

**MODALITIES & PRACTICE MANAGEMENT**

## The ROI of PEM

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**Benefits to patients coupled with positive financial impact make positron emission mammography a smart solution at Boca Raton Regional Hospital.**

When I began my career in breast imaging 20 years ago, the only tools



*Naviscan high resolution PET scanner for positron emission mammography.*

available to us were anatomic in nature. What we were able to see with these tools, which include mammography and ultrasound, was the appearance of cancers in the form of masses, distortions, and microcalcifications. By looking at the form, we attempted to predict whether findings were benign or malignant. Mammography is the best and least expensive tool we have to identify breast cancers. However, we know that in certain populations, its sensitivity may be as low as 50%. Mammography typically identifies cancers of a larger size than those found with functional imaging tools, some of which may potentially have metastatic disease or smaller additional lesions in the breast in the adjacent tissue. This is because both cancers and breast tissue appear white on mammography, making breast density a limitation in identifying breast cancer. We have added ultrasound to find more cancers because it functions well with dense breast tissue, but it is time-consuming and depends on user accuracy to identify breast lesions.

In the last 10 years, functional imaging tools have become available. These provide information on how cancer cells function differently from normal cells. Breast MRI is one of these tools that rely on tumor angiogenesis to detect breast cancer. Through the use of MRI, we have been able to find

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cancers at an earlier stage.

### **Positron Emission Mammography (PEM)**

Positron emission tomography (PET) relies on differences in glucose metabolism for differentiating cancers from normal cells. Positron emission mammography (PEM) is the breast application of a high-resolution PET scanner. With PEM, we have the opportunity to find cancers at an even earlier stage given the improved resolution when compared to whole body PET. There even exists the possibility that we may find atypia with PEM because, different from other blood flow-reliant technologies like MRI and molecular breast imaging (MBI) or breast specific gamma imaging (BSGI), we are looking at cellular metabolism, which will increase prior to the onset of neoangiogenesis. PEM provides a 3D tomographic view of the breast, allowing us to very easily identify the exact location of the lesion. With PEM imaging, we inject <sup>18</sup>F-FDG into the patient's vein. Uptake of FDG in the cells is proportional to metabolic activity. This positron emitter will release gamma rays, which contributes to the formation of an image, allowing us to quantitate the amount of FDG uptake in the breast and infer the metabolic rate and therefore the pathology. A high metabolic rate may indicate the presence of cancer.

The scanner is small and compact, mobile and on wheels. It has a similar configuration to mammography, which allows for capture of all standard mammographic views including axillary imaging. The breast is gently immobilized at about 50% pressure of a mammogram. The spatial resolution is very high, down to 1.6 mm, in the range of ductal size, thereby successfully imaging ductal carcinoma in situ (DCIS). Each scan takes between 4 and 10 minutes to acquire. Patients tolerate the exam very well and remain in an upright position in the same room as the technologist, which is comforting for them. The FDA cleared breast biopsy guidance software to facilitate PEM-guided biopsy in 2008. This permits accurate sampling of lesions identified only with PEM imaging minimally invasively.

### **How We Use Different Breast Imaging Tools at BRRH**

At BRRH, we practice personalized breast imaging. Women who are at normal risk for developing breast cancer receive high-quality digital mammography. If patients have dense breast tissue, we add bilateral breast ultrasound in an attempt to find incremental cancers. For our patients who are at highest risk, for example our BRCA patients, Hodgkins patients treated with mantle radiation, or those who have a recent diagnosis of breast cancer, we recommend a functional tool, either MRI or PEM. PEM is the tool of choice if patients have a history of claustrophobia or if they are obese and are unable to tolerate a breast MRI. If patients are hormonally active or premenopausal, or have a pacemaker, renal insufficiency, cerebral aneurysm clips, or other MRI contraindications, we automatically refer to PEM. However, MRI is the tool of choice for the more posterior lesions in the breast, particularly if we suspect chest wall involvement clinically or if patients have poorly controlled diabetes.

### **Challenges with PEM**

False negatives include very tiny tumors and those of low metabolic rate. Lesion location is important, particularly early on with use of the technology when technologists are learning how to best position the patient. Tumors with low metabolic activity or micrometastatic disease of the lymph nodes can be a challenge for PEM imaging. Lowest grade DCIS may be difficult to identify. Patients who have poorly controlled diabetes have high circulating levels of glucose, which will compete with FDG uptake within the tumor cells. In our experience, we have seen a very small number of false positives. These most commonly occur in patients who have fat necrosis or

granulation post-biopsy. Rarely, we see uptake within papillomas or fibroadenomas. Especially today, the dose of radiation is challenging, particularly as we potentially move into the screening realm. Fortunately, recent studies presented at SNM 2011 have shown that 5 mCi, or 50% the previous standard of care dose, does not alter image quality and is clinically acceptable. We have adopted this lower dose clinically at our center for the past year.

