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New study points to important information regarding radiation dose of BSGI/MBI; presented at the Chicago International Breast Course

Early results indicate that breast-optimized gamma cameras may help reduce exposure

Chicago, October 4, 2010 -- Marcela Böhm-Vélez, M.D., a breast radiologist from Pittsburgh, PA and Fellow of the American College of Radiology, recently presented on Breast-Specific Gamma Imaging (BSGI) at the Chicago International Breast Course. Dr. Böhm-Vélez discussed the practice guidelines for BSGI- a molecular breast imaging procedure, and related radiation dose considerations. The data presented on dose related to the early clinical results from a prospective dose reduction study, the only one of its kind looking at lowering the dose for molecular breast imaging.

BSGI is complementary imaging to mammography, providing a diagnostic tool that looks at function as compared to the anatomical imaging of mammography and ultrasound. BSGI studies are performed using an injection of the pharmaceutical Sestamibi, an imaging tracer cleared by the FDA in 1991 and commonly used in a variety of medical imaging procedures,. Breast imaging was added to the drug data sheet for Sestamibi in 1996 with a recommended dose of 20 – 30 millicuries (mCi). Since that time, new detector technologies have been developed opening the possibility of reducing the dose needed for the imaging procedure.

"We wanted to safely lower the radiation dose to patients, but discovered that there were no studies examining whether reducing the dose would impact our ability to detect cancer. In fact, all of the published studies on breast imaging with Sestamibi have used a dose of 20 – 30 mCi, likely because reducing the dose would be an off label use of the pharmaceutical" said Dr. Böhm-Vélez. Ever conscious of minimizing dose, Dr. Böhm-Vélez and her colleagues at Weinstein Imaging embarked on a study to determine the efficacy of using less radiation when conducting BSGI.

Dr. Böhm-Vélez's said that for clinical imaging her group currently uses 20 mCi, the minimum amount of tracer recommended under the current FDA approved guidelines. The radiation exposure of 20 mCi delivered to the patient is 0.6 rem, a radiation dose lower than other common diagnostic imaging studies. According to the position statement released July 2010 by the Society of Health Physics, the nationally recognized association for health risks from radiation exposure, risk estimates should be used when an individual's dose exceeds 5.0 rem in a single year, which translates to 8 BSGI studies in a single year.

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For this study, patients who were routinely scheduled for BSGI due to diagnostic concerns were asked to participate. Each volunteer patient had BSGI imaging conducted using a Dilon 6800 Gamma Camera at a low dose of 5, 10 or 15 mCi followed by imaging at the normal 20 mCi dose. Although their study is still underway, results from the first 21 patients show promising results.

Similar to recent studies conducted at the Mayo Clinic with breast-optimized gamma cameras, the Weinstein investigation found the image quality at 10 mCi was technically sufficient for clinical imaging. However, when Bohm-Velez and her partners compared the uptake of Sestamibi at low and normal doses, they found something new, specifically that the uptake of Sestamibi in the breast tissue was not proportional to the dose administered to the patient. Images conducted using 15 mCi had 90% of the Sestamibi concentration in the breast when compared to images conducted at 20 mCi, but that relationship changed as the dose was lowered to 10 or 5 mCi. Böhm-Vélez notes, "Believe me, no one wants to use a lower dose more than I do, but we need to understand how lower dose imaging impacts our ability to detect cancer so that we don't run the risk of compromising patient care."

A recent article in *Radiology* on the radiation dose from breast imaging procedures by Edward Hendrick, PhD reported that the radiation dose from BSGI is substantially higher than mammography, and that molecular breast imaging technology should not be used for screening the general population. "I whole heartedly agree that BSGI is not for screening, but we do find it to be a valuable problem solving tool" said Dr. Böhm-Vélez. "The challenge is that in cases of dense or difficult to interpret breast tissue, mammography is less likely to detect cancer. Therefore we use BSGI in patients who have a diagnostic concern that has not been successfully addressed by mammography and ultrasound. For these patients, the risk of an undetected cancer is high and the radiation dose from BSGI is a very small concern compared to the threat of a missed breast cancer."

About Dilon Diagnostics

Dilon Diagnostics, *a brand of Dilon Technologies Inc.,* is bringing innovative medical imaging products to market. Dilon's cornerstone product, the Dilon 6800, is a digital high-resolution, compact 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.; and The Rose, Houston. For more information on Dilon Diagnostics please visit www.dilon.com.

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