Appendix A: PET Oncology Coverage Indications

Indication	Covered [1]	Nationally Non-covered [2]	Covered Under Prospective Clinical Studies [3]
Brain			X
Breast			
Diagnosis		X	
Initial staging of axillary nodes		X	
Staging of distant metastasis	X		
Restaging, monitoring *	X		
Cervical			
Staging as adjunct to conventional imaging	X		
Other staging			X
Diagnosis, restaging, monitoring *			X
Colorectal			
Diagnosis, staging, restaging	X		
Monitoring *			X
Esophagus			
Diagnosis, staging, restaging	X		
Monitoring *			X
Head and Neck (non-CNS/thyroid)			
Diagnosis, staging, restaging	X		
Monitoring *			X
Lymphoma			
Diagnosis, staging, restaging	X		
Monitoring *			X

[1] Covered nationally based on evidence of benefit. Refer to National Coverage Determination Manual for specific coverage language and limitations for each indication. http://www.cms.hhs.gov/manuals/103_cov_determ/ncd103c1_Part4.pdf

[2] Non-covered nationally based on evidence of harm or no benefit.

[3] Non-covered nationally based on lack of evidence sufficient to establish either benefit or harm, or no prior decision addressing this cancer.

* Monitoring = monitoring response to treatment when a change in therapy is anticipated.

Appendix A: PET Oncology Coverage Indications (continued)

Indication	Covered [1]	Non-covered [2]	Covered Under Prospective Clinical Studies [3]
Melanoma Diagnosis, staging, restaging Monitoring *	 X		 X
Non small cell lung cancer Diagnosis, staging, restaging Monitoring *	 X		 X
Ovarian			X
Pancreatic			X
Small cell lung			X
Soft tissue sarcoma			X
Solitary pulmonary nodule (characterization)	X		
Thyroid Staging of follicular cell tumors Restaging of medullary cell tumors Diagnosis, other staging & restaging Monitoring *	 X		 X X X
Testicular			X
All other cancers not listed herein			X

[1] Covered nationally based on evidence of benefit. Refer to National Coverage Determination Manual for specific coverage language and limitations for each indication. http://www.cms.hhs.gov/manuals/103_cov_determ/ncd103c1_Part4.pdf

[2] Non-covered nationally based on evidence of harm or no benefit.

[3] Non-covered nationally based on lack of evidence sufficient to establish either benefit or harm, or no prior decision addressing this cancer.

* Monitoring = monitoring response to treatment when a change in therapy is anticipated.

Appendix B

Synopsis of CMS NCD Manual
Section 220.6: Positron Emission Tomography (PET) Scans

Effective Date	Clinical Condition	Coverage
3-1-1995	Myocardial perfusion using Rubidium 82 tracer	Noninvasive imaging of myocardial perfusion
1-1-1998	Solitary pulmonary nodule	Characterization
1-1-1998	Non small cell lung cancer	Initial staging
7-1-1999	Colorectal cancer	Location of tumor if rising CEA suggests recurrence
7-1-1999	Lymphoma	Staging and restaging as an alternative to gallium scan
7-1-1999	Melanoma	Evaluating recurrence prior to surgery as an alternative to gallium scan
7-1-2001	Non small cell lung cancer	Diagnosis, staging, and restaging
7-1-2001	Esophageal cancer	Diagnosis, staging, and restaging
7-1-2001	Colorectal cancer	Diagnosis, staging, and restaging
7-1-2001	Lymphoma	Diagnosis, staging, and restaging
7-1-2001	Melanoma	Diagnosis, staging, and restaging. Non-covered for evaluating regional nodes.
7-1-2001	Head and neck (excluding CNS and thyroid)	Diagnosis, staging, and restaging
7-1-2001	Refractory seizures	Pre-surgical evaluation
7-1-2001 to 9-1-2002	Myocardial viability	Following inconclusive SPECT
10-1-2002	Breast cancer	As an adjunct to standard imaging modalities for staging patients with distant metastasis or restaging patients with locoregional recurrence or metastasis; as an adjunct to standard imaging modalities for monitoring tumor response to treatment for women with locally advanced and metastatic breast cancer when a change in therapy is anticipated.
10-1-2002	Myocardial viability	Primary or initial diagnosis, or following an inconclusive SPECT prior to revascularization. SPECT may not be used following an inconclusive PET scan.
10-1-2003	Thyroid cancer	Restaging of recurrent or residual thyroid cancer of follicular cell origin that has been previously treated by thyroidectomy and radioiodine ablation

Effective Date	Clinical Condition	Coverage
		and have serum thyroglobulin >10ng/ml and negative I-131 whole body scan performed.
10-1-2003	Myocardial perfusion using ammonia N-13 tracer	Noninvasive imaging of myocardial perfusion
9-15-2004	Dementia/Alzheimer's disease	Patients with Certain types of documented dementia/Alzheimer's disease who meet specified diagnostic criteria

APPENDIX C

General Methodological Principles of Study Design
(Section VI of the Decision Memorandum)

We divide the assessment of clinical evidence into three stages: 1) the quality of the individual studies; 2) the generalizability of findings from individual studies to the Medicare population; and 3) overarching conclusions that can be drawn from the body of the evidence on the direction and magnitude of the intervention's potential risks and benefits.

The methodological principles described below represent a broad discussion of the issues we consider when reviewing clinical evidence. However, it should be noted that each coverage determination has its unique methodological aspects.

1. Assessing Individual Studies

Methodologists have developed criteria to determine weaknesses and strengths of clinical research. Strength of evidence generally refers to: 1) the scientific validity underlying study findings regarding causal relationships between health care interventions and health outcomes; and 2) the reduction of bias. In general, some of the methodological attributes associated with stronger evidence include those listed below:

- Use of randomization (allocation of patients to either intervention or control group) in order to minimize bias.
- Use of contemporaneous control groups (rather than historical controls) in order to ensure comparability between the intervention and control groups.
- Prospective (rather than retrospective) studies to ensure a more thorough and systematical assessment of factors related to outcomes.
- Larger sample sizes in studies to demonstrate both statistically significant as well as clinically significant outcomes that can be extrapolated to the Medicare population. Sample size should be large enough to make chance an unlikely explanation for what was found.

- Masking (blinding) to ensure patients and investigators do not know to which group patients were assigned (intervention or control). This is important especially in subjective outcomes, such as pain or quality of life, where enthusiasm and psychological factors may lead to an improved perceived outcome by either the patient or assessor.

Regardless of whether the design of a study is a randomized controlled trial, a non-randomized controlled trial, a cohort study or a case-control study, the primary criterion for methodological strength or quality is the extent to which differences between

intervention and control groups can be attributed to the intervention studied. This is known as internal validity. Various types of bias can undermine internal validity. These include:

- Different characteristics between patients participating and those theoretically eligible for study but not participating (selection bias).
- Co-interventions or provision of care apart from the intervention under evaluation (performance bias).
- Differential assessment of outcome (detection bias).
- Occurrence and reporting of patients who do not complete the study (attrition bias).

In principle, rankings of research design have been based on the ability of each study design category to minimize these biases. A randomized controlled trial minimizes systematic bias (in theory) by selecting a sample of participants from a particular population and allocating them randomly to the intervention and control groups. Thus, in general, randomized controlled studies have been typically assigned the greatest strength, followed by non-randomized clinical trials and controlled observational studies. The design, conduct and analysis of trials are important factors as well. For example, a well designed and conducted observational study with a large sample size may provide stronger evidence than a poorly designed and conducted randomized controlled trial with a small sample size. The following is a representative list of study designs (some of which have alternative names) ranked from most to least methodologically rigorous in their potential ability to minimize systematic bias:

- Randomized controlled trials
- Non-randomized controlled trials
- Prospective cohort studies
- Retrospective case control studies
- Cross-sectional studies
- Surveillance studies (e.g., using registries or surveys)
- Consecutive case series
- Single case reports

When there are merely associations but not causal relationships between a study's variables and outcomes, it is important not to draw causal inferences. Confounding refers to independent variables that systematically vary with the causal variable. This distorts measurement of the outcome of interest because its effect size is mixed with the effects of other extraneous factors. For observational, and in some cases randomized controlled trials, the method in which confounding factors are handled (either through stratification or appropriate statistical modeling) are of particular concern. For example, in order to interpret and generalize conclusions to our population of Medicare patients, it may be necessary for studies to match or stratify their intervention and control groups by patient age or co-morbidities.

Methodological strength is, therefore, a multidimensional concept that relates to the design, implementation, and analysis of a clinical study. In addition, thorough documentation of the conduct of the research, particularly study selection criteria, rate of attrition and process for data collection, is essential for CMS to adequately assess and consider the evidence.

2. Generalizability of Clinical Evidence to the Medicare Population

The applicability of the results of a study to other populations, settings, treatment regimens and outcomes assessed is known as external validity. Even well-designed and well-conducted trials may not supply the evidence needed if the results of a study are not applicable to the Medicare population. Evidence that provides accurate information about a population or setting not well represented in the Medicare program would be considered but would suffer from limited generalizability.

The extent to which the results of a trial are applicable to other circumstances is often a matter of judgment that depends on specific study characteristics, primarily the patient population studied (age, sex, severity of disease and presence of co-morbidities) and the care setting (primary to tertiary level of care, as well as the experience and specialization of the care provider). Additional relevant variables are treatment regimens (dosage, timing and route of administration), co-interventions or concomitant therapies, and type of outcome and length of follow-up.

The level of care and the experience of the providers in the study are other crucial elements in assessing a study's external validity. Trial participants in an academic medical center may receive more or different attention than is typically available in non-tertiary settings. For example, an investigator's lengthy and detailed explanations of the potential benefits of the intervention and/or the use of new equipment provided to the academic center by the study sponsor may raise doubts about the applicability of study findings to community practice.

Given the evidence available in the research literature, some degree of generalization about an intervention's potential benefits and harms is invariably required in making coverage determinations for the Medicare population. Conditions that assist us in making reasonable generalizations are biologic plausibility, similarities between the populations studied and Medicare patients (age, sex, ethnicity and clinical presentation) and similarities of the intervention studied to those that would be routinely available in community practice.

A study's selected outcomes are an important consideration in generalizing available clinical evidence to Medicare coverage determinations. The goal of our determination process is to assess net health outcomes. These outcomes include resultant risks and benefits such as increased or decreased morbidity and mortality. In order to make this determination, it is often necessary to evaluate whether the strength of the evidence is

adequate to draw conclusions about the direction and magnitude of each individual outcome relevant to the intervention under study. In addition, it is important that an intervention's benefits are clinically significant and durable, rather than marginal or short-lived.

If key health outcomes have not been studied or the direction of clinical effect is inconclusive, we may also evaluate the strength and adequacy of indirect evidence linking intermediate or surrogate outcomes to our outcomes of interest.

3. Assessing the Relative Magnitude of Risks and Benefits

An intervention is not reasonable and necessary if its risks outweigh its benefits. Among other things, CMS evaluates whether reported benefits translate into improved net health outcomes. The direction, magnitude and consistency of the risks and benefits across studies are important considerations. Based on the analysis of the strength of the evidence, CMS assesses whether an intervention or technology's benefits to Medicare beneficiaries outweighs its harms.

Appendix D: Assessment Questions by Cancer

Brain

1) How does the diagnostic test performance of FDG PET, as an adjunct to conventional imaging (e.g., CT, MRI), compare to conventional imaging alone with respect to the following clinical situations:

> In performing guided lesion biopsy of recurrent low-grade brain tumors in patients with an indeterminate MRI?
>
> In distinguishing high-grade from low-grade tumors and distinguishing tumor from radiation necrosis in recurrent brain lesions?

2) How does the diagnostic test performance of FDG PET, as an adjunct to biopsy, compare to biopsy alone with respect to the following clinical situation:
In the initial grading of the degree of malignancy for patients with primary brain tumors when the initial biopsy result was indeterminate grade II/III glioma?

Cervical

1) How does the diagnostic test performance of FDG-PET compare to conventional imaging (e.g., CT, MRI, lymphangiography) in the detection of pre-treatment metastases in newly diagnosed cervical cancer?

2) How does the diagnostic test performance of FDG-PET compare to conventional imaging (e.g., CT, MRI) in the detection of a) residual cervical cancer following treatment (surgery, radiation, chemotherapy, or combinations; b) recurrent cervical cancer following treatment?

Ovarian

1) How does the diagnostic test performance of FDG PET as an adjunct to conventional imaging (e.g., CT, MRI) compare to conventional imaging alone in staging at the time of initial diagnosis?

2) How does the diagnostic test performance of FDG PET as an adjunct to conventional imaging (e.g., CT, MRI) compare to conventional imaging alone in detecting recurrent disease following treatment (surgery, radiation, chemotherapy, or combination)?

3) Does FDG PET accurately and reliably detect, localize, and yield appropriate staging of recurrence in a patient with a history of ovarian cancer who has a rising CA-125 titre and negative conventional imaging (e.g., CT, MRI)? (Note: This is a subset of question 2 from the original request).

4) How does the diagnostic test performance of FDG PET as an adjunct to conventional imaging (e.g., CT, MRI) compare to conventional imaging alone in monitoring the effect of chemotherapy?

Pancreatic

1) How does the diagnostic test performance of FDG-PET as an adjunct to conventional imaging (e.g., CT, MRI, endoscopic ultrasound) compare to conventional imaging alone in the following clinical situations:

In differentiating benign from malignant pancreatic lesions?

In detecting metastatic pancreatic cancer?

2) If adjunctive use of FDG-PET is superior to conventional imaging alone for detection of metastatic pancreatic cancer, for what subpopulation(s) of patients has this superiority been shown?

3) How does FDG-PET compare to conventional imaging (e.g., MRI, CT) for detection of residual or recurrent disease following treatment of primary pancreatic cancer

SCLC

1) How does the diagnostic test performance of FDG PET compare to conventional imaging modalities (e.g., CT, MRI) with respect to the following clinical situations?

In staging to determine the true extent of disease at initial diagnosis in patients with SCLC?

In restaging post treatment to evaluate the response to initial treatment (detect residual or new disease sites) in patients with SCLC?

In diagnosing occult small cell lung cancer in patients with paraneoplastic syndrome(s) commonly associated with this neoplasm?

Testicular

In patients with an established diagnosis of pure seminomas or non-seminomatous germ cell tumors, how does the diagnostic test performance of FDG PET compare to conventional imaging modalities (e.g., CT, MRI) or histology with respect to the following clinical situations:

For initial staging?

In evaluation of residual masses or suspected recurrent disease to reliably distinguish between viable tumor and fibrosis/necrosis?

In determining if there has been a recurrence of tumor in patients with rising serum tumor markers and a normal CT?

Appendix E: Results and Appraisal of AHRQ TA by Cancer

Brain

The TA authors found no studies addressing FDG PET as an adjunct to conventional imaging versus conventional imaging alone in biopsy of recurrent low-grade tumor when there is an indeterminate MRI.

Comparing FDG PET to conventional imaging in distinguishing tumor versus radiation necrosis in recurrent brain tumors, the TA authors found FDG PET sensitivity ranged from 76% to 83% and specificity ranged from 50% to 62%. In three studies, the authors found PET had comparable operating characteristics to SPET/SPECT. The TA authors noted that, although the use of FDG PET "may be a valuable modality" in distinguishing tumor from radiation necrosis, this assessment is "tempered by the results of three studies in which PET had comparable operating characteristics to the more accessible radionuclide studies (SPET/SPECT)."

The TA authors sought data on FDG PET as an adjunct to biopsy versus biopsy alone in grading tumors with indeterminate grade II/III biopsy. No studies identified in the current review examined the performance of PET in clarifying the grade of tumor for patients with indeterminate (grade II/III) biopsy. However, four studies provided data on patients with definite biopsy grade; these provide estimates of sensitivity for high-grade tumor ranging from 69% to 100%, and specificity from 57% to 100%. The TA notes that it is unclear the degree to which FDG PET performance for patients with truly indeterminate biopsy results will resemble the reviewed studies.

Individual study characteristics and study results can be found under Appendix E, which contains the evidence tables for brain cancer included in the AHRQ TA.

Cervical

The TA authors found with respect to PET compared to conventional imaging in detecting pre-treatment metastasis that "PET is more sensitive than CT or MRI for detection of retroperitoneal nodal metastasis in patients with newly diagnosed cervical cancer. Given the potential for PET to have a substantial impact on patient outcomes and costs by altering management strategies (e.g., by avoiding surgery in patients with known lymph node metastases), a well-designed study which addressed the issues of sample size and bias discussed should be a high priority."

The TA authors drew the following conclusions with respect to PET compared to conventional imaging in detecting residual or recurrent cancer following treatment: "Data suggest that PET is more sensitive than conventional imaging and has the potential to improve the early diagnosis of recurrent cervical cancer. These data are limited by small sample sizes. In addition, it is unclear whether improved early diagnosis of extra-pelvic recurrent cervical cancer leads to improved patient outcomes except in the setting of patients who have not previously received radiation.

Ovarian

The TA authors were unable to identify studies providing evidence for the utility of PET in the initial staging of ovarian cancer. The authors concluded that FDG PET as an adjunct to conventional imaging "is not expected to be useful in the routine surveillance of patients with a history of ovarian cancer". The TA authors noted that for patients with rising CA-125 titer and negative conventional imaging there is "fair evidence to support the use of FDG PET for the detection of recurrent ovarian cancer". The authors were unable to identify studies providing evidence for the utility of FDG PET in monitoring the response to chemotherapy for ovarian cancer.

Pancreatic

All studies reviewed assessed PET only as an adjunct to other imaging and diagnostic modalities. No studies assessed PET as a stand-alone method of diagnosing, staging or monitoring for residual disease in pancreatic malignancy.

The TA notes that when PET is used as an adjunct to conventional imaging in diagnosing metastatic disease, studies generally demonstrate a trend toward greater sensitivity of FDG PET compared to use of conventional imaging alone. The TA finds that specificity of FDG PET for the detection of metastasis is somewhat lower than the comparators.

The TA also notes that comparisons between PET and other imaging techniques were incomplete in a number of studies without explanation for the omissions. Although there was a trend toward greater sensitivity for PET results, the lack of complete comparisons makes it difficult to assess the strength of this finding. Additionally, there is a general absence of information in the literature about the quality of the imaging studies being compared to PET. (Delbeke's 1999 study is a notable exception in that the quality of comparative studies was assessed and reported. See further discussion below).

