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BSGI Posts Higher Sensitivity than Mammography or MRI for the Detection of Ductal Carcinoma In Situ

Newport News, Virginia: August 10, 2007 – Study results recently published in the *Journal of Academic Radiology* indicate that Breast-Specific Gamma Imaging (BSGI) provides higher sensitivity for the detection of ductal carcinoma In Situ (DCIS) than mammography or MRI and can reliably detect small, sub-centimeter lesions. The study, performed by Dr. Rachel Brem and colleagues at The George Washington University Medical Center, evaluated the procedure on women with mammographically suspicious microcalcifications and other high risk factors.

According to Dr. Brem, Breast Specific Gamma Imaging (BSGI) -- nuclear medicine imaging of the breast utilizing a high-resolution gamma camera -- is an increasingly utilized adjunct imaging modality for the diagnosis of breast cancer. Many recent studies and clinical work around the country on over 20,000 patients have demonstrated the significant value of BSGI as a complement to mammography in detecting breast cancer.

The Brem study demonstrated the efficacy of BSGI in helping to find otherwise mammographically occult cancers and in determining the true extent of disease in order to optimize surgical planning. BSGI accurately detected all four DCIS ≤ 5 mm (100 percent) and all six DCIS ≤ 10 mm (100 percent) with measurable residual disease at surgical excision. Overall, BSGI demonstrated 91 percent sensitivity for DCIS, specifically detected low-grade DCIS and identified several lesions not found on mammography or MRI. The smallest lesion noted was 2 mm.

"We believe this is an important contribution to the literature in that it compares different imaging modalities for the diagnosis of DCIS, a timely issue," said Dr. Brem.

DCIS

Ductal carcinoma In Situ (DCIS), the most common type of non-invasive breast cancer, occurs in approximately 28 percent or over 58,000 cases of breast cancer in the U.S. Mammography, the only accepted screening tool for breast cancer, detects the majority of clinically occult DCIS as microcalcifications, the hallmark mammographic finding of DCIS. Yet, the diagnosis of DCIS remains difficult as mammography is unreliable in predicting the histology and extent of DCIS.

Breast MRI has been shown to have a sensitivity of 73-89 percent for DCIS, but a limited specificity (58-89 percent) and variable positive predictive value (25-84 percent). As with mammography, small foci of DCIS are difficult to detect on MRI, particularly lesions less than 5 mm.

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“In addition, MRI may overestimate DCIS extent in as many as 50 percent of cases and often cannot distinguish benign from malignant lesions, high-grade from low-grade DCIS, or detect an invasive component concurrent with the DCIS,” added Dr. Brem. “As a result, MRI remains a secondary study with limitations in DCIS detection and evaluation.”

Study Methods & Materials

In the retrospective study, 20 women with 22 biopsy-proven DCIS lesions were reviewed. Patients had BSGI with the Dilon 6800, a high-resolution, small-field-of-view gamma camera in craniocaudal and mediolateral oblique projections. Image findings were compared to findings at biopsy or surgical excision. MRI was performed with a GE 1.5-T system using a dedicated breast coil. The sensitivity of BSGI, mammography, and when performed, MRI were determined for the detection of DCIS. The sensitivities were compared using a two-tailed “t” test and confidence intervals were determined.

BSGI versus MRI

The findings indicate that the pathologic tumor size of the DCIS ranged from 2-21 mm. Of the 22 cases of biopsy proven DCIS in 20 women, 91 percent were detected with BSGI, 82 percent were detected with mammography, and 88 percent were detected with magnetic resonance imaging. BSGI had the highest sensitivity for the detection of DCIS, although this small sample size did not demonstrate a statistically significant difference. Two cases of DCIS (9 percent) were diagnosed only after BSGI demonstrated an occult focus of radiotracer uptake in the contra lateral breast, previously undetected by mammography. There were two false negative BSGI studies.

Details about BSGI with the Dilon 6800 Gamma Camera

Breast-Specific Gamma Imaging (BSGI) performed with the Dilon 6800, is a molecular breast imaging technique that can see lesions independent of tissue density and discover very early stage cancers. BSGI serves as a complementary diagnostic adjunctive procedure to mammography and ultrasound for difficult-to-diagnose patients. With BSGI, the patient receives a radioactive tracing agent that is absorbed by all the cells in the body. Cancerous cells in the breast, due to their increased rate of metabolic activity, absorb a greater amount of the tracing agent than normal, healthy cells and generally appear as “hot spots” on the BSGI image.

BSGI is ideal for patients with mammograms that are difficult to interpret due to a variety of factors, such as: dense breast tissue, suspicious areas on a mammogram, lumps that can be felt but not seen with mammography or ultrasound, implants and breast augmentation, scarring from previous surgeries and for women with a strong positive family history of breast cancer.

About Dilon Technologies

Dilon Technologies is bringing innovative new medical imaging products to market. Dilon’s cornerstone product, the Dilon 6800, is a high-resolution, small field-of-view gamma camera, optimized to perform BSGI, a molecular breast imaging procedure which images the metabolic activity of breast lesions through radiotracer uptake. Many leading medical centers around the country are now offering BSGI to their patients, including: Cornell University Medical Center, New York; George Washington University Medical Center, Washington, D.C.; Northwestern Memorial Hospital, Chicago; and The Rose, Houston. For more information about Dilon Technologies please visit www.dilon.com.

Detection of Ductal Carcinoma in Situ with Mammography, Breast Specific Gamma Imaging, and Magnetic Resonance Imaging: A Comparative Study Academic Radiology, Volume 14, No 8, August 2007 (Rachel F. Brem, MD, Michael Fishman, Jocelyn A. Rapelyea, MD).