintigraphy with breast-specific gamma camera. (2) It lists a set of potential indications with references apparently to support each set of indications but does not provide a systematic review of the literature on the uses of breast scintigraphy with breast-specific gamma camera, which would take into account the quality of the studies. The guideline is based on consensus, and most of it is devoted to the procedures and specifications of the examination, documentation, and recording, quality control, and radiation safety.

References:


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ICD-10-CM (effective 10/1/13)

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Type of Service: Radiology

Place of Service: Outpatient

Index

Breast Specific Gamma Imaging
Miraluma®
Radionuclide Scanning, Breast
Scintimammography, Breast