With respect to FDG PET providing useful data in subpopulations with likely metastatic disease, the TA authors found it was difficult to identify subgroups that might achieve a substantially greater benefit from FDG PET data.

Diabetes and abnormal glucose metabolism, both of which are increased in the population with pancreatic malignancy and chronic pancreatic disease, can affect PET results (usually with false negatives), but are treated inconsistently from study to study.

The TA authors found only one study comparing FDG PET to conventional imaging in monitoring response to neoadjuvant treatment. Results indicated some potential for change in patient management, although despite not showing response to initial treatment some patients underwent further treatment anyhow.

Small cell lung cancer

The TA authors commented that inadequate information was present to comment on the comparative performance of FDG PET relative to conventional imaging in staging SCLC.

The TA authors note that due to lack of comparative data on CT/MRI performance, no conclusion could be made in evaluating FDG PET performance compared to conventional imaging in restaging SCLC post treatment.

The TA authors found with respect to FDG PET compared to conventional imaging in diagnosing occult SCLC cancer in patients with paraneoplastic syndrome(s) that the single study identified "suggests a role for PET in diagnosing occult small cell lung cancer, but one that remains to be confirmed using larger sample size as well as a comparator test."

Testicular

When comparing FDG PET to conventional imaging for staging testicular cancer at initial diagnosis, the TA authors commented that although all studies are limited by small sample size, five studies provide fairly consistent evidence that the sensitivity and specificity of FDG PET is higher than CT for the initial staging of patients with germ cell tumors.

In evaluating residual mass or suspected recurrence, the TA authors did not identify any studies which evaluated the role of FDG PET in detecting recurrent disease following initial treatment for germ cell tumors.

In distinguishing between tumor vs. necrosis, the TA authors noted that in four studies FDG PET shows low sensitivity. This is largely due to the inability of FDG PET to distinguish between teratoma and necrosis/fibrosis. The TA authors commented that the specificity of FDG PET is consistently higher than that of CT in this context, but with significant study limitations.

In detecting recurrence in patients with rising tumor markers and negative CT, the authors note that one study addressed this question. FDG PET was found to have a sensitivity of 71% and a specificity of 83% for the diagnosis of recurrent germ cell tumor in patients with rising tumor markets but normal CT, but the study had significant limitations.

6.4. Appendix F – AHRQ TA Evidence Tables by Cancer

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Bader **1999** **PROCITE#** 920 **Cancer Type:** Brain **SOW Question(s) Addressed:** 1b **Fryback et al. Level:** 2	**Dates of data collection:** Unspecified, "over 30 months" **Geographic Location:** Hamburg/Saar, Germany **Prospective/ Retrospective Study:** NS **Enrolled Consecutively:** No (of a "larger" consecutive group, 30 had SPET and PET) **Study Setting:** Academic/ Research **Patient Incl Crit:** • PET result **Result led to incl:** • Abnorm and norm **Comparisons:** • Matched **Use of ref stand:** • Histology	***Patients:*** **N =** 30 **Mean(Median) Age:** 50.6 years **Gender:** 73% Male **High-grade recurrence: Mean Age:** 54.4 years **Gender:** 87% Male **Low-grade recurrence: Mean Age:** 46.7 years **Gender:** 60% Male **Inclusion criteria:** Subset of group of larger patients consecutively referred for routine IMT-SPET and FDG-PET for suspected recurrent tumor or for determination of upgrading after primary therapy **Exclusion Criteria:** NS	**Scanner Model:** ECAT ART (Siemens/CTI) **Resolution:** • **Spatial:** 6.4 mm in plane, 8.2 mm between planes **Acquisition Mode:** 3-D **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** NS **Dose of FDG:** 200 MBq **Time between injection and performance:** NS **Reconstruction Algorithm used:** Filtered back-projection **Glucose Monitoring:** Fasting – 12 hours	**PET done:** Quantitatively and Qualitatively **Criteria used for diagnosis:** Qualitative: positive or negative for tumor tissue by agreement of 2; Quantitative: ROI ratios of tumor to mean brain activity. **Comparator Test done:** SPET **Criteria used for diagnosis:** Qualitative: Positive or negative for the presence of tumor by agreement of 2; Quantitative: ROI ratio of tumor to mean brain activity. **Gold Standard test done:** Qualitatively **Criteria used for diagnosis:** WHO classification and Daumas-Duport scheme – included grade III. Stereotaxic biopsy by CT – progression assessed by comparing previous biopsy result with current histopathologic sample. **Blinding:** **Radiologist:** Yes **Gold Standard reader:** NS	**Clinical diagnosis and PET results** Upgrade PET | | + | - | | + | 7 | 16 | | - | 0 | 5 | Sensitivity = 100% Specificity = 24% Recurrence PET | | + | - | | + | 22 | 0 | | - | 7 | 1 | Sensitivity = 76% Specificity = 100% **Clinical diagnosis and SPET results** Upgrade IMT-SPET | | + | - | | + | 7 | 18 | | - | 0 | 3 | Sensitivity = 100% Specificity = 14% Recurrence IMT-SPET | | + | - | | + | 24 | 0 | | 5 | 1 | 187 | Sensitivity = 70% Specificity = 98%	***Quality Score:*** **Rep.sample: 0** **Setting selection: 0** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 4** **Notes:**

<table>
<tr><th>Study, Year/ General Inclusion Criteria</th><th>Study Design</th><th>Patients/ Subject Characteristics</th><th>PET Technical Characteristics</th><th>Criteria for Abnormality</th><th>Results/ Notes</th><th>Quality Score/Notes</th></tr>
<tr>
<td>
Barker

1997

PROCITE# 1370

Cancer Type: Brain

SOW Question(s) Addressed: 1b

Fryback et al. Level: 2
</td>
<td>
Dates of data collection: 9/92 – 1/94

Geographic Location: San Francisco, CA

Prospective/ Retrospective Study: NS

Enrolled Consecutively:

Study Setting: Academic/ Research

Patient Incl Crit:
• Clin Pres
• Comp test result – MRI

Result led to incl:
• Grade III or IV tumors

Comparisons:
• No comp

Use of ref stand:
• Histology
• Prolonged follow-up – survival
</td>
<td>
Patients:

N = 55

Median Age: 45 years
Age Range: 11-65 years

Gender: 51% Male

Staging:
Grade IV: n=40
Grade III: n=15

Inclusion criteria: All patients who underwent PET for suspected recurrent glioma;
All patients who underwent external beam radiotherapy; MR image showed new enhancement compatible with tumor progression or radiation necrosis

Exclusion Criteria: NS
</td>
<td>
Scanner Model: Siemens ECAT EXACT 921/47

Resolution:
• Intrinsic: 5.4 mm
• Image: NS

Acquisition Mode: NS

Acquisition time per FOV:
• Emission Scan: 20 min
• Transmission Scan: NS

Dose of FDG: 0.143 mCi/kg
Average dose = 10 mCi

Time between injection and performance: 30 min

Reconstruction Algorithm used: Parzen Filter

Glucose Monitoring: Fasting – 4 hours
</td>
<td>
PET done: Qualitatively
Criteria used for diagnosis: Assessment made of abnormality at site of MR image enhancement.
Grade:
0 – no visability;
1 – activity < adjacent area;
2 – activity ≥ adjacent cortex but < contralateral cortex;
3 – activity ≥ contralateral cortex

Gold Standard test done: Clinical follow-up
Criteria used for diagnosis: NS – criteria for diagnosis of necrosis or recurrent brain tumor not stated

Blinding:
Radiologist: NS
Gold Standard reader: NS
</td>
<td>
Survival is the outcome of interest.

All patients with suspected recurrence of a glioma based on an abnormal MRI were studied, N=55, retrospectively.

Clinical treatment was based on the results of all available studies and information.

Survival was analyzed using Kaplan Meier and multivariate analysis.

In Kaplan Meier analysis, a higher PET score was significantly correlated with worse survival.

In Cox multivariate analysis, PET score, number of recurrence, and age all significantly predicted survival.

Survival*
<table>
<tr><th></th><th></th><th>Median</th><th>80%</th></tr>
<tr><td rowspan="4">PET Score</td><td>3</td><td>280.6 (23)</td><td>158.6 (13)</td></tr>
<tr><td>2</td><td>305 (25)</td><td>195.2 (16)</td></tr>
<tr><td>1</td><td>341.6 (28)</td><td>195.2 (16)</td></tr>
<tr><td>0</td><td>NR</td><td>280.6 (23)</td></tr>
</table>

*Survival reported in days (mm), with 1 mm = 1/30 year = 12.2 days.

PET score 2 or 3 – median survival = 299.7 days
PET score 1 or 2 – median survival = 586.6 days
</td>
<td>
Quality Score:

Rep.sample: 1

Setting selection: 1

Design minimizes diffs: 0

Scanner: 1

Interpretation criteria defined: 1

Hist or clin confirmation: 1

Blinded: 0

Total Score = 5

Notes:
</td>
</tr>
</table>

<table>
<tr><th>Study, Year/ General Inclusion Criteria</th><th>Study Design</th><th>Patients/ Subject Characteristics</th><th>PET Technical Characteristics</th><th>Criteria for Abnormality</th><th>Results</th><th>Quality Score/Notes</th></tr>
<tr>
<td>
De Witte

2000

PROCITE#
540

Cancer Type:
Brain

SOW Question(s) Addressed:
2a

Fryback et al. Level:
2
</td>
<td>
Dates of data collection:
1991 – 1996

Geographic Location:
Brussels, Belgium

Prospective/ Retrospective Study: NS

Enrolled Consecutively: NS

Study Setting:
Academic/ Research

Patient Incl Crit:
• Ref stand result

Result led to incl:
• Abnormal only

Comparisons:
• No comp

Use of ref stand:
• Histology
</td>
<td>
Patients:

N = 91
Grade III – n=30
Grade IV – n=61

Mean(Median) Age:
Grade III – 46.33 yrs
Grade IV – 61.62 yrs

Gender: NS

Inclusion criteria:
NS

Exclusion Criteria:
NS
</td>
<td>
Scanner Model:
CTI-Siemens 933/08-12

Resolution:
• Spatial: 5 mm

Acquisition Mode:
NS

Acquisition time per FOV:
• Emission Scan: 20 min
• Transmission Scan: NS

Dose of FDG:
Approximately 260 MBq

Time between injection and performance:
40 min

Reconstruction Algorithm used:
NS

Glucose Monitoring:
NS
</td>
<td>
PET done: Qualitatively

Criteria used for diagnosis: Metabolic grading scale:
1 – Uptake less than contralateral white matter;
2 – Between levels of uptake in contralateral white and gray matters;
3 – Uptake equal or greater than in contralateral matter.

Gold Standard test done: Histology

Criteria used for diagnosis: WHO classification

Blinding:
Radiologist: NS
Gold Standard reader: NS
</td>
<td>
Grade vs. t_{50} (50% survival time)

All Patients
<table>
<tr><th></th><th>t_{50} (months)</th></tr>
<tr><td>Grade 1 and 2</td><td>24</td></tr>
<tr><td>Grade 3</td><td>10.5</td></tr>
</table>
Glioblastoma (n=61)
<table>
<tr><th></th><th>t_{50} (months)</th></tr>
<tr><td>Grade 2</td><td>9.2</td></tr>
<tr><td>Grade 3</td><td>9</td></tr>
</table>
</td>
<td>
Quality Score:

Rep.sample: 0

Setting selection: 0

Design minimizes diffs: 0

Scanner: 1

Interpretation criteria defined: 1

Hist or clin confirmation: 1

Blinded: 0

Total Score = 3

Notes:
</td>
</tr>
</table>

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Delbeke **1995** **PROCITE#** 1650 **Cancer Type:** Brain **SOW Question(s) Addressed:** 2a **Fryback et al. Level:** 2	**Dates of data collection:** NS **Geographic Location:** Nashville, TN **Retrospective Study** **Enrolled Consecutively:** No – retrospective **Study Setting:** Academic/ Research **Patient Incl Crit:** • Clin Pres • Ref stand result – Histology **Result led to incl:** • Abnormal only – known brain tumor histologically proven **Comparisons:** • No comp **Use of ref stand:** • Histology	***Patients:*** **N =** 59 tumors in the brain, N=38 gliomas **Staging (all tumors):** N=18 High Grade Glioma N=8 High Grade "other" N=20 Low Grade Glioma N=12 High Grade "other" **Mean Age:** 38±25 years **Gender:** 71.2% Male **Inclusion criteria:** Histologically proven brain tumors; CT or MR shows lesion > 1 cm **Exclusion Criteria:** Prior surgery, radiation or chemotherapy; N=1 patient who had seizures during PET scan, and was therefore excluded	**Scanner Model:** Siemens ECAT 933/08/16 (Iselin, NJ) **Resolution:** • **Intrinsic:** 4.8 mm • **Reconstructed:** 6.5 mm **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** 15 min • **Transmission Scan:** 15 min **Dose of FDG:** 370 MBq (10 mCi) **Time between injection and performance:** 35 min **Reconstruction Algorithm used:** NS **Glucose Monitoring:** Fasting – 4 hours; Glucose measured, maximum amount permitted not specified	**PET done:** Semi-Qualitatively **Criteria used for diagnosis:** 1. FDG uptake in white matter and cortex contralateral to lesion used as reference; 2. ROI identified visually, ratios of tumor uptake to tumor and white matter uptake were made (T/WM and T/C, T=tumor and C=cortex); 3. Optimal cut-off rates for predicting grade were estimated. **Gold Standard test done**: **Qualitatively** **Criteria used for diagnosis:** Histology – type of tumor (grade high or low) **Blinding:** **Radiologist:** NS **Gold Standard reader:** NS	**Results for Gliomas** Sensitivity of their cutoff to predict High Grade vs. Low Grade. Grade T/WM ratio | | High | Low | | > 1.5 | 20 | 6 | | < 1.5 | 0 | 12 | Sensitivity = 100% Specificity = 67% Difference between T/WM and T/C uptake ratios for high-grade and low-grade tumors was significant (p=0.0001).	***Quality Score:*** **Rep.sample: 0** **Setting selection: 1** **Design minimizes diffs: 0** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 4** **Notes:** Overestimates OC: Multiple look problem – adjusted cutpoint to derive a derivative OC estimate *a posterini.* Original data only provided as a Figure.

<table>
<tr><th>Study, Year/ General Inclusion Criteria</th><th>Study Design</th><th>Patients/ Subject Characteristics</th><th>PET Technical Characteristics</th><th>Criteria for Abnormality</th><th>Results</th><th>Quality Score/Notes</th></tr>
<tr>
<td>
Deshmukh

1996

PROCITE# 1410

Cancer Type: Brain

SOW Question(s) Addressed: 1b, 2a

Fryback et al. Level: 3, 4
</td>
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Dates of data collection: 9/90 – 6/92

Geographic Location: Boston, MA

Retrospective Study

Enrolled Consecutively: No – retrospective series

Study Setting: Academic/ Research

Patient Incl Crit:
• Clin Pres
• PET result

Result led to incl:
• Abnormal only
• Abnorm and norm

Comparisons:
• No comp

Use of ref stand:
• Histology
</td>
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Patients:

N = 75 patients (89 scans)

Mean(Median) Age: NS

Gender: NS

Inclusion criteria:
1. Patient had a PET scan – primary glioma;
2. Known histological grade;
3. Good history present in records;
4. Records give the data on which clinical decisions were based

Exclusion Criteria: Of 159 patients with primary brain tumors, 106 had glioma. Of these, 31 excluded because record did not show clinical question to be addressed by PET, or did not contain “explicit enumeration of the data on which clinical decisions were based.”
</td>
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Scanner Model: NS

Resolution:
• Intrinsic: NS
• Image: NS

Acquisition Mode: NS

Acquisition time per FOV:
• Emission Scan: NS
• Transmission Scan: NS

Dose of FDG: Approximately 10 mCi

Time between injection and performance: > 45 min

Reconstruction Algorithm used: NS

Glucose Monitoring: NS
</td>
<td>
PET done: NS

Criteria used for diagnosis: Visual inspection of static images

Gold Standard test done: NS

Criteria used for diagnosis: NS

Blinding:
Radiologist: No
Gold Standard reader: NS
</td>
<td>
I. Reasons for PET (overall N=125 because study reports all reasons for all PET scans)
<table>
<tr><th>Reasons</th><th>N</th><th>%</th></tr>
<tr><td>No reason given and/or no statement in record about how PET related to decision making</td><td>31</td><td>25</td></tr>
<tr><td>Radiation necrosis compared with recurrent tumor</td><td>77</td><td>62</td></tr>
<tr><td>Substitute for biopsy</td><td>10</td><td>8</td></tr>
<tr><td>Localization of hypermetabolic regions to aid biopsy or surgery</td><td>2</td><td>2</td></tr>
<tr><td>Localization of hypermetabolic regions to aid radiotherapy</td><td>2</td><td>2</td></tr>
<tr><td>Post-surgical evaluation for residual</td><td>2</td><td>2</td></tr>
<tr><td>Established baseline tumor metabolism prior to therapy</td><td>1</td><td>1</td></tr>
</table>
II. Proportion of PETs done for a stated reason that played a “valuable clinical role”: 86/89 = 96.6%

III. PET findings led to consideration of a new therapy in 31% of cases.

IV. Therapeutic decision made on basis of PET alone in 28% of cases.

V. In 72% of cases the therapeutic decision was supported by information from other sources such as CT, MRI or clinical findings.
</td>
<td>
Quality Score:

Rep.sample: 0

Setting selection: 0

Design minimizes diffs: 0

Scanner: 0

Interpretation criteria defined: 0

Hist or clin confirmation: 0

Blinded: 0

Total Score = 0

Notes:
</td>
</tr>
</table>

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Janus **1993** **PROCITE#** 2010 **Cancer Type:** Brain **SOW Question(s) Addressed:** 1b **Fryback et al. Level:** 2	**Dates of data collection:** NS **Geographic Location:** Houston, TX **Prospective/ Retrospective Study:** NS **Enrolled Consecutively:** Yes **Study Setting:** Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnormal only • Abnorm and norm **Comparisons:** • Matched • PET and comp – random • PET and comp – not random • No comp **Use of ref stand:** • Histology • Prolonged follow-up	***Patients:*** Overall: **N =** 50 **Age Range:** 15-66 years **Gender:** 64% Male **Surgery after PET:** **N =** 20 **Age Range:** 15-64 years **Gender:** 65% Male **Clinical follow-up after PET:** **N =** 30 **Age Range:** 15-66 years **Gender:** 63% Male **Inclusion criteria:** Primary brain tumor; Prior surgery, radiotherapy and chemotherapy; Abnormal MRI suggesting possible recurrence **Exclusion Criteria:** NS	**Scanner Model:** Posicam 6.5 (Positron Co.) **Resolution:** • **Radial:** 5.5 mm • **Axial:** 11.9 mm **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** 20 min per set (3 sets) **Dose of FDG:** 5-10 mCi **Time between injection and performance:** NS **Reconstruction Algorithm used:** NS **Glucose Monitoring:** NS	**PET done:** Qualitatively **Criteria used for diagnosis:** Increased activity relative to the contralateral hemisphere or adjacent area suggestive of tumor progression; Decreased activity suggestive of radionecrosis **Comparator Test:** MR **Done:** Qualitatively **Criteria used for diagnosis:** Visual inspection **Gold Standard test:** Histology and clinical follow-up **Done:** Qualitatively **Criteria used for diagnosis:** Histology: n=20; Clinical follow-up: n=30. Survival less than 26 weeks considered tumor recurrence. Survival more than 26 weeks considered no tumor recurrence. **Blinding:** **Radiologist:** Yes **Gold Standard reader:** NS	**Biopsy Done:** Recurrence PET | | + | - | | + | 10 | 3 | | - | 2 | 5 | Sensitivity = 83% Specificity = 62% Recurrence MRI | | + | - | | + | 9 | 8 | | - | 2 | 0 | Sensitivity = 82% Specificity = 0% **Clinical follow-up only:** Survival PET | | + | - | | + | 4 | 6 | | - | 2 | 17 | Sensitivity = 67% Specificity = 74% Notes: Best data is the histology criteria data (n=20) which shows SN = 83% and SP = 62%. Clinical criteria for recurrence are weak. For example, if a patient died of their cancer at 27 weeks, they were considered not to have recurred because of the cut-off point of 26 weeks. Reviewer would exclude the 30 patients with “clinical data only” because of this.	***Quality Score:*** **Rep.sample: 0** **Setting selection: 1** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 5** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Kahn **1994** **PROCITE#** 1760 **Cancer Type:** Brain **SOW Question(s) Addressed:** 1b **Frybeck et al. Level:**	**Dates of data collection:** NS **Geographic Location:** Iowa City, IA **Enrolled Consecutively:** Yes **Prospective/ Retrospective Study:** NS **Study Setting:** Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnormal only – CT or MRI interpreted as compatible with tumor **Comparisons:** • Matched **Use of ref stand:** • Histology • Prolonged follow-up – no	***Patients:*** **N =** 19 (21 studies in 19 patients) N=17 Astrocytomas N=2 non-brain tumors (excluded) **Mean Age:** 40 years **Age Range:** 26-58 years **Gender:** **53% Male** **Grade:** I: n=1 II: n=4 III: n=7 IV: n=5 Other: n=2 **Inclusion criteria:** Suspected recurrent tumor vs. radiation necrosis based on suspicious CT/MR or deteriorating clinical response; CT or MR compatible with tumor	**Scanner Model:** GE 4096 Plus PET (GEMS) **Resolution:** 5.5 mm in 3 directions **Acquisition Mode:** 3-D **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** NS **Dose of FDG:** 10 mCi **Time between injection and performance:** 45 min **Reconstruction Algorithm used:** Butterworth filter **Glucose Monitoring:** Fasting – 4 hours	**PET done:** Qualitatively **Criteria used for diagnosis:** Markedly reduced uptake in the confines of the tumor region compatible with radiation necrosis; Visual 5 point scale: 1=no FDG uptake 3=equivocal uptake 5=markedly increased uptake **Comparator Test:** SPECT **Done:** Qualitatively and Quantitatively **Criteria used for diagnosis:** Visual inspection by radiologists judgment, looking at 3 reference regions. Considered malignant if tumor region with hottest activity was > than activity in: 1. Tissue immediately adjacent to the tumor 2. homologous contralateral region 3. contralateral scalp region **Quantitative assessment:** ROI uptake vs. contralateral healthy tissue ratio; For transverse slices, the ^{201}Ti index = highest ratio slice **Gold Standard test done:** Histology (n=5) and clinical follow-up (n=14) **Criteria used for diagnosis:** NS **Blinding:**	**Tumor (T) vs. Radiation Necrosis (RN):** PET Diagnosis RN / T RN: 2, 3 T: 2, 12 Sensitivity = 50% Specificity = 80% SPECT Diagnosis RN / T RN: 2, 5 T: 2, 10 Sensitivity = 50% Specificity = 67%	***Quality Score:*** **Rep.sample: 0** **Setting selection: 1** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 5** **Notes:** No minimum follow-up was given for the 15 patients who did not have a biopsy diagnosis of recurrence. Authors conclude that PET has only 40% specificity for detecting recurrence. SPET had notably

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
	minimum follow-up given	**Exclusion Criteria:** NS		**Radiologist:** Yes **Gold Standard reader:** No		higher reliability than PET.

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Kaschten **1998** **PROCITE#** 1080 **Cancer Type:** Brain **SOW Question(s) Addressed:** 2a **Frybeck et al. Level:** 2	**Dates of data collection:** NS **Geographic Location:** Liege, Belgium **Prospective/ Retrospective Study:** NS **Enrolled Consecutively:** NS **Study Setting:** Academic/ Research **Patient Incl Crit:** • Ref stand result **Result led to incl:** • Abnorm and norm – various grades **Comparisons:**	***Patients:*** **N =** 45 patients with PET (54 patients in all) **Mean Age:** 50±17 years **Age Range:** 12.8-74.9 years **Tumor Grade:** I: N = 1 II: N = 23 III: N = 10 IV: N = 20 **Gender:** 51.8% Male **Inclusion criteria:** Suspected brain gliomas **Exclusion Criteria:** NS	**Scanner Model:** NeuroEcat (EG&G, ORTEC) (N=16) or Siemens ECAT 951/31R (CTI PET Systems) (N=38) **Resolution:** • **NeuroEcat:** 8 mm FWHM • **Siemens ECAT:** 6 mm FWHM **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** 20 min • **Transmission Scan:** NS **Dose of FDG:** 222-370 MBq **Time between injection and performance:** > 30 min **Reconstruction**	**PET done:** Qualitatively and Quantitatively **Criteria used for diagnosis:** **Qualitative:** 2 methods: 1. Comparison with surrounding parenchyma – hypermetabolic (hot) areas considered positive; 2. Visual analysis (Schifter et. al) Grades I-V: I = tumor< white matter II = tumor = white matter **III = WM < tumor < cortex** IV = tumor = cortex V = tumor > cortex **Quantitative:** Tracer uptake ratios – tumor compared to: CTX (contralateral cortex in front of tumor) CCR (same contralateral corresponding region) MCU (mean cortical uptake of 7 ROI's) WM (two ROI's in centrum ovale) W*C (mean uptake of WM and temporal cortex) **Gold Standard test done:** Qualitatively	Histological Grade PET [ ] III/IV III VG > 3 13 10 VG ≤ 3 2 16 Sensitivity = 87% Specificity = 62% Histological Grade SPECT [ ] III/IV III VG ≥ 3 13 10 VG < 3 2 16 Sensitivity = 87% Specificity = 62%	***Quality Score:*** **Rep.sample: 0** **Setting selection: 0** **Design minimizes diffs: 0** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 3** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
	• No comp **Use of ref stand:** • Histology • Prolonged follow-up		**Algorithm used:** NS **Glucose Monitoring:** Fasting – 4 hours	**Criteria used for diagnosis:** WHO and Mayo-Sainte Anne classifications **Blinding:** **Radiologist:** No **Gold Standard reader:** NS		

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Meyer **2001** **PROCITE#** 500 **Cancer Type:** Brain **SOW Question(s) Addressed:** 2a **Frybeck et al. Level:** 2	**Dates of data collection:** 6/97 – 12/99 **Geographic Location:** Aachen, Germany **Retrospective Study** **Enrolled Consecutively:** Yes **Study Setting:** Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnormal only **Comparisons:** • No comp **Use of ref stand:** • Histology	***Patients:*** **N =** 47 total Staging: Glioma II: N=7 Glioma III: N=10 **MeanAge:** 48.4±14.9 years **Gender:** 51% Male **Inclusion criteria:** All patients with supratentorial brain tumors – Imaging tests not specified and presentation not specified **Exclusion Criteria:**	**Scanner Model:** Siemens – CTI ECAT EXACT 922 **Resolution:** • **Spatial:** 5 mm **Acquisition Mode:** 2-D, n=39 patients 3-D, n=8 patients **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** NS **Dose of FDG:** 2-D scans: 188±56 MBq 3-D scans: 141±17 MBq **Time between injection and performance:** 30 min **Reconstruction Algorithm used:** Filtered Backposition **Glucose Monitoring: NS**	**PET done:** Qualitatively and Quantitatively **Criteria used for diagnosis:** Manual placement of ROIs under MRI guidance. Mean pixel counts of: 1. Tumor ROI of maximal FDG uptake (Tu); 2. Symmetric ROI within normal tissue of the contralateral hemisphere (TIS); 3. Gray matter ROI (GM); 4. White matter ROI (WM). Calculated Tu/TIS, Tu/GM, Tu/WM. Qualitative: FDG uptake assessed by visual grading scale (3 blinded observers) which used comparison to gray and white matter uptakes, and is categorized into grades. **Gold Standard test done:** Histology **Criteria used for diagnosis:** WHO classification based on histology after tumor resection **Blinding:** **Radiologist:** Yes **Gold Standard reader:** NS	Tu/Ti Grade (Glioma Grade): II: Low 6, Not Low 1 Not II: Low 3, Not Low 20 Sensitivity = 86% Specificity = 87% ROI cut-off = .78 Tu/GM Grade (Glioma Grade): II: Low 5, Not Low 2 Not II: Low 4, Not Low 19 Sensitivity = 71% Specificity = 83% ROI cut-off = .7 Tu/WM Grade (Glioma Grade): II: Low 4, Not Low 3 Not II: Low 2, Not Low 21 Sensitivity = 57% Specificity = 91% ROI cut-off = 1.26 VGS Grade (Glioma Grade): Not II: ≥3b 25, ≤3a 5 II: ≥3b 1, ≤3a 15 Sensitivity = 83% Specificity = 94% Note: "Low Grade" = Grade I or II **Prevalence:** Grade II = 23% Grade III = 33%	***Quality Score:*** **Rep.sample: 1** **Setting selection: 0** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 5** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Olivero **1995** **PROCITE#** 1660 **Cancer Type:** Brain **SOW Question(s) Addressed:** 1b **Fryback et al. Level:** 3, 4	**Dates of data collection:** 6/91 – 12/92 **Geographic Location:** Peoria, IL **Retrospective Study** **Enrolled Consecutively:** NS – retrospective chart review **Study Setting:** Academic/ Research **Patient Incl Crit:** • PET result **Result led to incl:** • Abnorm and norm **Comparisons:** • Matched **Use of ref stand:** • Histology • Prolonged follow-up	***Patients:*** **N =** 39 (35 known primary tumors, 4 newly suspected tumors) **Mean Age:** NS **Gender:** NS **Inclusion criteria:** NS **Exclusion Criteria:** NS	**Scanner Model:** Siemens 951-31 **Resolution:** • **Intrinsic:** 4 mm • **Image:** NS **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** 20 min **Dose of FDG:** NS **Time between injection and performance:** NS **Reconstruction Algorithm used:** NS **Glucose Monitoring:** NS	**PET done:** NS **Criteria used for diagnosis:** NS **Comparator Test done:** MRI – gadolinium-enhanced **Criteria used for diagnosis:** NS **Gold Standard test done:** Histology and/or Clinical Follow-up **Criteria used for diagnosis:** NS **Blinding:** **Radiologist:** NS **Gold Standard reader:** NS	In 2 out of 39 patients, PET influenced workup/treatment. In 5 out of 39 cases, PET was helpful in distinguishing tumor from other disease processes.	***Quality Score:*** **Rep.sample: 0** **Setting selection: 0** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 0** **Hist or clin confirmation: 0** **Blinded: 0** **Total Score = 2** **Notes:** Retrospective chart review.

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Sasaki **1998** **PROCITE#** 1010 **Cancer Type:** Brain **SOW Question(s) Addressed:** 2a **Frybeck et al. Level:** 2	**Dates of data collection:** 7/93 – 5/97 **Geographic Location:** Kyushu, Japan **Prospective/ Retrospective Study:** NS **Enrolled Consecutively:** NS **Study Setting:** Academic/ Research **Patient Incl Crit:** • Ref stand result **Result led to incl:** • Abnormal only **Comparisons:** • Matched **Use of ref stand:** • Histology	***Patients:*** **N =** 23 Grade: II: N = 7 III: N = 10 IV: N = 6 **Mean Age:** 49.4±16.5 years **Age Range:** 16-73 years **Gender:** 56.5% Male **Inclusion criteria:** All patients had undergone surgery; No patients had received any previous therapy for brain tumors. **Exclusion Criteria:** NS	**Scanner Model:** Headtome III (Shimadzu Corp.) **Resolution:** • **Spatial:** 8.2 mm • **Image:** NS **Acquisition Mode:** 2-D **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** 15 min **Dose of FDG:** 140-370 MBq **Time between injection and performance:** 20 min **Reconstruction Algorithm used:** NS **Glucose Monitoring:** NS	**PET done:** Qualitatively and Semi-Quantitatively **Criteria used for diagnosis:** Qualitative: Visual evaluation of tracer uptake: negative, clearly lower positive, almost equal intensity positive, clearly higher. Semi-quantitative: visually identified ROIs, SUV equaling the average of radioactivity in tumor divided by the injected radioactivity normalized to body weight. **Comparator Test:** Gd enhancement **Done:** Qualitatively **Criteria used for diagnosis:** NS **Gold Standard test done:** Histology **Criteria used for diagnosis:** NS **Blinding:** **Radiologist:** NS **Gold Standard reader:** NS	Visual Grade | | III / IV | III | | FDG + | 11 | 3 | | FDG - | 5 | 4 | Sensitivity = 69% Specificity = 57% Grade | | III/ IV | III | | MRI + | 11 | 0 | | MRI - | 5 | 7 | Sensitivity = 69% Specificity = 100%	***Quality Score:*** **Rep.sample: 0** **Setting selection: 0** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 0** **Blinded: 0** **Total Score = 3** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Stokkel **1999** **PROCITE#** 790 **Cancer Type:** Brain **SOW Question(s) Addressed:** 1b **Fryback et al. Level:** 2	**Dates of data collection:** Over an unspecified 10 month period **Geographic Location:** Utrecht, The Netherlands **Prospective/ Retrospective Study:** NS **Enrolled Consecutively:** Yes **Study Setting:** Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnormal only **Comparisons:** • Matched **Use of ref stand:** • Histology • Prolonged follow-up	***Patients:*** **N =** 16 **Overall:** **Mean Age:** 39.5 years **Gender:** 62% Male **FDG+ (n=8):** **Mean Age:** 39.7 years **Gender:** **75**% Male **Recurrence (n=4):** **Mean Age:** 40.5 years **Gender:** 25% Male **Necrosis (n=12):** **Mean Age:** 39 years **Gender:** 82% Male **Inclusion criteria:** Nondiabetic patients with suspected recurrent glioma after external focal radiotherapy. Suspicion included deteriorating clinical course or suspicious change on CT/MRI. **Exclusion Criteria:** NS	**Scanner Model:** ADAC; Vertex-MCD (Dual SPET/PET) **Resolution:** • **Spatial:** 5 mm **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** NS **Dose of FDG:** 185 MBq **Time between injection and performance:** 60 min **Reconstruction Algorithm used:** Filtered Backprojection **Glucose Monitoring:** Fasting - overnight	**PET done:** Qualitatively **Criteria used for diagnosis:** Increased uptake relative to adjacent tissue considered tumor; FDG Index using counts from ROI divided by counts from adjacent tissue (cut-off value not stated); Uptake graded on scale of 1-5: 1 = no uptake 3 = same uptake as adjacent tissue 5 = markedly increased uptake; FDG Index was highest ratio generated from any slices analysed **Comparator Test Done:** Thallium SPET **Criteria used for diagnosis:** Uptake increased compared to adjacent tissue AND greater than homologous contralateral region AND greater than contralateral scalp considered tumor; Ti Index – ROI counts divided by tissue counts (cut-off value not stated) **Gold Standard test done:** Clinical follow-up 12 months **Criteria used for diagnosis:** NS **Blinding:** **Radiologist:** NS **Gold Standard reader:** NS	PET Recurrence | | + | - | | + | 8 | 0 | | - | 4 | 4 | Sensitivity = 66% Specificity = 100% Ti-SPET Recurrence | | + | - | | + | 12 | 0 | | - | 0 | 4 | Sensitivity = 100% Specificity = 100% Prevalence: 12/16 = 75% **Subject disease characteristics:** N=1 Astrocytoma (II) N=6 Astrocytoma (III) N=1 Astrocytoma/ODG (II) N=4 Astrocytoma (IV) N=1 Astrocytoma/ODG (III) N=1 Glioma (IV) N=1 ODG (B) N=1 ODG (C)	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 0** **Hist or clin confirmation: 0** **Blinded: 0** **Total Score = 4** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Belhocine **2002** **PROCITE#** 2430 **Cancer Type:** Cervical **SOW Question(s) Addressed:** 1, 2b **Fryback et al. Level:** 2, 4	**Dates of data collection:** 9/97 – 6/01 **Geographic Location:** Liege, Belgium **Retrospective Study** **Enrolled Consecutively: Yes** **Study Setting:** Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnormal only- invasive cancer referred for PET **Comparisons:** • PET and comp – not random. Some had MRI, some had CT. **Use of ref stand:** • Histology • Prolonged follow-up	***Patients:*** **N =** 60 (all) N=22: PET for pre-therapy staging N=25: suspected recurrence – PET N=13: surveillance – PET **Mean(Median) Age:** 52±14 years **Inclusion criteria:** Histologically proven cervical cancer; Referred for PET; Technical quality of PET is OK; Confirmation of all positive PET results; Minimum follow-up 12 months for negative PET results. **Exclusion Criteria:** Poor technical quality of PET; Inadequate confirmation of positive PET result; Less than 12 month follow-up of negative PET result.	**Scanner Model:** PENN PET 240H / CPET-ADAC **Resolution:** • Intrinsic: NS • Image: NS **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** NS **Dose of FDG:** 6.3 mCi (average) **Time between injection and performance:** 64 min (average) **Reconstruction Algorithm used:** Iterative **Glucose Monitoring:** Fasting – 4-6 hrs	**PET done:** Qualitatively **Criteria used for diagnosis:** FDG uptake higher than background and noted on ≥ 2 consecutive slides. **Comparator Test:** MRI **Criteria used for diagnosis:** Nodes > 10 mm = pathologic **Comparator Test:** CT **Criteria used for diagnosis:** Nodes > 10 mm = pathologic **Gold Standard test done:** Histology and Clinical **Criteria used for diagnosis:** *Pre-treatment staging (n=22):* Histology: 18 had surgery, histology available Clinical: 4 "clinical and radiological outcomes" *Post-treatment assessment (n=38):* Histology: 11 histology available Clinical: 27 "clinical and radiological outcomes" **Blinding:** **Radiologist:** Yes **Gold Standard reader:** NS	**Pre-treatment Nodal Evaluation** Pathology (nodes) PET: + 19, 3; - 8, 187 Sensitivity = 70% Specificity = 98% Pathology (nodes) CT/ MRI: + 13, 6; - 14, 184 Sensitivity = 48% Specificity = 97% Prevalence = 12.4% **Post-treatment Evaluation** Recurrence PET: + 25, 3; - 0, 10 Sensitivity = 100% Specificity = 77% Recurrence CT/ MRI: + 12, 2; - 13, 11 Sensitivity = 48% Specificity = 85% Prevalence = 65.8% Pre-diagnosis: 4/22 had initial diagnosis changed by PET result. Post-diagnosis: PET finding influenced diagnosis of 13/25 patients (52%). Comparator tests had equivocal results.	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 0** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 5** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
					Note: Major design flaw. In this study each individual lymph node is an “n” and allegedly validated by histology. There is no way to assess individual nodes by PET. They should have defined each “n” as one patient – then if any lymph node was histologically positive and the PET was read as “positive lymph nodes”, it would count as one true positive. The authors may be counting this one patient as multiple true positives, thus magnifying results. It is impossible to re-calculate the SN and SP based on the data given.	