### **Benefits of PEM**

There are multiple benefits of PEM. It is a compact plug-in functional imaging tool that

requires no specific room shielding requirements. There are standardized imaging acquisition and interpretation methods with minimal training required for the technologist and physician, unlike breast MRI. We find that there is no hormone effect or specific timing of the exam, which is necessary with blood flow-based studies such as breast MRI and MBI/BSGI, so we can proceed with breast staging much more quickly. There is also improved specificity with PEM compared to MRI. Perhaps this will result in fewer prophylactic mastectomies, which are more prevalent since the adoption of breast MRI for preoperative staging. Finally, PEM's sensitivity is equivalent to that of MRI, so there is no compromise in the detection of breast cancer.

### **Financial Impact**

The goal of our study was to measure the impact that offering a cutting edge breast imaging technology had on the financials of our hospital. We chose to participate in a multisite clinical trial evaluating PEM and MRI and whole body PET imaging between June 2006 and November 2008. Women greater than 25 years of age with histologically proven breast cancer who qualified for breast conserving surgery were enrolled in this IRB-approved prospective trial. A retrospective analysis was undertaken to determine the number of women not previously affiliated with BRRH who enrolled because of PEM imaging, the number of women who stayed within the BRRH system who enrolled because of PEM imaging, and the number of patients who continue to receive their care at BRRH.

A total of 250 women enrolled for the PEM trial. Of these, 144/250 (58%) were women who previously received their care from outside the BRRH system. These 144 women resulted in approximately \$233,568 additional imaging revenue because of their participation in the PEM trial. Of these 144 subjects, imaging results prompted biopsies in 37 patients for an approximate revenue of \$19,240. Of the 144 participants not previously using the BRRH system, 73% chose to receive their cancer surgery at BRRH, bringing in an incremental \$2,625,000. Since surgery, 48% (50/105) are continuing their follow-up care at BRRH.

According to the Department of Labor, women make 80% of health care decisions for a family.<sup>2</sup> Although we have not yet documented the secondary impact of incremental patient volume from family members of the original study participants, it may be inferred that perhaps BRRH



***Kathy Schilling, MD***

benefited from additional referrals based on the positive experience related to trial participation. This is a topic of further investigation.

Conducting a PEM clinical trial offered “state of the art” breast cancer imaging technology to women both within and outside of the BRRH system, resulting in additional revenue for BRRH.

### **Future of PEM**

In our clinical practice, PEM has been able to identify lesions earlier than breast MRI including atypical hyperplasia. Based on our experience, I believe PEM may be potentially an attractive tool to screen patients who are at highest risk including BRCA 1 and 2 patients who begin screening at an early age. This may offer the opportunity to identify atypia and thereby prompt appropriate prophylactic management.

Recently published results have shown that of the additional unsuspected lesions found in the ipsilateral breast by PEM, there have been fewer false positives, fewer additional imaging studies, fewer additional biopsies, and a shorter time frame to get to surgery.<sup>3</sup> With contralateral lesions, we see sensitivity similar to MRI and improved specificity.<sup>4</sup> A study was recently presented at ARRS 2011 that reported the feasibility of performing PEM-guided biopsy as an initial procedure on an index lesion using the same injection of FDG as the initial diagnostic PEM scan.<sup>5</sup> Same day imaging and biopsy with one injection of contrast media is not feasible with MRI, MBI, or BSGI. Because we can image the specimen and confirm uptake within the material, we get immediate feedback that the PEM biopsy was successful, which expedites patient work-up.

I am confident that PEM will become a significant imaging tool for patients, possibly for screening in the future but certainly for monitoring patients with a history of breast cancer and to stage those patients with newly diagnosed breast cancer. It is clear from our study results that PEM not only is a useful tool for our patients and physicians that attracts new business to the hospital, but it also may save health care dollars when compared to breast MRI.

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***Kathy Schilling, MD***, is Medical Director of Imaging and Intervention, Women’s Center/Center for Breast Care, Boca Raton Regional Hospital, Boca Raton, Fla. She can be reached at

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