Clinical Area: FDG PET for breast cancer: Restaging FDG PET, breast cancer, whole-body PET

Reference: Moon DS, Maddahi J, Silverman DHS, Glapsy JA, Phelps ME, Hoh CK. Accuracy of whole-

body fluorine-18-FDG PET for the detection of recurrent or metastatic breast carcinoma. J

Nucl Med 1998; 39: 431-435.

Study Type: Comparison of diagnostic tests; <u>retrospective</u>.

Study Aim: To assess the diagnostic accuracy of whole-body FDG PET for the detection of tumor foci in patients with suspected recurrent or metastatic breast cancer.

Outcomes

• *Primary:* Sensitivity, specificity

Design

• *Number of subjects:* N=57

- Description of study population: Women referred to UCLA PET center with a clinical suspicion of disease recurrence. Mean age=55 years (range 33-80 years); mean time interval between breast cancer diagnosis and PET scan=4 years (range 1 mo-18 years).
- *Inclusion and exclusion criteria:* <u>Inclusion:</u> Female patients with breast carcinoma who had surgery with or without adjuvant chemotherapy or radiation therapy. <u>Exclusion:</u> Patients who had chemotherapy or radiation therapy within 3 months of PET scan; lesions that were already biopsied or known to have recurrent disease before PET scan.
- *Power*: Not discussed.

Validity

- Independent blind comparison with a gold standard or follow-up of those not receiving the gold standard test? Yes. Gold standard=biopsy of the lesion and 6 months of clinical follow-up data. Three independent assessors interpreted PET scan findings. They were blinded to biopsy data but informed of clinical reason for PET scan.
- Was "normal" defined? No.
- Appropriate spectrum of disease? Yes, for restaging.
- *Consecutive patients?* Does not appear to be.
- *Methods described in enough detail to enable you to replicate the test?* Yes.
- Reproducible results? Yes.

Conclusions regarding validity of methods:

Patients do not appear to be consecutive which could introduce selection bias. Sensitivity and specificity of PET scans were not compared to findings from other diagnostic tests.

Results

Inter-rater reliability:

27/56 (48%) of patients All 3 observers agreed

2257 (38%) of patients Score of 1 observer deviated one score grade

8/57 (14%) of patients Score of 1 observer deviated more than one grade

Score: 1=definitely negative; 2=probably negative; 3=possibly positive; 4=probably positive; 5=definitely positive.

PPV=positive predictive value; NPV=negative predictive value

Findings of whole-body FDG PET scans by patient (n=57)

%

Positive = score of 4-5

Sensitivity 93 Specificity 79 PPV 82 NPV 92

Positive = score of 3-5

Sensitivity 93 Specificity 61

PPV not given NPV not given

Findings of whole-body FDG PET scans by lesion (n=80)

%

Positive = score of 4-5

Sensitivity 85 Specificity 79

Positive = score of 3-5

Sensitivity 90 Specificity 54

Bone metastases had a substantially larger proportion of false-negative lesions than other malignant sites when positive=score of 4-5.

Sensitivity=69% for bone metastases

Sensitivity=96% for non-bone metastases

Authors' Conclusions

Whole body FDG PET scans are a sensitive diagnostic test for the detection of recurrent or metastatic lesions of breast cancer. Sensitivity for metastasis to bone is lower than for other tissues. Specificity was relatively low on a lesion basis compared to most PET studies for other cancers. More strict attention to patient preparation and better recognition of physiological or artifactual uptake will likely improve specificity in future studies.

Reviewer's Conclusions

Sensitivity and specificity of FDG PET may not be high enough to forego biopsy. The authors did not discuss the sensitivity and specificity of other diagnostic tests or the extent to which FDG PET scan findings affected patient management decisions. Three people independently assessed the PET scans. They all agreed less than half the time suggesting the need for multiple interpretations of PET findings.