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Grigsby **2003** **PROCITE#** 2380 **Cancer Type:** Cervical **SOW Question(s) Addressed:** 2a, 2b **Fryback et al. Level:** 2, 5	**Dates of data collection:** 3/98 – 8/01 **Geographic Location:** St. Louis, MO **Retrospective Study** **Enrolled Consecutively:** No **Study Setting:** General outpatient clinics/ physician office; Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnorm and norm **Comparisons:** • No comp **Use of ref stand:** • Prolonged follow-up – survival was analyzed – did abnormal PET predict survival.	***Patients:*** **N =** 76 (retrospective) **Mean(Median) Age:** 50 years **Age Range:** 23-88 years **Inclusion criteria:** Patients who presented with invasive cervical cancer for definitive radiation therapy and who had a pre- and post-treatment PET scan (routine). **Exclusion Criteria:** Patients with suspected recurrent disease.	**Scanner Model:** ECAT Exact – Siemens CTI **Resolution:** • Intrinsic: 10 mm • Image: NS **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** NS **Dose of FDG:** 10-15 mCi **Time between injection and performance:** 40 min **Reconstruction Algorithm used:** Filtered Backposition **Glucose Monitoring:** Fasting – 4 hours. Glucose measured with NS maximum amount permitted.	**PET done:** NS **Criteria used for diagnosis:** NS **Gold Standard test:** Survival **Done:** Quantitatively **Criteria used for diagnosis:** Progression free survival and overall survival (Kaplan Meier and Cox) **Blinding:** Radiologist: NS Gold Standard reader: NS	1. Persistent abnormal PET after treatment significantly predicts lower survival (KM & Cox) 2. New areas of uptake on PET after treatment significantly predicts lower survival (KM & Cox)	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 0** **Scanner: 1** **Interpretation criteria defined: 0** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 4** **Notes:** Main issue is no criteria given for how PET was interpreted.

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Grigsby **2001** **PROCITE#** 2500 **Cancer Type:** Cervical **SOW Question(s) Addressed:** 1 **Fryback et al. Level:** 2, 5	**Dates of data collection:** 2/98 – 6/00 **Geographic Location:** St. Louis, MO **Retrospective Study** **Enrolled Consecutively:** Yes **Study Setting:** General outpatient clinics/ Physician office; Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnormal only – must have known cervical cancer **Comparisons:** • Matched **Use of ref stand:** • Prolonged - survival	***Patients:*** **N =** 101 **Mean Age:** 53 years **Age Range:** 26-88 years **Inclusion criteria:** 101 consecutive patients presenting with invasive cervical cancer for primary radiation therapy **Stage:** 1a: N = 2 $1b_1$: N= 8 $1b_2$: N = 18 IIb: N = 39 III: N = 29 Iva: N = 1 Ivb: N = 4	**Scanner Model:** ECAT Exact (Siemens) **Resolution:** • **Intrinsic:** 10 mm • **Image:** NS **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** NS **Dose of FDG:** 10-15 mCi **Time between injection and performance:** 40 min **Reconstruction Algorithm used:** Filtered Backprojection/ Iterative **Glucose Monitoring:** Fasting – 4 hrs. Glucose measured, maximum amount of glucose permitted not specified.	**PET done:** Qualitatively **Criteria used for diagnosis:** NS – "routine clinical" **Comparator Test:** CT Scan **Done:** Quantitatively **Criteria used for diagnosis:** Lymph nodes > 10 mm diameter are considered abnormal **Gold Standard test:** Progression-free survival **Criteria used for diagnosis:** Kaplan Meier and Cox multivariate **Blinding**: **Radiologist:** No **Gold Standard reader:** No	PET Primary Tumor | | + | - | | + | 100 | 0 | | - | 1 | 0 | Sensitivity = 99% CT Primary Tumor | | + | - | | + | 77 | 0 | | - | 24 | 0 | Sensitivity = 76% Survival used as outcome. Patients followed, stratified by node status by CT or PET. 1. Patients with PET positive lymph nodes had significantly worse progression-free survival than those with PET negative lymph nodes. 2. In multivariate analysis, positive aortic nodes on PET significantly predicted lower progression-free survival, whereas nodal involvement by CT scan did <u>not</u> predict survival.	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 0** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 5** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Lin **2003** **PROCITE#** 10520 **Cancer Type:** Cervical **SOW Question(s) Addressed:** 1 **Frybeck et al. Level:** 2	**Dates of data collection:** NS **Geographic Location:** Taipei, Taiwan **Prospective Study** **Enrolled Consecutively:** NS **Study Setting:** Academic/ Research Setting Patient Incl Crit: • Clin pres – negative CT **Result led to incl:** • Abnorm and norm **Comparisons:** • No comp **Use of ref stand:** • Histology	***Patients:*** **N =** 50 Stage IIB-IVA **Mean Age:** NS **Inclusion criteria:** Advanced cervical cancer confined to pelvis; Negative abdominal CT findings; At least 18 years of age; Medically fit to undergo surgical para-aortic staging lymphadenectomy **Exclusion Criteria:** Diabetic, lactating and pregnant women	**Scanner Model:** GE Nxi PET **Resolution:** • **Nominal:** 4.8 mm • **Axial:** 4.0 mm **Acquisition Mode:** 2-D **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** 3 min **Dose of FDG:** 370 MBq (10 mCi) **Time between injection and performance:** 60 min **Reconstruction Algorithm used:** NS **Glucose Monitoring:** Fasting – 4 hours	**PET done:** Qualitatively **Criteria used for diagnosis:** Visual interpretation by 2 of 3 nuclear medicine physicians, not blinded to pathological results **Gold Standard test done:** Qualitatively **Criteria used for diagnosis:** Histology of surgical specimen from para-aortic lymphadenectomy **Blinding:** **Radiologist:** No **Gold Standard reader:** NS	Histology (Nodes) PET | | + | - | |---|---|---| | + | 12 | 2 | | - | 2 | 34 | Sensitivity = 85.7% Specificity = 94.4% Prevalence: 14/50 = 28%	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 0** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 5** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Miller **2003** **PROCITE#** 2400 **Cancer Type:** Cervical **SOW Question(s) Addressed:** 1 **Fryback et al. Level:** 2, 5	**Dates of data collection:** 1/98 – 9/99 **Geographic Location:** St. Louis, MO **Retrospective Study** **Enrolled Consecutively:** No (retrospective) **Study Setting:** General outpatient clinics/ physician office; Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnormal only – cervical cancer on biopsy **Comparisons:** • No comp **Use of ref stand:** • Prolonged follow-up – survival	***Patients:*** **N =** 47 **Stage:** I: N=11 II: N=23 III: N=12 IV: N=1 **Mean Age:** 48 years **Age Range:** 24-87 years **Inclusion criteria:** 1. Invasive cervical cancer; 2. Referred for primary treatment with radiotherapy; 3. Had PET before treatment began. **Exclusion Criteria:** NS	**Scanner Model:** Siemens ECAT/ EXACT **Resolution:** • **Reconstructed Spatial Resolution:** 8 mm **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** 10 min • **Transmission Scan:** 2 min **Dose of FDG:** 10-15 mCi **Time between injection and performance:** 40-90 min **Reconstruction Algorithm used:** Ordered subsets expectation maximization algorithm **Glucose Monitoring:** Fasting – 4 hrs	**PET done:** Quantitatively **Criteria used for diagnosis:** Score for lymph nodes: 0 – None 1 – Pelvic 2 – Para-aortic 3 - Distant Validated and tested in same group of patients. **Note:** Per the SOW criteria, only analysis of lymph node involvement is mentioned, not visual assessment of primary tumor. **Gold Standard test:** Survival **Done:** Quantitatively **Criteria used for diagnosis:** Survival analysis by Kaplan-Meier analysis, broken down into groups based on PET assessment of lymph nodes. No multivariate analysis. **Blinding:** **Radiologist:** Yes **Gold Standard reader:** NS	There was a significant difference in overall (p=0.03) and progression-free (p=0.04) survival between patients felt to have positive nodes on PET and those felt to have negative nodes.	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 6** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results/Notes	Quality Score
Nakamoto **2002** **PROCITE#** 2470 **Cancer Type:** Cervical **SOW Question(s) Addressed:** 2a **Fryback et al. Level:** 2	**Dates of data collection:** 8/94 – 8/99 **Geographic Location:** Baltimore, MD **Prospective/ Retrospective Study:** NS **Enrolled Consecutively:** No **Study Setting:** General outpatient clinics/ Physician office; Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnormal only – invasive cancer **Comparisons:** • CT **Use of ref stand:** • Histology • Prolonged follow-up	***Patients:*** **N =** 20 (19 newly diagnosed cancers – PET pre- and post- radiation treatment. 1 recurrent cancer – PET pre- and post-radiation treatment.) **Age Range:** 26-82 years **Inclusion criteria:** Histologically proven cervical cancer. Radiation treatment planned. **Exclusion Criteria:** NS	**Scanner Model:** Model 921 EXACT/ Siemens **Resolution:** • Intrinsic: 12mm • Image: NS **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** 10 min • **Transmission Scan:** 10 min **Dose of FDG:** 370 MBq **Time between injection and performance:** NS **Reconstruction Algorithm used:** NS **Glucose Monitoring:** Fasting ≥ 4 hrs	**PET done:** Quantitatively and Qualitatively **Criteria used for diagnosis:** Qualitatively, visual scale: 0 – normal 1 – prob. normal 2 – equivocal 3 – prob. abnormal 4 – definitely abnormal Quantitatively: SUV-L standardized uptake value corrected for lean body mass. **Comparator test:** CT **Done:** NS **Criteria used for diagnosis:** NS **Gold Standard test done:** Qualitatively: Histology (n=4), Clinical follow-up ≥ 6 months (n=16) **Blinding:** **Radiologist:** Yes **Gold Standard reader:** NS	**Detection of Recurrence** Recurrence PET | | + | - | | + | 5 | 6 | | - | 0 | 9 | Sensitivity = 100% Specificity = 60% **Notes:** 1. 19 patients were being evaluated for persistent disease after primary radiation. 1 patient was being evaluated after a prior recurrence – they should not have been grouped together because it can not be determined in the results which patient has already had a recurrence. 2. It is unclear what the author's cutoff was for classifying patients' PET as + or -. Quantitative or "visual scale." 3. CT results presented in discussion for 9 patients. Four true negative CT and PET were the same. Five true positive – PET was positive in all 5, CT positive in 2.	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 0** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 5**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Park **2000** **PROCITE#** 2540 **Cancer Type:** Cervical **SOW Question(s) Addressed:** 2b **Fryback et al. Level:** 2	**Dates of data collection:** 10/97 – 5/98 **Geographic Location:** Seoul, Korea **Retrospective Study** **Enrolled Consecutively:** NS **Study Setting:** Inpatient; Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnormal only **Comparisons:** • Matched **Use of ref stand:** • Histology • Prolonged follow-up	***Patients:*** **N =** 36 **Mean(Median) Age:** NS **Inclusion criteria:** Suspicion of recurrence **Exclusion Criteria:** NS **Initial Treatment:** N=13 surgery only; N=14 radiation therapy only; N=9 surgery and postoperative radiation therapy	**Scanner Model:** GE Advance **Resolution:** • **Intrinsic:** NS • **Image:** NS **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** NS **Dose of FDG:** 10 mCi **Time between injection and performance:** NS **Reconstruction Algorithm used:** NS **Glucose Monitoring:** Fasting – 6 hours	**PET done:** Quantitatively **Criteria used for diagnosis:** SUV > 2.5 ml/Kg **Comparator Test:** CT **Done:** Qualitatively **Criteria used for diagnosis:** Mass > 1 cm **Gold Standard test done:** Qualitatively **Criteria used for diagnosis:** Considered positive recurrence if: 1. Positive histology; Increased tumor marker; 2. Increased size of masses or lymph nodes on CT; 3. Decreased size of masses and lymph nodes after chemotherapy and radiation therapy **Blinding:** **Radiologist:** NS **Gold Standard reader:** NS	PET Recurrence | | + | - | |+| 18 | 1 | |-| 0 | 17 | Sensitivity = 100% Specificity = 94.4% CT Recurrence | | + | - | |+| 14 | 3 | |-| 4 | 15 | Sensitivity = 77.8% Specificity = 83.3% Prevalence: 18/36 = 50%	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 6** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Reinhardt **2001** **PROCITE#** 2520 **Cancer Type:** Cervical **SOW Question(s) Addressed:** 1 **Fryback et al. Level:** 2	**Dates of data collection:** 1995 – 1998 **Geographic Location:** Freiberg, Germany **Prospective Study** **Enrolled Consecutively:** Yes **Study Setting:** Inpatient; Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnormal only **Comparisons:** • Matched **Use of ref stand:** • Histology	***Patients:*** **N =** 35 **Stage:** IB N=21 (60%) II N=14 (40%) **Age Range:** 26-70 years **Inclusion criteria:** 1. Cervical cancer; 2. Candidate for surgical treatment **Exclusion Criteria:** NS	**Scanner Model:** Siemens ECAT EXACT 921 **Resolution:** • **Intrinsic:** NS • **Image:** NS **Acquisition Mode:** 2-D **Acquisition time per FOV:** • **Emission Scan:** 9 min • **Transmission Scan:** 3-8 min **Dose of FDG:** 5 MBq/kg **Dose Range:** 300-500 MBq **Time between injection and performance:** 100±20 min **Reconstruction Algorithm used:** Iterative **Glucose Monitoring:** Fasting overnight; Maximum glucose permitted: 130 mg/dL	**PET done:** Qualitatively **Criteria used for diagnosis:** Consensus of 3 investigators focal increased FDG uptake **Comparator Test:** MRI **Done:** Quantitatively **Criteria used for diagnosis:** Node diameter ≥ 1 cm **Gold Standard test done:** Qualitatively **Criteria used for diagnosis:** Histology after lymph node sampling **Blinding:** **Radiologist:** Yes **Gold Standard reader:** No	**By Patient:** Pathology (nodes) PET: + 10, 0; - 1, 24 Sensitivity = 91% Specificity = 100% Pathology (nodes) MRI: + 8, 4; - 3, 20 Sensitivity = 73% Specificity = 83% Prevalence: 18/35 = 51.4% **By Node Site:** Pathology (nodes) PET: + 17, 2; - 4, 269 Sensitivity = 81% Specificity = 99% Pathology (nodes) MRI: + 14, 8; - 7, 263 Sensitivity = 67% Specificity = 97%	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 6** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Rose **1999** **PROCITE#** 2580 **Cancer Type:** Cervical **SOW Question(s) Addressed:** 1 **Fryback et al. Level:** 2	**Dates of data collection:** 5/94 – 4/98 **Geographic Location:** Cleveland, OH **Prospective Study** **Enrolled Consecutively:** Yes **Study Setting:** Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnorm and norm **Comparisons:** • No comp **Use of ref stand:** • Histology	***Patients:*** **N =** 32 **Staging:** IIB: n=6 (18%) IIIB: n=24 (75%) IVA: n=2 (6%) **Mean(Median) Age:** NS **Inclusion criteria:** 1. Previously untreated cervical cancer stages IIB-IVA; 2. No extrapelvic diseas on CT or CXR; 3. Medically fit for surgery **Exclusion Criteria:** 1. Known extrapelvic disease; 2. Pregnant/ lactating; 3. Weight >350 lbs	**Scanner Model:** Siemens ECAT EXACT **Resolution:** • **Axial:** 5.4 mm • **Image:** NS **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** NS **Dose of FDG:** 20 mCi **Time between injection and performance:** 60 min **Reconstruction Algorithm used:** NS **Glucose Monitoring:** Fasting – 4 hours	**PET done:** Qualitatively **Criteria used for diagnosis:** NS **Gold Standard test done:** Histology **Criteria used for diagnosis:** Histology results of nodes removed at surgery **Blinding:** **Radiologist:** NS **Gold Standard reader:** NS	PET for pelvic nodes: Pathology (nodes) PET | | + | - | |---|---|---| | + | 11 | 0 | | - | 0 | 6 | Sensitivity = 100% Specificity = 100% CT for pelvic nodes: Pathology (nodes) CT | | + | - | |---|---|---| | + | 5 | - | | - | 6 | - | Sensitivity = 45% Specificity = N/A	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 0** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 5** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Ryu **2003** **PROCITE#** 10530 **Cancer Type:** Cervical **SOW Question(s) Addressed:** 2b **Frybeck et al. Level:** 2	**Dates of data collection:** 9/97 – 3/00 **Geographic Location:** Seoul, Korea **Retrospective Study** **Enrolled Consecutively:** Yes, if considered high-risk disease **Study Setting:** Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Normal only – no evidence of disease after treatment **Comparisons:** • No comp **Use of ref stand:** • Histology • Prolonged follow-up	***Patients:*** **N =** 249 **Mean Age:** 57 years **Age Range:** 31-78 years **Disease:** 59.7% Stages Ib and Iia; 90.7% Squamous **Median duration since completion of treatment by stage (range):** Ib: 30 mo (7-129) IIa: 35 mo(7-108) IIb: 31 mo (6-282) III/IV: 16 mo (6-165) **Median duration of PET from last CT or MRI:** 6 mo (3-12) **Inclusion criteria:** History of histologically-proven cervical cancer,; No evidence of disease after treatment **Exclusion Criteria:** NS	**Scanner Model:** GE Advance HR+ **Resolution:** • **Intrinsic:** NS • **Image:** NS **Acquisition Mode:** 2-D **Acquisition time per FOV:** • **Emission Scan:** 8 min • **Transmission Scan:** 3-5 min **Dose of FDG:** 370-555 MBq (10-15 mCi) **Time between injection and performance:** 50 min **Reconstruction Algorithm used:** Ordered-subset expectation maximization **Glucose Monitoring:** Fasting – 8 hours	**PET done:** Quantitatively and Qualitatively **Criteria used for diagnosis:** SUV and any focal uptake considered not to be physiologic **Gold Standard test done:** Fine needle aspiration **Criteria used for diagnosis:** Histology showing no change in size if lesion after follow-up for 1 year **Blinding:** **Radiologist:** Yes **Gold Standard reader:** Yes	Recurrence PET | | + | - | |+| 28 | 52 | |-| 3 | 166 | Sensitivity = 90.3% Specificity = 76.1% Prevalence: 31/249 = 12.4%	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 0** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 1** **Total Score = 6** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Sugawara **1999** **PROCITE#** 2590 **Cancer Type:** Cervical **SOW Question(s) Addressed:** 1, 2b **Fryback et al. Level:** 2	**Dates of data collection:** 5/93 – 5/97 **Geographic Location:** Ann Arbor, MI **Retrospective Study** **Enrolled Consecutively:** NS **Study Setting:** Inpatient; Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnormal only **Comparisons:** • Matched **Use of ref stand:** • Histology • Prolonged follow-up	***Patients:*** **N =** 21 **Mean Age:** 45 years **Age Range:** 26-82 years **Stage:** IB: N = 4 (19%) IIB: N = 9 (43%) IIIB: N = 7 (33%) IVA: N = 1 (5%) **Inclusion criteria:** Histologically proven cervical cancer **Exclusion Criteria:** NS	**Scanner Model:** Siemens 921 EXACT **Resolution:** • **Intrinsic:** NS • **Image:** NS **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** 10 min • **Transmission Scan:** 10 min **Dose of FDG:** 370 MBq **Time between injection and performance:** NS **Reconstruction Algorithm used:** NS **Glucose Monitoring:** Fasting – 4 hours	**PET done:** Qualitatively **Criteria used for diagnosis:** SUV – calculated by not reported **Comparator Test:** CT **Done:** Quantitatively **Criteria used for diagnosis:** Positive if > 1 cm; Equivocal if = 1 cm; Negative if < 1 cm **Gold Standard test done:** Quantitatively **Criteria used for diagnosis:** Histology, prolonged follow-up and additional imaging studies **Blinding:** **Radiologist:** Blinded to other radiology findings, not blinded to clinical findings **Gold Standard reader:** NS	PET Pathology (nodes) | | + | - | | + | 6 | 0 | | - | 1 | 10 | Sensitivity = 86% Specificity = 100% CT (equiv +) Pathology (nodes) | | + | - | | + | 6 | 0 | | - | 1 | 10 | Sensitivity = 86% Specificity = 100% CT (equiv -) Pathology (nodes) | | + | - | | + | 4 | 0 | | - | 3 | 10 | Sensitivity = 57% Specificity = 100% Prevalence: 7/7* = 100% * 4 patients not confirmed, not included in report	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 6** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Sun **2001** **PROCITE#** 2490 **Cancer Type:** Cervical **SOW Question(s) Addressed:** 2b **Fryback et al. Level:** 2	**Dates of data collection:** NS **Geographic Location:** Taichung, Taiwan **Retrospective Study** **Enrolled Consecutively:** No (retrospective) **Study Setting:** General outpatient clinics/ Physician office; Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • See inclusion criteria **Comparisons:** • No comp test results presented (CT done) **Use of ref stand:** • Histology • ≥ 1 year follow-up	***Patients:*** **N = 20** Stage I – 5 Stage II – 9 Stage III – 5 Stage IV – 1 **Age Range:** 45-65 years **Inclusion criteria:** History of cervical cancer, suspicion of recurrence **Exclusion criteria:** History of diabetes	**Scanner Model:** Siemens ECAT-EXHACT 47 or HR+ **Resolution:** • **Nominal:** 5 mm • **Axial:** 4 mm **Acquisition Mode:** 2-D **Acquisition time per FOV:** • **Emission Scan:** 7 min • **Transmission Scan:** 3 min **Dose of FDG:** 10 mCi **Time between injection and performance:** 30 min **Reconstruction Algorithm used:** NS **Glucose Monitoring:** Fasting ≥ 4hrs	**PET done:** Qualitatively **Criteria used for diagnosis:** NS **Gold Standard test done:** Quantitatively **Criteria used for diagnosis:** Operative histology or clinical follow-up ≥ 1 year **Blinding:** Radiologist: NS Gold Standard reader: NS	**Overall Recurrence** Recurrence PET: + 19 1; - 0 0 Sensitivity = 100% Specificity = 0% **Local Recurrence** Local Recurrence PET: + 12 1; - 2 5 Sensitivity = 86% Specificity = 83% **Pelvic Lymph Nodes** Pelvic Nodes PET: + 16 1; - 0 3 Sensitivity = 100% Specificity = 75% **Para Aortic Nodes** PA Nodes PET: + 14 0; - 0 6 Sensitivity = 100% Specificity = 100% **Distant Metastasis** Distant Metastasis PET: + 4 0; - 0 16 Sensitivity = 100% Specificity = 100%	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 0** **Scanner: 1** **Interpretation criteria defined: 0** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 4** **Notes:** Author's calculations for sensitivity and specificity do not match reviewer's calculations. Tables reflect reviewer's calculations.

