Clinical Area:	FDG PET for breast cancer: Diagnosis
Keywords:	FDG PET, breast cancer, carcinomas, diagnosis
Reference:	Avril N, Rose M, Schelling J, Dose W, Kuhn S, Weber W. et al. Breast imaging with Positron
	Emission Tomography and fluorine-18 fluorodeoxyglucose: Use and limitations. J Clin Oncol
	2000; 18: 3495-3502.

Study Type:Comparison of diagnostic testsStudy Aim:To evaluate the diagnostic value of FDG PET for the diagnosis of primary breast cancer.

Outcomes

• Primary: Sensitivity, specificity

Design

- *Number of subjects:* N=144
- *Description of study population:* Women referred for breast surgery. Mean age=50.6 ±10.3 years, 46% postmenopausal.
- *Inclusion and exclusion criteria:* <u>Inclusion</u>: At least 18 years old; abnormal mammographic findings or palpable breast masses. <u>Exclusion</u>: prior surgery to the breast, chemotherapy or radiation therapy within the last 3 months; pregnant, known diabetes.

Validity

- *Independent blind comparison with a gold standard or follow-up of those not receiving the gold standard test?* Yes, observers blinded to clinical history. All women had surgery; histopathological findings were the gold standard.
- *Was "normal" defined?* Implied but did not give specific SUV values.
- *Appropriate spectrum of disease?* Yes.
- Consecutive patients? Not specified.
- *Methods described in enough detail to enable you to replicate the test?* Yes.
- *Reproducible results?* Yes.

Conclusions regarding validity of methods:

Basically valid. A possible limitation is that patients may not have been consecutive which could introduce selection bias.

Results

Among the 144 patients, histological findings detected 185 breast masses

132 breast carcinomas, mean diameter 3.1 ± 2.2 cm (range=0.3-12.0 cm)

53 benign lesions

Categorization of FDG PET results:

Grade 1 (unlikely malignancy)= regional FDG uptake within the background activity of normal breast tissue

Grade 2 (probably malignancy) = diffuse or moderate focally increased FDG uptake

Grade 3 (definite malignancy)=focally marked increased FDG uptake

FDG PET results

Image analysis including all histologically confirmed breast masses (n=185)

	CIR ¹		SIR ²
True positive, n 85		106	
False-negative, n False-negative, n	3 47	40	13 26
Sensitivity Specificity PPV NPV	%, 95% CI 64.4 (56-73) 94.3 (84-99) 96.6 (90-99) 51.5 (41-62)		%, 95% CI 80.3 (73-87) 75.5 (62-86) 89.1 (82-94) 60.6 (48-72)

PPV=positive predictive value; NPV=negative predictive value; CI=confidence interval

¹Conservative image reading (CIR): Only grade 3=malignancy ²Sensitive image reading (SIR): Grade 2 and grade 3=malignancy

Sensitivity by tu	ımor size		
Size (cm) ¹	No. of tumors	CIR %, 95% CI	SIR %, 95% CI
Stage T1			
≤0.5	4	0.0	25.0
>0.5-1.0	8	12.5	25.0
>1.0-2.0	32	62.5	84.4
Stage T2			
>2.0-5.0	62	80.6	91.9
Stage T3			
>5.0	14	78.6	100

¹WHO classification of tissue specimens: T1=tumor diameter 2 cm or less; T1a, more than 0.1 cm, not more than 0.5 cm; T1b, more than 0.5 cm, not more than 1 cm; T1c, more than 1 cm, not more than 2 cm: T2, diameter more than 2 cm, not more than 5 cm:

Authors' Conclusions

Our study demonstrates that FDG PET does not provide sufficient accuracy to exclude breast cancer in patients who present with abnormal mammography or palpable breast masses. In a patient population with a significantly lower prevalence of breast cancer, SIR PPV will decrease compared with CIR. Diagnostic accuracy was dependent on tumor size. These results suggest that the number of unnecessary invasive procedures may not be significantly reduced by the use of currently available PET imaging techniques.

Reviewer's Conclusions

There was a trade-off between sensitivity and specificity using CIR vs. SIR. Negative predictive values were low for both interpretation method, limiting the usefulness of PET to assist surgical decisions.