Evidence Table

Clinical Area: Breast-specific gamma imaging

Study Type: Comparison of diagnostic tests
Study Aim: To evaluate a breast-specific gamma camera (scintimammograms) to detect occult breast cancer in women with dense breasts and an increased risk of breast cancer but with normal mammograms and exam findings. To compare a breast-specific gamma camera to a standard gamma camera.

Outcomes
• Primary: Diagnostic yield.

Design
• Number of subjects: n= 37
• Description of study population: Mean age=54 years (range=34-80). Most women had a strong family history of breast cancer; 9 had a personal history of breast cancer.
• Inclusion criteria: Women with normal findings on clinical breast examination, BI-RADS category I or II mammography findings, Bi-RADS parenchymal pattern of “heterogeneously dense” or “extremely dense” breast tissue.
• Exclusion criteria: Pregnant, lactating or physically unable to undergo procedure.
• Procedure: Patients received an injection of 740 MBq of $^{99m}$Tc sestamibi into a vein on the dorsum of the patient’s foot. Imaging with a standard gamma camera began approximately 10 minutes after the injection, and consisted of a lateral view of each breast and an anterior view. About 1 hour after the initial injection, an additional 740 MBq of $^{99m}$Tc sestamibi was injected. Imaging with a dedicated breast camera began about 10 minutes later. Each breast was imaged in 2 projections, caudal and lateral oblique. Patients with positive findings underwent biopsy. The dedicated breast camera was used for localization before biopsy.

Validity
• Independent blind comparison with a gold standard? No. The investigators who interpreted the images from the gamma cameras knew the clinical and mammographic findings. There was no additional follow-up in the protocol for patients with negative findings.
• Was “normal” defined? Yes.
• Appropriate spectrum of disease? Yes.
• Consecutive patients? Yes.
• Completeness of follow-up: Had data on 37% patients.
• Methods described in enough detail to enable you to replicate the test? Yes.
• Reproducible results? Yes.
• Conclusions regarding validity of methods: Threats to validity include lack of confirmatory testing on all samples (biopsy or follow-up in 6 months or a year) and the small sample size leading to imprecise estimates. All women also underwent standard gamma imaging, but this was not considered a gold standard comparison.
The study was funded by Bristol Myers Squibb, the manufacturer of the radiotracer, and Gamma Medica, the makers of the LumaGem camera.

Results

Standard gamma camera results were positive in 8.1% (3/37)
Dedicated breast camera results were positive in 13.5% (5/37). This included the 3 patients detected by the standard gamma camera.

Biopsy of the 5 positive cases yielded 3 carcinomas (1 infiltrating lobular carcinoma, 1 infiltrating tubular carcinoma, 1 DCIS). Only one of these was readily detected by the standard gamma camera.
The other 2 biopsies yielded a case of fat necrosis and a case of fibrocystic change.

Authors’ Conclusions

“Scintimammography using a dedicated breast camera may augment mammography and clinical breast examination for the subset of women who have dense breast tissue and are at high risk of breast cancer.”

Reviewer’s Conclusions

The study evaluated diagnostic yield with a breast-specific gamma camera compared to a standard gamma camera in high-risk women with negative mammograms and clinical examinations. The breast-specific gamma camera identified 3 carcinomas, and there were two false-positives. Limitations of the study were that there was no independent gold standard comparison, the sample size was small and the study was industry funded.