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Yeh **2002** **PROCITE#** 2390 **Cancer Type:** Cervical **SOW Question(s) Addressed:** 1 **Fryback et al. Level:** 2	**Dates of data collection:** NS **Geographic Location:** Taipei, Taiwan **Prospective Study** **Enrolled Consecutively:** NS (prospective) **Study Setting:** Inpatient; General outpatient clinics/ physician office. **Patient Incl Crit:** • Clin Pres – negative MRI and diagnosis of cervical cancer **Result led to incl:** • Abnormal only – known cancer • Abnorm and norm – normal abdominal MRI **Comparisons:** • No comp **Use of ref stand:** ▪ Histology – surgery and lymph node pathology	***Patients:*** **N =** 42 **Mean(Median) Age:** NS **Inclusion criteria:** Advanced stage IIB – IVA cervical cancer or stage IB – IIA with tumor > 5 cm or positive pelvic LN; Negative abdominal MRI (PA node < 10 mm). **Exclusion Criteria:** <18yrs; Diabetic; Pregnant/ nursing; Medically unfit for surgery.	**Scanner Model:** Siemens ECAT/ EXACT **Resolution:** • Intrinsic: 5 mm • Image: NS **Acquisition Mode:** 2-D **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** 3 min **Dose of FDG:** 10 mCi **Time between injection and performance:** 60 min **Reconstruction Algorithm used:** NS **Glucose Monitoring:** Fasting – 4 hrs	**PET done:** Qualitatively **Criteria used for diagnosis:** Visual agreement of at least 2 of 3 nuclear medicine physicians, not blinded to pathological results **Gold Standard test:** Histology **Done:** Qualitatively **Criteria used for diagnosis:** Positive or negative metastasis in lymph nodes removed surgically after PET scan. **Blinding:** **Radiologist:** No **Gold Standard reader:** NS	**Pathology** Pathology Nodes PET Nodes | | + | - | |---|---|---| | + | 10 | 1 | | - | 2 | 29 | Sensitivity = 83% Specificity = 97% Prevalence: 12/42 = 29%	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 0** **Scanner: 1** **Interpretation criteria defined: 0** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 4** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Chang **2002** **PROCITE#** 6570 **Cancer Type:** Ovarian **SOW Question(s) Addressed:** 1b, 1bi **Fryback et al. Level:** 2	**Dates of data collection:** NS **Geographic Location:** Taipei, Taiwan **Prospective/ Retrospective Study:** NS **Enrolled Consecutively:** No **Study Setting:** Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnorm and norm – abnormal CA125, normal imaging other than PET **Comparisons:** • No comp **Use of ref stand:** • Histology • Prolonged follow-up	***Patients:*** **N =** 28 **Stage:** IIa: N=4 IIb: N=3 IIc: N=5 IIIa: N=5 IIIb: N=3 IIIc: N=4 IV: N=4 **Age Range:** 44 – 76 years **Inclusion criteria:** 1. History of ovarian cancer; 2. Prior surgery and chemotherapy; 3. Elevated CA125; 4. Negative or equivocal CT or MRI, or other imaging modality **Exclusion Criteria:** NS	**Scanner Model:** Siemens ECAT EXACT 47 or HR+ **Resolution:** • **Nominal:** 5 mm • **Axial:** 4 mm **Acquisition Mode:** 2-D **Acquisition time per FOV:** • **Emission Scan:** 7 min • **Transmission Scan:** 3 min **Dose of FDG:** 10 mCi **Time between injection and performance:** 30 min **Reconstruction Algorithm used:** NS **Glucose Monitoring:** Fasting – 4 hours	**PET done:** Qualitatively **Criteria used for diagnosis:** NS **Gold Standard test done:** Histology or follow-up **Criteria used for diagnosis:** Histology (biopsy or surgery) or clinical follow-up of greater than one year **Blinding:** **Radiologist:** No **Gold Standard reader:** No	Recurrence PET | | + | - | |---|---|---| | + | 19 | 1 | | - | 1 | 7 | Sensitivity = 95% Specificity = 87.5% Prevalence: 20/28 = 71.4% Note: • 6/28 patients did not have 2nd look surgery • 4/6 patients no recurrence, 2/4 had recurrence • Diagnosis not specified	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 0** **Scanner: 1** **Interpretation criteria defined: 0** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 4** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Cho **2002** **PROCITE#** 6660 **Cancer Type:** Ovarian **SOW Question(s) Addressed:** 1b **Fryback et al. Level:** 2	**Dates of data collection:** 1/96 – 3/00 **Geographic Location:** Seoul, South Korea **Retrospective Study** **Enrolled Consecutively:** No **Study Setting:** Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnormal only **Comparisons:** • PET and comp – not random **Use of ref stand:** • Histology	***Patients:*** **N =** 31 **Mean(Median) Age:** 46 years **Inclusion criteria:** 1. Pathologically proven epithelial ovarian cancer; 2. Planned second look surgery within 1 month **Exclusion Criteria:** Imaging performed > 1 month before the second look surgery	**Scanner Model:** ECAT EXACT 47 (Siemens) **Resolution:** • **Intrinsic:** NS • **Image:** NS **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** 30 min • **Transmission Scan:** 20 min **Dose of FDG:** 370 MBq **Time between injection and performance:** 45 min **Reconstruction Algorithm used:** Filtered Backposition **Glucose Monitoring:** Fasting – 12 hours	**PET done:** Qualitatively and Quantitatively **Criteria used for diagnosis:** Quantitatively: Correlation with CT was used. If nodules were > 2 cm diameter SUV was measured. Qualitatively: If nodules were < 2 cm, visual analysis was used in image interpretation. **Confidence Scoring:** 0 = absent 1 = visual suspicion only 2 = SUV > 3 was positive for tumor recurrence. Scores 1 and two considered positive for final analysis. **Comparator Test done:** CT **Criteria used for diagnosis:** NS **Gold Standard test done:** Histology **Criteria used for diagnosis:** At surgery, the presence or absence of tumor at 15 specific sites was recorded **Blinding:** **Radiologist:** Yes **Gold Standard reader:** NS Blinded biopsies done at each site if no gross mass was seen	**Patient-based analysis *:** PET alone Recurrence | | + | - | | + | 9 | 1 | | - | 2 | 9 | Sensitivity = 82% Specificity = 90% CT alone Recurrence | | + | - | | + | 11 | 1 | | - | 0 | 9 | Sensitivity = 100% Specificity = 90% PET and CT Recurrence | | + | - | | + | 11 | 1 | | - | 0 | 9 | Sensitivity = 100% Specificity = 90% * Authors did lesion- and patient-based analysis. Lesion-based analysis can not be very accurate for PET and the specific locations of the lesions because the results are not given. Therefore, only patient-based results are shown here.	***Quality Score:*** **Rep.sample:1** **Setting selection: 1** **Design minimizes diffs: 0** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 5** **Notes:** Authors' conclusion was that PET does not add much to conventional imaging for detection of recurrent ovarian cancer.

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Hubner **1993** **PROCITE#** 6900 **Cancer Type:** Ovarian **SOW Question(s) Addressed:** 1b **Fryback et al. Level:** 2	**Dates of data collection:** 1/92 – 4/93 **Geographic Location:** Knoxville, TN **Prospective/ Retrospective Study:** NS **Enrolled Consecutively:** NS **Study Setting:** Inpatient; Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnorm and norm **Comparisons:** • No comp **Use of ref stand:** • Histology • Prolonged follow-up	***Patients:*** **N =** 14 patients followed for recurrence – 57 total patients in study, but mostly with diagnostic information **Mean(Median) Age:** NS **Inclusion criteria:** NS **Exclusion Criteria:** NS	**Scanner Model:** Siemens ECAT 931; Siemens ECAT EXACT **Resolution:** • **Intrinsic:** 6 mm • **Image:** 5 mm **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** NS **Dose of FDG:** 185-370 MBq **Time between injection and performance:** NS **Reconstruction Algorithm used:** NS **Glucose Monitoring:** NS	**PET done:** Qualitatively and Quantitatively **Criteria used for diagnosis:** Visual interpretation; SUV calculated. **Gold Standard test done:** Qualitatively and Quantitatively **Criteria used for diagnosis:** Histology of repeat surgery or biopsy, or survival **Blinding:** **Radiologist:** NS **Gold Standard reader:** NS	1st PET Recurrence | | + | - | | + | 10 | 0 | | - | 1 | 3 | Sensitivity = 91% Specificity = 100% 2nd PET Recurrence | | + | - | | + | 7 | 0 | | - | 0 | 7 | Sensitivity = 100% Specificity = 100% Note: Timing of PET in relation to diagnosis, as well as the length of follow-up are unclear, therefore results are of questionable usefulness.	***Quality Score:*** **Rep.sample: 0** **Setting selection: 0** **Design minimizes diffs: 0** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 3** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Jimenez-Bonilla **2000** **PROCITE#** **Cancer Type:** Ovarian **SOW Question(s) Addressed:** 1bi, 1bii **Frybeck et al. Level:** 2, 4	**Dates of data collection:** NS **Geographic Location:** Madrid and Grenada, Spain **Prospective/ Retrospective Study:** NS **Enrolled Consecutively:** No **Study Setting:** Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnorm and norm **Comparisons:** • No comp – normal/equivocal CT/MRI inclusion criteria **Use of ref stand:** • Histology (in 7 patients) • Prolonged follow-up (in 7 patients)	***Patients:*** **N =** 20 **Mean Age:** 51 years **Inclusion criteria:** Suspected recurrent ovarian carcinoma; Rising tumor markers; Normal or equivocal CT or MRI **Exclusion Criteria:** NS	**Scanner Model:** Siemens/CTI ECAT Exact 47 **Resolution:** • **Intrinsic:** NS • **Image:** NS **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** NS **Dose of FDG:** 1.5 MBq/kg **Time between injection and performance:** 45 min **Reconstruction Algorithm used:** NS **Glucose Monitoring:** Fasting – 6 hours; Mean glycemia: 78 mg/dl, maximum permitted not stated	**PET done:** Qualitatively **Criteria used for diagnosis:** Abnormal increased FDG uptake **Gold Standard test done:** Qualitatively **Criteria used for diagnosis:** Histology or resolution of increased serum markers **Blinding:** **Radiologist:** Yes **Gold Standard reader:** NS	Recurrence PET: + 12, 1; - 0, 1 Sensitivity = 100% Specificity = 50% Prevalence: 12/14 = 85.7%	***Quality Score:*** **Rep.sample: 0** **Setting selection: 1** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 0** **Hist or clin confirmation: 0** **Blinded: 0** **Total Score = 3** **Notes:** Confirmation of results provided for only 14 of 20 subjects; No minimum time for clinical follow-up was given; Therapeutic option was altered in 10 of 14 cases or 71% of patients who had PET results confirmed.

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Karlan **1993** **PROCITE#** 6910 **Cancer Type:** Ovarian **SOW Question(s) Addressed:** 1b **Fryback et al. Level:** 2	**Dates of data collection:** NS **Geographic Location:** Los Angeles, CA **Prospective/ Retrospective Study:** NS **Enrolled Consecutively:** No **Study Setting:** Inpatient; Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnormal only • Abnorm and norm **Comparisons:** • No comp **Use of ref stand:** • Histology for n=12, 1 patient did not have surgery	***Patients:*** **N =** 13 (12 Ovarian Cancer, 1 Fallopian Tube Cancer) **Mean (Median) Age:** 51 years **Inclusion criteria:** Patients with history of documented ovarian or tubal cancer **Exclusion Criteria:** NS	**Scanner Model:** Siemens 931/ 08-12 **Resolution:** • **Intrinsic:** NS • **Image:** NS **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** NS **Dose of FDG:** 10 mCi **Time between injection and performance:** 30 min **Reconstruction Algorithm used:** NS **Glucose Monitoring:** Fasting – 6 hours	**PET done:** Qualitatively **Criteria used for diagnosis:** Uptake higher than surrounding tissues **Gold Standard test done:** Histology at surgery **Criteria used for diagnosis:** Histological results **Blinding:** **Radiologist:** Yes **Gold Standard reader:** NS	Recurrent Disease PET | | + | - | |---|---|---| | + | 6 | 0 | | - | 5 | 1 | Sensitivity = 55% Specificity = 100%	***Quality Score:*** **Rep.sample: 1** **Setting selection: 0** **Design minimizes diffs: 0** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 4** **Notes:** One patient did not have histology and her follow up period was not defined and therefore should have been excluded. One patient had fallopian tube cancer which is very similar clinically to ovarian cancer, so this is not a major drawback.

