Clinical Area: **FDG PET for melanoma**
Keywords: **melanoma, PET, metastatic**
Reference: **Tyler DS, Onaitis M, Kherani A, Hata A, Nicholson E, Keogan M et al. Positron emission tomography scanning in malignant melanoma. Cancer 2000; 89: 1019-25.**

Study Type: Comparison of diagnostic tests
Study Aim:. To investigate the efficacy and clinical utility of PET scans in patients with stage III melanoma.

Outcomes
- *Primary:* Sensitivity, specificity
- *Secondary:* Change in patient management

Design
- *Number of subjects:* N=95, N=106 FDG PET scans
- *Description of study population:* Patients evaluated at a university medical center melanoma clinic. n=49, lymph node disease alone, n=8 in-transit disease, n=48 both lymph node and in-transit disease. No demographic information given.
- *Inclusion and exclusion criteria:* Inclusion: believed to have at least Stage III disease on clinical exam (defined as either clinically evident regional lymph node disease, in-transit disease or both; candidates for further surgical intervention. Exclusion criteria not specified.
- *Power*: Not discussed.

Validity
- *Independent blind comparison with a gold standard or follow-up of those not receiving the gold standard test?* Yes, FDG PET activity was assessed independently by two independent observers who were blinded to computed tomography (CT) results and to clinical and pathological findings. Pathological findings were the gold standard (biopsies of areas of increased PET activity).
- *Was "normal" defined?* Not clearly defined. Assessors rated sites as positive (activity greater than background) or negative (activity less than or equal to background).
- *Appropriate spectrum of disease?* Advanced disease only (Stage III or greater)
- *Consecutive patients?* Yes.
- *Methods described in enough detail to enable you to replicate the test?* Yes.
- *Reproducible results?* Yes.

Conclusions regarding validity of methods:
Reasonably well done study evaluating a diagnostic test. Sample size was relatively small.

Results

Sensitivity and specificity of FDG PET by lesion

PET results	Pathology results Positive	Negative	**Totals**
Positive	144	39	**183**
Negative	21	30	**51**
Totals	**165**	**69**	**234**

Sensitivity=144/165= 87% Specificity=30/69= 43%

PPV= 144/183=79% NPV=30/51=59%

Breakdown by site: FDG PET vs. pathological findings

Site of increased PET activity*	**No. confirmed****	**No. not confirmed****
Head and neck	2	2
Brain	0	1
Upper extremity	2	5
Trunk	3	3
Lower extremity	5	6
Spleen	1	0
Lung	6	3
Liver	2	0
Colon	0	1
Diaphragm	1	0
Spine	2	0
Axillary lymph nodes	2	4
Cervical lymph nodes	0	3
Inguinal lymph nodes	0	2
Illac lymph nodes	3	4
Supraclavicular lymph nodes	3	2
Mediastinal lymph nodes	3	2
Skin	0	1
Female genitals	1	0
Total	**36**	**39**

*These areas were not suspected by clinical examination to be areas of metastatic disease.
** Confirmed or not confirmed pathologically to be melanoma.

FDG PET scan findings changed the management of 15 out of 95 (16%) of patients.

Authors' Conclusions:
"Our study suggests that PET scanning is sensitive in detecting metastatic disease and identifies unsuspected disease. Of note, much as with CT scans, false-positive results also occur with PET. Twenty percent of increased areas of PET activity was found not be represent melanoma; however, this could be decreased to approximately 10% with the application of clinical history to eliminate areas of infection, recent surgery and inflammation."

Reviewer's Conclusions:
This recent study, which had a reasonably valid methodology (prospective, consecutive patients, blinded interpretation of PET results) found a low sensitivity and NPV for FDG-PET scans. Sensitivity was relatively high (87%), but did not approach 100%. Patient management was changed as the result of FDG PET findings, but patients outcome information was not given.