Evidence Table

Clinical Area: **FDG-PET scan for imaging of patients with a history of cervical cancer.**

Reference: **Yen T-C, See L-C, Change T-C et al. Defining the priority of using FDG-PET for recurrent cervical cancer. J of Nuclear Med 2005; 45: 1632-1639.**

Study Type: Case Series
Study Aim: To define appropriate criteria for selecting candidates for PET among patients with recurrent cervical cancer.

Outcomes

- *Primary*: Factors associated with having treatment changed due to PET findings.
- *Secondary:* Sensitivity, specificity. Survival.

Design

- *Number of subjects:* N=55
- *Description of study population:* Study conducted in Taiwan. Mean age at first recurrence=51 years (range=25-86 years).
- *Inclusion criteria:* Enrolled in one of two studies evaluating the role of FDG-PET in cervical cancer treatment. Common eligibility criteria were completion of definitive radiotherapy (RT) or surgery; no contraindications to CT/MRI and PET scans; potentially curable and willing to receive curative salvage therapy. One study included patients with biopsy-documented recurrent or persistent cervical cancer. In the other study, an additional criterion was elevated serum makers.
- *Exclusion criteria:* Common to enrollment in the two studies: Salvage therapy for previous recurrence; unfit to receive curative salvage therapy; history of other malignancy other than basal cell carcinoma of the skin.
- *Consecutive patients?* No.
- *Intervention*: All patients received abdominal and pelvic CT/MRI before enrollment. PET was performed within 2 weeks of CT/MRI. Three experienced physicians interpreted the PET data; agreement of findings from at least 2 was obtained. Visual analysis was the primary PET evaluation method. CT/MRI and PET images were fused with a commercially available software program when there was an abnormally elevated region of 18F-FDG uptake or discrepant results. A biopsy was attempted when there were discrepant findings between the CT/MRI and PET scans. If biopsy was not feasible, patients were followed up 3-6 months later with a CT/MRI or PET.
- *Source of outcome data*: Scanning images, biopsy.
- *Length of follow-up:* Median length of follow-up from recurrence=16 months (range=8-28 months).

Validity

- *Was population homogenous?* All were cervical cancer patients but varied in disease severity, initial treatment and other factors.
- *Were intervention/ care/follow-up similar in each group?*

- *Did an objective observer assess outcomes?*
- *Completeness of follow-up:*
- **Conclusions regarding validity of methods:**

Results

Accuracy of imaging in recurrent cervical cancer patients (n=55)

	Sensitivity (%) (95% CI)	Specificity (%) (95% CI)
PET	89.4 (81.3-94.8)	98.2 (96.6-99.2)
CT/MRI	47.9 (37.5-58.4)	98.2 (96.6-99.2)

Modification of treatment due to PET and prognostic factors.

All 55 patients were considered potentially curable for salvage therapy at enrollment.

36/55 (65%) had treatment modification plans after scanning.
- 9/36 (25%) had treatment remaining curative in intent, with a change in the modality or field of radiation
- 27/36 (75%) switched to palliative therapy.

Note: no details were given on treatments recommended by results of CT/MRI imaging vs. treatment recommended by PET findings.

Prognostic scoring system

In multivariate analysis, three factors were associated with survival: squamous cell carcinoma antigen (SCC-Ag) serum levels at recurrence; primary treatment modality; and the presence of symptoms at recurrence. The following point system was developed:
- 1 point for SCC-Ag >4 ng/mL
- 1 point for presence of symptoms at recurrence
- 1 point for primary treatment with radiotherapy (0 points for radical surgery).

A score of 0-1=low-risk, 2=intermediate risk, 3=high-risk

Modification of salvage treatment due to PET according to the risk score (n=52)

Risk score	Treatment planning	No. pts	No. deaths (95% CI)	HR for death in 2 yrs (CI)
0-1 (n=27)	No change	10	1	1 (reference)
	Change: curative intent	7	0	
	Change: palliation	10	1	
2	No change	5	3	6.9 (1.5-32.1)

(n=19)	Change: curative intent	2	0	
	Change: palliation	12	7	
3	No change	1	1	60.5 (9.7-378.1)
(n=6)	Change: curative intent	0	0	
	Change: palliation	5	4	

Authors' Conclusions

"Using this score system, 18F-FDG PET may offer maximal benefits by selecting appropriate recurrent cervical cancer patients for salvage therapy with precise restaging information."

Reviewer's Conclusions

The investigators report that 36 out of 55 patients had their treatment plans modified after PET, 9 had a change in curative therapy and 27 switched to palliative therapy. The authors did not provide details of how the PET findings led to this change in treatment plan, or how PET findings differed from that of CT/MRI.

A risk scoring system (0 to 3) was developed based on study results. In the discussion section, the authors state that the highest priority use of PET in countries with limited resources might be for patients with a score of 0 or 1, those with a better prognosis. This risk scoring system has the potential for helping to identify patients with a better prognosis. However, data in this study are inadequate to show that it is useful, the sample size was insufficient. The probability of dying in two years was significantly higher for patients with a risk score of 2 or 3, compared to 0-1. However, the estimates were based on very small numbers and the estimates are unreliable, as evidenced by the wide confidence intervals.