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Nakamoto **2001** **PROCITE#** 6770 **Cancer Type:** Ovarian **SOW Question(s) Addressed:** 1b **Fryback et al. Level:** 2, 4	**Dates of data collection:** NS **Geographic Location:** Kyoto, Japan **Prospective Study** **Enrolled Consecutively:** No **Study Setting:** Inpatient; General outpatient clinics/ physician office; Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Some with suspected recurrence, some not **Comparisons:** • PET and comp on different patients – not random **Use of ref stand:** • Histology • Prolonged follow-up	***Patients:*** **N =** 24 (N=12 suspected recurrence N=12 thought to be disease free) **Mean(Median) Age:** 51.8 years **Inclusion criteria:** Positive history of ovarian cancer **Exclusion Criteria:** NS	***Set 1 = 6/24 patients*** **Scanner Model:** PCT 3600W **Resolution:** • **Intrinsic:** 7 mm • **Image:** NS **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission:** 10 min • **Transmission:** 10 min **Dose of FDG:** 370 MBq **Time between injection and performance:** 60 min **Reconstruction Algorithm used:** NS **Glucose Monitoring:** NS ***Set 2 = 18/24 patients*** **Scanner Model:** Advance/ 9E **Resolution:** • **Axial:** 4.2 mm • **Image:** NS **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission:** NS • **Transmission:** NS **Dose of FDG:** 370 MBq **Time between injection and performance:** 60 min **Reconstruction Algorithm used:** NS **Glucose Monitoring:** NS	**PET done:** Qualitatively **Criteria used for diagnosis:** Abnormal – accumulation of FDG moderately to markedly increased relative to normal structures **Comparator Test done:** CT – not done on all patients **Criteria used for diagnosis:** NS **Comparator Test done:** MR – not done on all patients **Criteria used for diagnosis:** NS **Gold Standard test done:** **Histology or follow-up** **Criteria used for diagnosis:** Histology n=11; At least 6 months for follow-up n=12; One patient did not have at least 6 month follow-up **Blinding:** **Radiologist:** No **Gold Standard reader:** No	**All:** Recurrence PET: + 10, 2; - 3, 9 Sensitivity = 77% Specificity = 82% **Clinically suspicious:** Recurrence PET: + 8, 1; - 2, 1 Sensitivity = 80% Specificity = 50% **Clinically disease free:** Recurrence PET: + 2, 1; - 1, 8 Sensitivity = 67% Specificity = 89% **CT/MRI alone*:** Recurrence CT/MRI: + 8, 1; - 3, 3 Sensitivity = 73% Specificity = 75% **PET plus CT/MRI*:** Recurrence PET plus CT/MRI: + 12, 0; - 1, 5 Sensitivity = 92% Specificity = 100% * Conventional imaging done on only 18 patients, with 3 having inconclusive results.	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 0** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 5** **Notes:** When assessing SN and SP for the combination of PET and conventional imaging, the authors do not give enough information about findings in each case to decide whether to judge overall constellation of radiographic findings as + or -. Therefore Table 2 questionable. "PET alone" calculations not given by author. Overall calculated to be: SN=77%, SP=82%.

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Rose **2001** **PROCITE#** 6760 **Cancer Type:** Ovarian **SOW Question(s) Addressed:** 1b, 1c **Fryback et al. Level:** 2	**Dates of data collection:** 6/94 – 5/96 **Geographic Location:** Cleveland, OH **Prospective Study** **Enrolled Consecutively:** Yes **Study Setting:** Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnorm and norm **Comparisons:** • No comp **Use of ref stand:** • Histology	***Patients:*** **N =** 22 **Staging:** IIIA – 3 (14%) IIIB – 4 (18%) IIIC – 12 (55%) IV – 3 (14%) **Mean Age:** 50 years **Age Range:** 24-67 years **Race:** 91% White 9% Black **Inclusion criteria:** 1. Stage III or IV ovarian or peritoneal cancer; 2. Complete clinical response after chemotherapy; 3. Medically fit for second look surgery **Exclusion Criteria:** **1.** Can't undergo CT; 2. Abnormal CA125; 3. Definitive diagnosis of persistent disease is known	**Scanner Model:** Siemens ECAT EXACT **Resolution:** • **Axial:** 5.4 mm **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** NS **Dose of FDG:** 20 mCi **Time between injection and performance:** 60 min **Reconstruction Algorithm used:** NS **Glucose Monitoring:** Fasting – 4 hours	**PET done:** NS **Criteria used for diagnosis:** NS **Comparative test:** CT **Done:** NS **Criteria used for diagnosis:** NS **Gold Standard test done:** Histology **Criteria used for diagnosis:** Histology at second look surgery: 1. Negative; 2. Macroscopically positive; 3. Microscopically positive **Blinding:** **Radiologist:** NS **Gold Standard reader:** NS	Pathology PET | | + | - | |---|---|---| | + | 2 | 6 | | - | 9 | 5 | Sensitivity = 18% Specificity = 45%	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 0** **Scanner: 1** **Interpretation criteria defined: 0** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 4** **Notes:** Well designed. Conclusion is that the sensitivity of PET for small-volume disease is low in ovarian cancer.

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Torizuka **2002** **PROCITE#** 6600 **Cancer Type:** Ovarian **SOW Question(s) Addressed:** 1b **Fryback et al. Level:** 2	**Dates of data collection:** NS **Geographic Location:** Hirakuchi, Japan **Prospective/ Retrospective Study:** NS **Enrolled Consecutively:** No **Study Setting:** Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnorm and norm **Comparisons:** • Matched **Use of ref stand:** • Histology • Prolonged follow-up	***Patients:*** **N =** 25 **Mean(Median) Age:** 55 years **Stage:** I: N=6 II: N=1 III: N=16 IV: N=2 **Inclusion criteria:** **1.** Ovarian cancer; 2. Have had initial surgery and chemotherapy; 3. Suspected recurrence based on CA125, conventional imaging or symptoms **Exclusion Criteria:** NS	**Scanner Model:** SHR 22000 (Hamamatsu) **Resolution:** • **Spatial:** 3-4 mm **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** NS **Dose of FDG:** 300-400 MBq **Time between injection and performance:** 60 min **Reconstruction Algorithm used:** NS **Glucose Monitoring:** Fasting – 5 hours	**PET done:** NS **Criteria used for diagnosis:** Any foci of FDG uptake that were increased relative to the background **Comparator Test done:** CT **Criteria used for diagnosis:** NS **Comparator Test done:** MRI **Criteria used for diagnosis:** NS **Comparator Test done:** Ca 125 **Criteria used for diagnosis:** ≥ 35 U/mL **Gold Standard test done:** Histology or follow-up **Criteria used for diagnosis:** Positive histology or > 6 months clinical follow-up **Blinding:** **Radiologist:** No **Gold Standard reader:** NS	PET Recurrent Disease | | + | - | | + | 16 | 1* | | - | 4 | 5 | Sensitivity = 80% Specificity = 83% Conv. Image Recurrent Disease | | + | - | | + | 11 | 1** | | - | 9 | 5 | Sensitivity = 55% Specificity = 83 % CA125 Recurrent Disease | | + | - | | + | 15 | 0 | | - | 5 | 5 | Sensitivity = 75% Specificity = 100% * One patient with both FN and FP findings is included in the FN category ** One patient with both TP and FP findings is included in the TP category	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 6** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Yen **2001** **PROCITE#** 6700 **Cancer Type:** Ovarian **SOW Question(s) Addressed:** 1b **Fryback et al. Level:** 2	**Dates of data collection:** NS **Geographic Location:** Taipei, Taiwan **Prospective/ Retrospective Study:** NS **Enrolled Consecutively:** NS **Study Setting:** Inpatient; Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnormal only **Comparisons:** • Matched **Use of ref stand:** • Histology	***Patients:*** **N =** 24 **Age Range:** 41-66 years **Inclusion criteria:** 1. Suspected recurrent ovarian cancer; 2. Prior surgery and chemotherapy **Exclusion Criteria:** NS	**Scanner Model:** Siemens ECAT/ EXACT 47 or HR+ **Resolution:** • **Intrinsic:** NS • **Image:** NS **Acquisition Mode:** 2-D **Acquisition time per FOV:** • **Emission Scan:** 7 min • **Transmission Scan:** 3 min **Dose of FDG:** 10 mCi **Time between injection and performance:** 45 min **Reconstruction Algorithm used:** Filtered Backposition **Glucose Monitoring:** Fasting – 6 hours	**PET done:** Qualitatively **Criteria used for diagnosis:** NS **Comparator Test done:** CT **Criteria used for diagnosis:** NS **Comparator Test done:** MRI **Criteria used for diagnosis:** NS **Comparator Test done:** CA125 **Criteria used for diagnosis:** NS **Gold Standard test done:** Histology or clinical follow-up Histology: n=16 Follow-up: n=8 **Criteria used for diagnosis:** Clinical results **Blinding:** **Radiologist:** Yes **Gold Standard reader:** NS	**Patients with Histology as reference standard (n=16):** PET Diagnosis | | + | - | | + | 10 | 1 | | - | 1 | 12 | Sensitivity = 91% Specificity = 92.3% CT/ MRI Diagnosis | | + | - | | + | 10 | 7 | | - | 1 | 6 | Sensitivity = 91% Specificity = 46% CA 125 Diagnosis | | + | - | | + | 10 | 3 | | - | 1 | 10 | Sensitivity = 91% Specificity = 77%	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 0** **Hist or clin confirmation: 0** **Blinded: 0** **Total Score = 4** **Notes:** No minimum clinical follow-up given (clinical follow-up was gold standard in 8 cases). Results SN/SP calculations based on cases that had histology as gold standard (n=16).

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Zimny **2001** **PROCITE#** 6750 **Cancer Type:** Ovarian **SOW Question(s) Addressed:** 1b **Fryback et al. Level:** 2	**Dates of data collection:** 4/96 – 12/00 **Geographic Location:** Aachen, Germany **Retrospective Study** **Enrolled Consecutively:** NS **Study Setting:** Inpatient; Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnorm and norm **Comparisons:** • No comp **Use of ref stand:** • Histology • Prolonged follow-up	***Patients:*** **N =** 54 (106 PET scans in 54 patients) **Mean(Median) Age:** 55±14 yrs **Inclusion criteria:** 1. History of ovarian cancer; 2. Either suspected recurrence <u>or</u> clinically disease free **Exclusion Criteria:** NS	**Scanner Model:** ECAT 953/15 (CTI) **Resolution:** • **Intrinsic:** NS • **Image:** NS **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** NS **Dose of FDG:** 228±53 MBq **Time between injection and performance:** 45-60 min **Reconstruction Algorithm used:** NS **Glucose Monitoring:** Fasting – 4 hours; Maximum glucose permitted: 7.5 mmol/L	**PET done:** Quantitatively **Criteria used for diagnosis:** 5 point scale ranging from definitely normal to definitely abnormal **Gold Standard test done:** Histology and/or clinical follow-up **Criteria used for diagnosis:** Histology: n=37; Follow-up: n=66; Median follow-up was 12-22 months **Blinding:** **Radiologist:** Yes **Gold Standard reader:** NS	**PET scans performed (n=106):** Recurrence PET | | + | - | |---|---|---| | + | 73 | 3 | | - | 15 | 15 | Sensitivity = 83% Specificity = 83% PET was more accurate in patients with suspected recurrence with a diagnosis accuracy of 93% and sensitivity of 94%.	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 0** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 5** **Notes:** No minimum clinical follow-up was stipulated but the median follow-up was given.

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Bares **1994** **PROCITE#** 7570 **Cancer Type:** Pancreatic **SOW Question(s) Addressed:** 1a, 1b **Frybeck et al. Level:** 2	**Dates of data collection:** NS **Geographic Location:** Aachen, Germany **Prospective Study** **Enrolled Consecutively:** NS **Study Setting:** Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnormal only **Comparisons:** • Matched **Use of ref stand:** • Histology	***Patients:*** **N =** 40 **Final Diagnosis:** N = 27 malignant N = 13 benign **Mean Age:** 59 years **Gender:** 62.5% Male **Inclusion criteria:** Either: 1. Previously obtained CT scan revealing a pancreatic mass suggestive of malignancy, or 2. Recurrent abdominal and lumbar pain in patients with chronic pancreatitis without morphologic signs of cancer **Exclusion Criteria:** Evidence of enopathy or solitary liver metastasis for highly advanced disease only (life expectancy < 3 months)	**Scanner Model:** CTI ECAT 953/15 (Siemens) **Resolution:** • **Intrinsic:** NS • **Image:** NS **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** 15 min per bed position (3-4 bed positions) • **Transmission Scan:** NS **Dose of FDG:** 150-300 MBq **Time between injection and performance:** 45 min **Reconstruction Algorithm used:** Iterative **Glucose Monitoring:** Fasting – 12 hours	**PET done:** Qualitatively and Quantitatively **Criteria used for diagnosis:** Focal accumulation is the ROI; Tumor to liver ratio (TLR); Differential uptake ratio (DUR) = Tissue radioactivity / Injected dose / body weight **Comparator Test done:** CT **Criteria used for diagnosis:** NS **Comparator Test done:** US **Criteria used for diagnosis:** NS **Gold Standard test done:** Histology **Criteria used for diagnosis:** NS **Blinding:** **Radiologist:** NS **Gold Standard reader:** NS	**Question 1a:** Histology PET | | + | - | | + | 24 | 2 | | - | 3 | 11 | Sensitivity = 92% Specificity = 85% Histology CT | | + | - | | + | 27 | 10 | | - | 0 | 3 | Sensitivity = 100% Specificity = 23% **US:** Sensitivity: 75% Specificity: 33% Prevalence: 67% Quantitation with FDG uptake did not improve results. **17 lymph node metastasis:** 76% detected by PET 18% detected by CT 7% detected by US	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 6** **Notes:** Lack of FDG accumulation in diabetic patients. Close relationship between visual classification and quantification of FDG uptake or TLRs. No correlation between uptake or TLR and tumor size.

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
					Question 1b: LN PET Histology + / - ; + 27 10 ; - 0 3 Sensitivity = 100% Specificity = 23% CT Histology + / - ; + 3 10 ; - 14 13 Sensitivity = 17.6% Specificity = 56.5% Prevalence = 42% Liver PET Histology + / - ; + 4 4 ; - 3 29 Sensitivity = 57.1% Specificity = 87.9% CT Histology + / - ; + 2 11 ; - 5 22 Sensitivity = 28.6% Specificity = 66.7% Prevalence = 17%	

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Bares **1993** **PROCITE#** 7580 **Cancer Type:** Pancreatic **SOW Question(s) Addressed:** 1a, 1b **Frybeck et al. Level:** 2	**Dates of data collection:** NS **Geographic Location:** Aachen, Germany **Prospective Study** **Enrolled Consecutively:** NS **Study Setting:** NS Patient Incl Crit: • Comp test result **Result led to incl:** • Abnormal only **Comparisons:** • Matched **Use of ref stand:** • Histology	***Patients:*** **N =** 15 11 pancreatic cancer 2 carcinoma of ampulla vater **Mean(Median) Age:** 61.5 yrs **Gender:** **73% Male** **Inclusion criteria:** Pancreatic masses on CT suggestive of Pancreatic Cancer. **Exclusion Criteria:** NS	**Scanner Model:** CTI – Siemens ECAT 953/15 **Resolution:** • Intrinsic: 3.4 mm • Image: 9 mm **Acquisition Mode:** 3-D **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** 15 min **Dose of FDG:** 150-300 MBq **Time between injection and performance:** 45 min **Reconstruction Algorithm used:** Iterative **Glucose Monitoring:** 12 patients fasted ≥ 18 hrs; 3 patients given 500 ml 40% glucose before scan.	**PET done:** *Qualitatively:* Compared image contrast between lesion and surrounding background (+ / ++) *Quantitatively:* Calculated differential uptake ratio **Criteria used for diagnosis:** No values were given as to what was considered positive and what was considered negative. **Comparator Test done:** Ultrasound **Criteria used for diagnosis:** NS **Comparator Test done:** ERCP **Criteria used for diagnosis:** NS **Gold Standard test done:** Histology **Criteria used for diagnosis:** NS **Blinding:** **Radiologist:** NS **Gold Standard reader:** NS	**Question 1a** PET Histology | | + | - | | + | 12 | 0 | | - | 1 | 2 | Sensitivity = 92% Specificity = 100% VIS Histology | | + | - | | + | 11 | 1 | | - | 2 | 12 | Sensitivity = 85% Specificity = 92% ERCP Histology | | + | - | | + | 13 | 1 | | - | 0 | 1 | Sensitivity = 100% Specificity = 50% Overall prevalence: 87% **Question 1b** LN PET Histology | | + | - | | + | 8 | 0 | | - | 1 | 6 | Sensitivity = 89% Specificity = 100% CT Histology | | + | - | | + | 2 | 1 | | - | 7 | 3 | Sensitivity = 22.2% Specificity = 75%	***Quality Score:*** **Rep.sample: 1** **Setting selection: 0** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 0** **Hist or clin confirmation: 0** **Blinded: 0** **Total Score = 3** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
					Prevalence = 60% Liver Histology PET | | + | - | | + | 4 | 0 | | - | 1 | 10 | Sensitivity = 80% Specificity = 100% Histology CT | | + | - | | + | 3 | 2 | | - | 2 | 8 | Sensitivity = 60% Specificity = 80% Prevalence = 33%	

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Delbeke **1999** **PROCITE#** 7340 **Cancer Type:** Pancreatic **SOW Question(s) Addressed:** 1a, 1b **Fryback et al. Level:** 2, 4	**Dates of data collection:** NS **Geographic Location:** Nashville, TN **Prospective Study** **Enrolled Consecutively:** Yes **Study Setting:** NS **Patient Incl Crit:** • Clin Pres **Result led to incl:** • NS **Comparisons:** • Matched **Use of ref stand:** • Histology • Prolonged follow-up	***Patients:*** **N =** 65 **Mean Age:** 60±20 years **Age Range:** 36-80 years **Gender:** 51% Male **Inclusion criteria:** Patients with suspected pancreatic carcinoma who underwent both FDG PET and CT **Exclusion Criteria:** NS	**Scanner Model:** ECAT 933/08/16 (Siemens) **Resolution:** **Intrinsic:** 8 mm • **Image:** 8 mm **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** 15 min • **Transmission Scan:** 10 min **Dose of FDG:** 370 MBq **Time between injection and performance:** 60 min **Reconstruction Algorithm used:** Filtered backprojection **Glucose Monitoring:** Fasting – 4 hours	**PET done:** Qualitatively and Quantitatively **Criteria used for diagnosis:** Background liver uptake used as reference for normal uptake; SUV used and ROC curve generated using two cutoffs for malignancy – SUV ≥ 2.0 and ≥ 3.0; SUV_{gluc} is SUV corrected for glucose. **Comparator Test:** CT **Done:** Qualitatively **Criteria used for diagnosis:** Discrete low attenuation lesions in pancreas or diffuse enlargement of pancreatic head/uncinate process when distant metastases were suspected considered positive for cancer **Gold Standard test done:** Histology **Criteria used for diagnosis:** NS **Blinding:** **Radiologist:** No **Gold Standard reader:** NS	CT and PET (SUV≥ 2.0) Cancer | | + | - | | + | 52 | 3 | | - | 0 | 10 | Sensitivity = 100% Specificity = 77% CT and PET (SUV≥ 3.0) Cancer | | + | - | | + | 48 | 2 | | - | 4 | 11 | Sensitivity = 92% Specificity = 85% CT Cancer | | + | - | | + | 34 | 5 | | - | 18 | 8 | Sensitivity = 65% Specificity = 62% CT Stage | | I | II | III | IV | | + | 6 | 7 | 1 | 10 | | - | 0 | 3 | 11 | 11 | PET and CT Stage | | I | II | III | IV | | + | 6 | 0 | 2 | 17 | | - | 0 | 10 | 10 | 4 |	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 4** **Notes:** Unclear how population was selected.

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes

		I	II	III	IV
PET/ CT	SN	100%	0%	17%	81%
	SP	56%	36%	38%	50%
CT	SN	100%	70%	8%	48%
	SP	58%	56%	38%	50%

Therapeutic impact:

30% of patients who would not have had surgery if using CT results because either 1) no malignancy or 2) probable metastasis present – had surgery due to PET results.

13% avoided surgery because PET identified presence of metastasis or found pancreatic lesions to be benign.

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Diederichs **2000** **PROCITE#** 7220 **Cancer Type:** Pancreatic **SOW Question(s) Addressed:** 1a, 1b **Fryback et al. Level:** 2	**Dates of data collection:** 4/92 – 8/95 **Geographic Location:** NS **Retrospective Study** **Enrolled Consecutively:** NS **Study Setting:** Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnormal only **Comparisons:** • Matched **Use of ref stand:** • Histology: N = 120 • Prolonged follow-up: N = 39	***Patients:*** **Group I (all patients):** **N =** 159 **MeanAge:** 56±13 years **Gender:** NS **Group II (Glucose not ≥130, not elevated CRP):** **N =** 123 **MeanAge:** 56±13 years **Gender:** NS **Group III(all not in group II):** **N =** 36 **MeanAge:** 58±13 years **Gender:** NS **Inclusion criteria:** NS **Exclusion Criteria:** NS	**Scanner Model:** CTI ECAT 931/08/12 (Siemens) **Resolution:** • **Intrinsic:** NS • **Image:** NS **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** 10 min per bed position **Dose of FDG: 85-448 MBq** **Time between injection and performance:** 60 min **Reconstruction Algorithm used:** Iterative **Glucose Monitoring:** Fasting – 12 hours	**PET done:** Qualitatively and Quantitatively **Criteria used for diagnosis:** ROI used to calculate SUV; Visual analysis – focally increased FDG uptake considered positive **Comparator Test:** ERCP **Done:** Qualitatively **Criteria used for diagnosis:** Visual grading: 1 = no sign malignant 2 = probably no malignancy 3 = indecisive or technically unsuccessful 4 = probably malignant 5 = definite malignant 4 and 5 considered positive. **Comparator Test:** CT **Done:** Qualitatively **Criteria used for diagnosis:** Visual grading, same as for ERCP – 1-2 considered negative 3 considered indeterminate 4-5 considered positive **Gold Standard test done:** Quantitatively **Criteria used for diagnosis:** Histology or Clinical follow-up **Blinding:** **Radiologist:** NS **Gold Standard reader:** NS	**Question 1a** Cancer PET | | + | - | | + | 60 | 7 | | - | 8 | 47 | Sensitivity = 88% Specificity = 87% * Note: 1 indeterminate study excluded Cancer ERCP | | + | - | | + | 53 | 4 | | - | 3 | 41 | Sensitivity = 95% Specificity = 91% * Note: 22 indeterminate studies excluded Cancer CT | | + | - | | + | 52 | 12 | | - | 7 | 32 | Sensitivity = 88% Specificity = 73% * Note: 20 indeterminate studies excluded Prevalence: 66/123 = 54% Question 1b LN Cancer PET | | + | - | | + | 22 | 6 | | - | 23 | 10 | Sensitivity = 49% Specificity = 62.5% Prevalence: 22%	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 6** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
					Liver Cancer CT | | + | - | |---|---|---| | + | 14 | 4 | | - | 6 | 65 | Sensitivity = 70% Specificity = 94% Prevalence: 22%	

<table>
<tr><th>Study, Year/ General Inclusion Criteria</th><th>Study Design</th><th>Patients/ Subject Characteristics</th><th>PET Technical Characteristics</th><th>Criteria for Abnormality</th><th>Results</th><th>Quality Score/Notes</th></tr>
<tr>
<td>
Friess

1995

PROCITE# 7500

Cancer Type: Pancreatic

SOW Question(s) Addressed: 1a

Fryback et al. Level: 2
</td>
<td>
Dates of data collection: 2/92 – 11/93

Geographic Location: Berne, Switzerland and Ulm, Germany

Retrospective Study

Enrolled Consecutively: Yes

Study Setting: Academic/ Research

Patient Incl Crit:
• Clin Pres

Result led to incl:
• Abnormal only

Comparisons:
• Matched

Use of ref stand:
• Histology
</td>
<td>
Patients:

N = 80

Median Age: see results

Gender: see results

Inclusion criteria: NS

Exclusion Criteria: NS
</td>
<td>
Scanner Model: ECAT 931-08 (Siemens/CTI)

Resolution:
• Actual: 7 mm FWHM

Acquisition Mode: NS

Acquisition time per FOV:
• Emission Scan: 10 min
• Transmission Scan: 10 min

Dose of FDG: 250-350 MBq

Time between injection and performance: 45 min

Reconstruction Algorithm used: Iterative

Glucose Monitoring: Fasting – 6 hours; Glucose measured, maximum amount permitted not specified.
</td>
<td>
PET done: Qualitatively

Criteria used for diagnosis: Visual analysis – focally increased FDG uptake considered positive

Comparator Test: CT
Done: Qualitatively
Criteria used for diagnosis: Suspicious tumor mass with direct or indirect signs of malignancy considered positive

Gold Standard test done: Quantiatively

Criteria used for diagnosis: Histology

Blinding:
Radiologist: NS
Gold Standard reader: NS
* Designed as “blind” study
</td>
<td>
PET
<table>
<tr><th></th><th>Cancer +</th><th>Cancer -</th></tr>
<tr><td>+</td><td>45</td><td>4</td></tr>
<tr><td>-</td><td>3</td><td>28</td></tr>
</table>
Sensitivity = 94%
Specificity = 88%

CT
<table>
<tr><th></th><th>Cancer +</th><th>Cancer -</th></tr>
<tr><td>+</td><td>33</td><td>10</td></tr>
<tr><td>-</td><td>9</td><td>22</td></tr>
</table>
Sensitivity = 79%
Specificity = 69%

Prevalence:
PET: 48/80 = 60%
CT: 42/74 = 57%

Patient groups:
<table>
<tr><th></th><th>I</th><th>II</th><th>III</th><th>Control</th></tr>
<tr><td>N</td><td>42</td><td>6</td><td>32</td><td>10</td></tr>
<tr><td>Median Age</td><td>60.5</td><td>58.5</td><td>50</td><td>51.5</td></tr>
<tr><td>Age Range</td><td>36-79</td><td>42-76</td><td>25-74</td><td>29-71</td></tr>
<tr><td>Gender</td><td>71.4</td><td>50.0</td><td>84.3</td><td>60.0</td></tr>
<tr><td>Stage II</td><td>6</td><td>N/A</td><td>N/A</td><td>N/A</td></tr>
<tr><td>Stage III</td><td>19</td><td>N/A</td><td>N/A</td><td>N/A</td></tr>
<tr><td>Stage IV</td><td>17</td><td>N/A</td><td>N/A</td><td>N/A</td></tr>
</table>
Group I: Pancreatic ductal cancer
Group II: Periampullary cancer
Group III: Chronic pancreatitis
Control: Normal controls
</td>
<td>
Quality Score:

Rep.sample: 1

Setting selection: 1

Design minimizes diffs: 1

Scanner: 1

Interpretation criteria defined: 1

Hist or clin confirmation: 1

Blinded: 1

Total Score = 7

Notes:
</td>
</tr>
</table>

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Ho **1996** **PROCITE#** 7470 **Cancer Type:** Pancreatic **SOW Question(s) Addressed:** 1a **Frybeck et al. Level:** 2	**Dates of data collection:** NS **Geographic Location:** St. Louis, MO **Retrospective/ Prospective Study:** NS **Enrolled Consecutively:** NS **Study Setting:** NS Patient Incl Crit: • Comp test result – CT **Result led to incl:** • Abnormal only **Comparisons:** • Matched **Use of ref stand:** • Histology – 12 patients • Prolonged follow-up – 2 patients	***Patients:*** **N =** 14 12 indeterminate masses by CT; 2 typical cancer by CT **Mean(Median) Age:** NS **Gender:** NS **Inclusion criteria:** Abnormal or indeterminate CT result **Exclusion Criteria:** NS	**Scanner Model:** Super PET-IIB (8 patients) and Siemens ECAT-EXACT (6 patients) **Resolution:** • **Intrinsic:** NS • **Image:** 10 mm **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** 10-15 min **Dose of FDG:** 10 mCi **Time between injection and performance:** 45 min **Reconstruction Algorithm used:** NS **Glucose Monitoring:** Fasting – 6 hrs; Glucose measured, maximum amount permitted not specified.	**PET done:** Qualitatively **Criteria used for diagnosis:** Focal areas of increased uptake; Modified SUV ≥ 2.5 **Comparator Test done:** CT **Criteria used for diagnosis:** NS **Gold Standard test:** Histology and Clinical follow-up **Done:** Qualitatively and Quantitatively **Criteria used for diagnosis:** Histology – 12 patients. Clinical follow-up for 12 months – 2 patients. **Blinding:** **Radiologist:** NS **Gold Standard reader:** NS	Cancer PET | | + | - | | + | 8 | 2 | | - | 0 | 4 | Sensitivity = 100% Specificity = 67% Prevalence = 57% CT used as inclusion criteria, therefore comparator tests could not be done.	***Quality Score:*** **Rep.sample: 1** **Setting selection: 0** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 5** **Notes:** CT indeterminate for cancer used as inclusion criteria. Article attempts to compare CT alone vs. PET and CT for indeterminate lesions but can't generate table.

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Imdahl **1999** **PROCITE#** 7320 **Cancer Type:** Pancreatic **SOW Question(s) Addressed:** 1a **Fryback et al. Level:** 2	**Dates of data collection:** 7/95 – 7/97 **Geographic Location:** Freiburg, Germany **Prospective Study** **Enrolled Consecutively:** Yes **Study Setting:** NS **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnorm and norm **Comparisons:** • Matched **Use of ref stand:** • Histology	***Patients:*** **N =** 48 42 patients with pancreatic disease; 6 controls **Mean(Median) Age:** 58 **Gender: 60% Male** **Inclusion criteria: NS** **Exclusion Criteria:** NS	**Scanner Model:** Siemens/ CTI ECAT-EXACT 921/31 **Resolution:** • **Intrinsic:** 6 mm • **Image:** NS **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** 10 min **Dose of FDG:** 350 ± 50 MBq **Time between injection and performance:** 90 min **Reconstruction Algorithm used:** NS **Glucose Monitoring:** NS	**PET done:** Quantitatively **Criteria used for diagnosis:** SUV corrected for body weight > 4.0 was a positive test. Focal increased uptake > normal ("normal" not explained) was also a positive test. **Comparator Test done:** ERCP **Criteria used for diagnosis:** NS **Comparator Test done:** CT **Criteria used for diagnosis:** NS **Gold Standard test done:** Histology **Criteria used for diagnosis:** Histologic diagnosis at biopsy or laparotomy except for controls. **Blinding:** **Radiologist:** Yes **Gold Standard reader:** NS	PET (Cancer) | | + | - | Control | | + | 26 | 0 | 0 | | - | 1 | 15 | 6 | Sensitivity = 96% Specificity = 100% n = 48 CT (Cancer) | | + | - | | + | 22 | 4 | | - | 5 | 17 | Sensitivity = 81% Specificity = 81% n = 48 ERCP (Cancer) | | + | - | | + | 17 | 3 | | - | 3 | 13 | Sensitivity = 85% Specificity = 81% n = 36 * * ERCP not done on all patients. Prevalence = 56% **Note:** Because results were broken down into cancer and pancreatitis there is not enough information to actually identify the appropriate number of patients in "Cancer Negative" column for CT. Calculated numbers show all non-cancer patients (i.e. both pancreatitis and normal) as "Cancer Negative."	***Quality Score:*** **Rep.sample: 1** **Setting selection: 0** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 5** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Inokuma **1995** **PROCITE#** 7520 **Cancer Type:** Pancreas **SOW Question(s) Addressed:** 1a **Frybeck et al. Level:** 2	**Dates of data collection:** 6/92 – 10/94 **Geographic Location:** Kyoto, Japan **Prospective Study** **Enrolled Consecutively:** Yes **Study Setting:** Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnormal only **Comparisons:** • Matched **Use of ref stand:** • Histology: n=41 • Prolonged follow-up: n=5	***Patients:*** **N =** 46 **Mean Age:** 62 years **Age Range:** 37-79 years **Gender:** 54.3% Male **Inclusion criteria:** Clinical findings suggestive of suspected pancreatic tumor and scheduled to undergo surgery **Exclusion Criteria:** NS	**Scanner Model:** PCT 3600W (Hitachi Medico) **Resolution:** • **Intrinsic:** 4.6 mm FWHM • **Axial:** 7 mm FWHM **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** 15 min • **Transmission Scan:** 20 min **Dose of FDG:** 150 MBq **Time between injection and performance:** 60 min **Reconstruction Algorithm used:** NS **Glucose Monitoring:** Fasting – overnight	**PET done:** Qualitatively and Quantitatively **Criteria used for diagnosis:** SUV calculated; Any obvious foci within the pancreatic area that had greater FDG uptake than the surrounding background were regarded as suggestive of malignancy. **Comparator Test done:** US – endoscopic and transabdominal **Criteria used for diagnosis:** Presence of mass, presence of vascular and/or lymph nodes imaging classification as diagnostic (positive or negative for malignancy) **Comparator Test done:** CT **Criteria used for diagnosis:** NS **Gold Standard test done:** Histology or clinical follow-up **Criteria used for diagnosis:** NS **Blinding:** **Radiologist:** Yes **Gold Standard reader:** NS	**Histologic diagnosis:** N = 26 Ductal Adenocarcinoma N = 7 Chronic Pancreatitis N = 4 Cystadenocarcinoma N = 3 Islet-cell Tumor N = 3 Cystadenoma N = 1 Ampullary Carcinoma N = 1 Inflammatory Pseudocyst N = 1 Metastasis from renal cell cancer PET Cancer | | + | - | | + | 34 | 1 | | - | 1 | 10 | Sensitivity = 97% Specificity = 91% US Cancer | | + | - | | + | 31 | 6 | | - | 4 | 5 | Sensitivity = 89% Specificity = 45% CT Cancer | | + | - | | + | 31 | 3 | | - | 4 | 8 | Sensitivity = 89% Specificity = 73% EUS (n=40) Cancer | | + | - | | + | 28 | 4 | | - | 1 | 7 | Sensitivity = 97% Specificity = 64%	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 0** **Blinded: 0** **Total Score = 5** **Notes:** Focus of increased FDG uptake is highly suggestive of malignancy. False-negative tumors are very small.

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Kalady **2002** **PROCITE#** 6960 **Cancer Type:** Pancreatic **SOW Question(s) Addressed:** 1a **Fryback et al. Level:** 4	**Dates of data collection:** 1/94 – 7/01 **Geographic Location:** Durham, NC **Retrospective Study** **Enrolled Consecutively:** No **Study Setting:** Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnorm and norm **Comparisons:** • Matched **Use of ref stand:** • Histology (n=47) • Prolonged follow-up (n=7)	***Patients:*** **N =** 54 **Mean Age:** NS **Gender:** NS **Final Diagnosis:** N=6 benign N=41 malignant **Inclusion criteria:** Suspected primary pancreatic cancer; Patients evaluated by both CT and FDG-PET **Exclusion Criteria:** NS	**Scanner Model:** GE Advance **Resolution:** • **Intrinsic:** 5 mm • **Image:** NS **Acquisition Mode:** 2-D **Acquisition time per FOV:** • **Emission Scan:** 10 min (before 1990) 4 min (after 1990) • **Transmission Scan:** 10 min (before 1990) 3 min (after 1990) **Dose of FDG:** 10 mCi **Time between injection and performance:** 60 min **Reconstruction Algorithm used:** NS **Glucose Monitoring:** Fasting – 4 hours; Maximum glucose permitted – 200 mg/dL	**PET done:** Qualitatively and Semi-quantitatively **Criteria used for diagnosis:** Visual inspection – FDG-PET with activity greater than background determined as positive; On a subset of patients (n=18) SUV calculated semi-quantitatively as mean activity within a 1-cm circular ROI. SUV = Mean ROI activity / Injected dose/ bodyweight **Comparator Test:** CT **Done:** Qualitatively **Criteria used for diagnosis:** Nodes > 6 mm considered suspicious **Gold Standard test done:** Qualitatively **Criteria used for diagnosis:** Confirmed by percutaneous or endoscopic biopsy, or by histopathology in n=47 patients. In n=7 patients, clinical follow-up of at least 12 months was standard. **Blinding:** **Radiologist:** Yes **Gold Standard reader:** NS	PET (Cancer): +: 36, 1 -: 5, 12 Sensitivity = 88% Specificity = 92% CT (Cancer): +: 37, 5 -: 4, 8 Sensitivity = 90% Specificity = 62% Prevalence: 41/54 = 76% **Clinical Utility of FDG-PET:** **Local extension** – PET provided no additional information. FDG-PET did not predict vascular involvement. 7/41 patients had unresectable disease: proved by CT in 4, celiotomy in 3. **Nodal metastasis** – PET did not identify any nodal disease not detected by CT. N=6 increased FDG – 3 proven malignant; N=13 no increased FDG – all proven non-malignant. **Distant metastasis** – PET detected one distant metastasis missed by CT. N=17 increased FDG – 9 proven malignant, 7 not assessed, 1 false positive (benign cyst). **Change in management based on diagnosis of primary disease compared to CT** – FDG-PET detected one additional patient with cancer, management did not change. CT detected 37/41 malignancies. PET could have spared 4 patients unnecessary operation, but missed 3 cancers.	***Quality Score:*** **Rep.sample: 0** **Setting selection: 0** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 4** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Kato **1995** **PROCITE#** 7550 **Cancer Type:** Pancreatic **SOW Question(s) Addressed:** 1a **Frybeck et al. Level:** 2	**Dates of data collection:** **Geographic Location:** Nagoya, Japan **Prospective Study** **Enrolled Consecutively:** NS **Study Setting:** Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnormal only **Comparisons:** • No comp **Use of ref stand:** • Histology: n=21 • Prolonged follow-up: n=23	***Patients:*** **N =** 24 **Mean Age:** 55.0±10.6 years **Gender:** 83.3% Male **Inclusion criteria:** Pancreatic masses **Exclusion Criteria:** NS	**Scanner Model:** Headtome-IV (Shimadzu Corp) **Resolution:** • **Intrinsic:** NS • **Image:** NS **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** NS **Dose of FDG:** 121-287 MBq **Time between injection and performance:** 50 min **Reconstruction Algorithm used:** NS **Glucose Monitoring:** Fasting for unspecified amount of time	**PET done:** Quantitatively **Criteria used for diagnosis:** Different absorption ratios were calculated (DAR) = Tissue tracer concentration / Injected dose/ body weight DAR diagnosis of benign and malignant masses were compared **Comparator Test done:** CT **Criteria used for diagnosis:** NS **Comparator Test done:** MR **Criteria used for diagnosis:** NS **Gold Standard test done:** Histology and Clinical follow-up ≥ 3 years **Criteria used for diagnosis:** NS **Blinding:** **Radiologist:** NS **Gold Standard reader:** NS	Cancer PET | | + | - | |---|---|---| | + | 14 | 2 | | - | 1 | 7 | Sensitivity = 93% Specificity = 78%	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 0** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 5** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Keogan **1998** **PROCITE#** 7370 **Cancer Type:** Pancreatic **SOW Question(s) Addressed:** 1a, 1b **Fryback et al. Level:** 2	**Dates of data collection:** 8/93 – 12/97 **Geographic Location:** Durham, NC **Prospective Study** **Enrolled Consecutively:** NS **Study Setting:** Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnorm and norm **Comparisons:** • Matched **Use of ref stand:** • Histology	***Patients:*** **N =** 37 **Mean Age:** 62 years **Age Range:** 44-80 years **Gender:** 59.5% Male **Inclusion criteria:** Patients with known or suspected pancreatic cancer, with suspicious findings on CT and ERCP **Exclusion Criteria:** NS	**Scanner Model:** GE Advance **Resolution:** • **Intrinsic:** 5 mm • **Image:** NS **Acquisition Mode:** 2-D **Acquisition time per FOV:** • **Emission Scan:** 10 min • **Transmission Scan:** NS **Dose of FDG:** 10 mCi **Time between injection and performance:** 60 min **Reconstruction Algorithm used:** NS **Glucose Monitoring:** Fasting – 4 hours; Glucose measured, maximum amount permitted 200 mg/dL	**PET done:** Quantitatively **Criteria used for diagnosis:** ROI and SUR values determined **Comparator Test:** CT **Done:** Qualitatively **Criteria used for diagnosis:** Positive, negative or equivocal **Comparator Test:** ERCP **Done:** NS **Criteria used for diagnosis:** NS **Gold Standard test done:** Quantitatively **Criteria used for diagnosis:** Histology - malignancy confirmed by fine-needle aspiration (n=18) or surgery (n=14) or both; Benign disease confirmed by fine-needle aspiration (n=6), surgery (n=5) and ERCP (n=1) **Blinding:** **Radiologist:** Yes **Gold Standard reader:** NS	Question 1a PET (Cancer): + / - : 22 / 2; + / - : 3 / 10 Sensitivity = 88% Specificity = 83% CT (Cancer): + / - : 18 / 2; + / - : 6 / 10 Sensitivity = 75% Specificity = 83% ERCP (Cancer): + / - : 12 / 5; + / - : 2 / 3 Sensitivity = 86% Specificity = 38% Prevalence: 25/37 = 68% Question 1b PET (Cancer): + / - : 2 / 0; + / - : 2 / 21 Sensitivity = 50% Specificity = 100% CT (Cancer): + / - : 3 / 0; + / - : 1 / 21 Sensitivity = 75% Specificity = 100% **Prevalence: 4/25 = 16%**	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 0** **Hist or clin confirmation: 1** **Blinded: 1** **Total Score = 6** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Koyoma **2001** **PROCITE#** 7070 **Cancer Type:** Pancreatic **SOW Question(s) Addressed:** 1a **Fryback et al. Level:** 2	**Dates of data collection:** 10/93 – 7/99 **Geographic Location:** Osaka, Japan **Retrospective Study** **Enrolled Consecutively:** NS **Study Setting:** Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnormal only **Comparisons:** • Matched – US, CT and/or MRI **Use of ref stand:** • Histology (n=55) • Prolonged follow-up (n=31)	***Patients:*** **N =** 86 **Diagnosis:** N=21 benign N=65 malignant **Mean Age:** 64±9.6 years **Gender:** 58% Male **Inclusion criteria:** NS **Exclusion Criteria:** NS	**Scanner Model:** HEADTOME IV SET-1400W-10 (Shimadzu Corp.) **Resolution:** • **Spatial:** 14 mm FWHM **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** 15 min **Dose of FDG:** 180-370 MBq **Time between injection and performance:** 40-55 min **Reconstruction Algorithm used:** Filtered Backposition **Glucose Monitoring:** Fasting – 4 hours; Glucose measured, maximum amount permitted not specified	**PET done:** Quantitatively and Qualitatively **Criteria used for diagnosis:** Visual interpretation – FDG accumulation greater than background considered positive; SUV calculated as tissue concentration (mCi/g) divided by infected activity per body weight (mCi/g); SUV_{gluc} equal to SUV if blood sugar was less than or equal to 130 mg/dL. If BS > 130 mg/dL, SUV_{gluc} = SUV * (130/BS) **Comparator Test:** CT **Done:** Qualitatively **Criteria used for diagnosis:** 1) More than one of: Low-attenuating regions on dynamic contrast images; 2) Vascular invasion; 3) Invasion of contiguous organs **Comparator Test:** MRI **Done:** Qualitatively **Criteria used for diagnosis:** More than one of: 1) Low signal intensity tumor on TIWI; 2) Dynamic TIWI; 3) Vascular invasion; 4) Infiltration of peri-pancreatic tissue **Gold Standard test done:** Qualitatively	**Visual interpretation of PET*** Overall: Sensitivity = 82% Specificity = 81% SUV with 2.1 cut-off (SUV_{gluc}): Sensitivity = 89% Specificity = 76% SUV with 2.2 cut-off: Sensitivity = 91% Specificity = 76% **MRI** Sensitivity = 78% Specificity = 70% PET (Cancer): | | + | - | | + | 53 | 4 | | - | 12 | 17 | Sensitivity = 82% Specificity = 81% CT (Cancer): | | + | - | | + | 59 | 13 | | - | 6 | 8 | Sensitivity = 91% Specificity = 38% Prevalence: 65/86 = 76%	***Quality Score:*** **Rep.sample: 0** **Setting selection: 0** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 4** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
				Criteria used for diagnosis: Classification of pancreatic carcinoma Japan Pancreatic Society First English Edition (1996). Clinical follow-up greater than 1 year. **Blinding:** **Radiologist:** Yes **Gold Standard reader:** NS		

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Mertz **2000** **PROCITE#** 7180 **Cancer Type:** Pancreatic **SOW Question(s) Addressed:** 1a, 1b **Fryback et al. Level:** 2	**Dates of data collection:** 8/96 – 1/99 **Geographic Location:** Nashville, TN **Retrospective Study** **Enrolled Consecutively:** No **Study Setting:** Academic/ Research **Patient Incl Crit:** • Clin Pres • Comp test result **Result led to incl:** • Abnormal only **Comparisons:** • Matched **Use of ref stand:** • Histology/ Cytology	***Patients:*** **N =** 35 **Final Diagnosis:** N = 31 malignant N = 4 benign **Mean(Median) Age:** NS **Gender:** NS **Inclusion criteria:** NS **Exclusion Criteria:** NS	**Scanner Model:** ECAT 933/08/16 (Siemens) **Resolution:** • **Intrinsic:** 4.8 mm • **Image:** NS **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** 15 min per bed position • **Transmission Scan:** 10 min per bed position **Dose of FDG:** 370 MBq **Time between injection and performance:** NS **Reconstruction Algorithm used:** NS **Glucose Monitoring:** Fasting – 4 hours	**PET done:** Qualitatively and Quantitatively **Criteria used for diagnosis:** Visual – liver uptake referral (greater than liver uptake indicates malignancy); SUR (spontaneous uptake ratio) = $\frac{\text{Mean activity in ROI}}{\text{injected dose / body weight}}$ SUR > 2.8 indicates malignancy. **Comparator Test:** CT **Done:** Qualitatively **Criteria used for diagnosis:** A focal low attenuation mass is positive; Vascular invasion assessed. **Comparator Test:** Endoscopic Ultrasound **Done:** Qualitatively **Criteria used for diagnosis:** Discrete hypoechoic lesion considered positive; Vascular invasion assessed. **Gold Standard test done:** Histology **Criteria used for diagnosis:** NS **Blinding:** **Radiologist:** No **Gold Standard reader:** NS	PET Cancer | | + | - | | + | 27 | 2 | | - | 4 | 2 | Sensitivity = 87% Specificity = 50% CT Cancer | | + | - | | + | 16 | 3 | | - | 15 | 1 | Sensitivity = 52% Specificity = 25% EUS Cancer | | + | - | | + | 27 | 1 | | - | 2 | 3 | Sensitivity = 94% Specificity = 75% **Vascular invasion:** PET: Not capable CT: 32% EUS: 42% (3 additional cases) **Metastatic diagnosis:** PET: 7 cases /9 = 78% CT: 3 cases / 9 =33% CT for local and metastatic disease. EUS for local disease and vascular invasion. PET as an adjunct to CT for metastatic disease.	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 6** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Nakamoto **2000** **PROCITE#** 7140 **Cancer Type:** Pancreatic **SOW Question(s) Addressed:** 1a **Fryback et al. Level:** 2	**Dates of data collection:** NS **Geographic Location:** Kyoto, Japan **Retrospective Study** **Enrolled Consecutively:** NS **Study Setting:** Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnormal only **Comparisons:** • No comp **Use of ref stand:** • Histology: N=31 • Prolonged follow-up: N=16	***Patients:*** **N =** 47 **Mean Age:** 60.2 years **Gender:** 66% Male **Inclusion criteria:** NS **Exclusion Criteria:** NS	**Scanner Model:** PCT 3600W (Hitachi) **Resolution:** • **Intrinsic:** 4.6 mm • **Axial:** 7 mm • **Effective:** 10 mm **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** 12 min • **Transmission Scan:** 11 min **Dose of FDG:** 10 mCi (370 MBq) **Time between injection and performance:** 1, 2 and 3 hours **Reconstruction Algorithm used:** NS **Glucose Monitoring:** Fasting – 5 hours Glucose measured, maximum amount permitted not specified	**PET done:** Quantitatively **Criteria used for diagnosis:** SUV in ROI value calculated Retention index calculated as: $\frac{SUV_{2\ hours} - SUV_{1\ hour}}{SUV_{1\ hour}}$ (Multiplied by 100) **Gold Standard test done:** Quantitatively **Criteria used for diagnosis:** Histopathology or clinical follow-up **Blinding:** **Radiologist:** No **Gold Standard reader**: **NS**	**Cut-off values: SUV: 2.3 and 2.4 at 2 hours and RI at -15** Final Diagnosis Malignant PET: + 27, 4; - 0, 16 Sensitivity = 100% Specificity = 80% **Cut-off values: SUV: 2.3 and 2.4 at 2 hours** Final Diagnosis Malignant PET: + 27, 5; - 0, 15 Sensitivity = 100% Specificity = 75% **Cut-off values: SUV: 2.8 at 1 hour** Final Diagnosis Malignant PET: + 26, 5; - 1, 15 Sensitivity = 96.3% Specificity = 75% **Cut-off values: RI at 0.0** Final Diagnosis Malignant PET: + 22, 3; - 5, 17 Sensitivity = 81.5% Specificity = 85% **Prevalence:** 27/47 = 57% **Retention Index:** Malignant = 12±13.37 Benign = -7.05±17.28 Difference statistically significant p< 0.0001	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 0** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 5** **Notes:** No comparator test done. PET done on all patients with "suspected" malignancy.

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results/ Notes	Quality Score/Notes
Nakamoto **1999** **PROCITE#** 7310 **Cancer Type:** Pancreatic **SOW Question(s) Addressed:** 1b **Frybeck et al. Level:** 2	**Dates of data collection:** 6/95 – 12/97 **Geographic Location:** Hokkaido, Japan **Retrospective Study** **Enrolled Consecutively:** NS **Study Setting:** NS Patient Incl Crit: • Ref stand result – histologically proven pancreatic cancer **Result led to incl:** • Abnormal only **Comparisons:** • Matched **Use of ref stand:** • Histology • Prolonged follow-up	***Patients:*** **N =** 34 **Mean(Median) Age:** 64 years **Gender:** 65% Male **Inclusion criteria:** Histologically proven pancreatic cancer **Exclusion Criteria:** NS	**Scanner Model:** PET 3600W; Hitachi Medico **Resolution:** • **Intrinsic:** 7 mm • **Image:** 10 mm **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** 15 min • **Transmission Scan:** 10 min **Dose of FDG:** 185-370 MBq **Time between injection and performance:** 55 min **Reconstruction Algorithm used:** NS **Glucose Monitoring:** Fasting – 5 hrs	**PET done:** Qualitatively and Quantitatively **Criteria used for diagnosis:** SUV > 3.3 considered positive for metastasis **Comparator Test done:** Ultrasound **Criteria used for diagnosis:** NS **Comparator Test done:** CT **Criteria used for diagnosis:** NS **Gold Standard test done:** Qualitatively and Quantitatively **Criteria used for diagnosis:** 29 patients had histological confirmation of pancreatic metastasis to liver; 5 patients had clinical follow-up confirming pancreatic metastasis to liver **Blinding:** **Radiologist:** Yes **Gold Standard reader:** NS	**Patient data:** PET (Metastasis): | | + | - | |---|---|---| | + | 11 | 2 | | - | 1 | 20 | Sensitivity = 92% Specificity = 91% US (Metastasis): | | + | - | |---|---|---| | + | 8 | 0 | | - | 4 | 22 | Sensitivity = 66.7% Specificity = 100% CT (Metastasis): | | + | - | |---|---|---| | + | 8 | 0 | | - | 4 | 22 | Sensitivity = 66.7% Specificity = 100% Overall Prevalence: 57% **Notes:** 1. Appears all patients had a positive PET for primary tumors which may detection for the metastatic lesions to the liver. 2. Only 17 patients with positive metastasis examined by ultrasound – not clear why, and not mentioned in the paper. 3. Recruitment of the patient population not described.	***Quality Score:*** **Rep.sample: 1** **Setting selection: 0** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 5** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Papos **2002** **PROCITE#** 7010 **Cancer Type:** Pancreatic **SOW Question(s) Addressed:** 1a **Fryback et al. Level:** 2	**Dates of data collection:** NS **Geographic Location:** Szeged, Hungary and Debrecen, Hungary **Prospective Study** **Enrolled Consecutively:** NS **Study Setting:** General outpatient clinics/ physician office; Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnorm and norm **Comparisons:** • Matched – US, CT, CRCP, CA **Use of ref stand:** • Histology • Prolonged follow-up	***Patients:*** **N =** 22 **Mean Age:** 39 years **Range:** 29-59 years **Gender:** 59% Male **Diagnosis:** N=16 benign N=6 malignant **Inclusion criteria:** NS **Exclusion Criteria:** NS	**Scanner Model:** GE 4096 plus **Resolution:** • **Spatial:** 6.5 mm FWHM **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** NS **Dose of FDG:** 232-418 MBq **Time between injection and performance:** 60 min **Reconstruction Algorithm used:** Filtered Backposition **Glucose Monitoring:** Fasting – overnight; Glucose measured, determined to be in "normal" range	**PET done:** Qualitatively **Criteria used for diagnosis:** Any FDG uptake over background in areas outside those with a normal FDG uptake or excretion was considered positive for cancer **Comparator Test:** CA 19-9 **Done:** Quantitatively **Criteria used for diagnosis:** CA level > 37 U/l considered positive **Comparator Test:** ERCP **Done:** Qualitatively **Criteria used for diagnosis:** Positive if complete duct obstruction, stricture, or dislocation of main pancreatic duct; Negative if chronic calcific pancreatitis, irregularity or dilation, or cyst filling and precipitate in main pancreatic duct **Comparator Test:** CT and US **Done:** Quantitatively **Criteria used for diagnosis:** Mass effect and loss of normal homogenous parechymal pattern on images of pancreas **Gold Standard test done:** Histology and follow-up > 6 months **Criteria used for diagnosis:** Histologic analysis after surgery (n=9) and clinical follow-up (n=13) **Blinding:** **Radiologist:** No **Gold Standard reader:** NS	PET Cancer | | + | - | | + | 6 | 2 | | - | 0 | 14 | Sensitivity = 100% Specificity = 87.5% CT Cancer | | + | - | | + | 6 | 7 | | - | 0 | 9 | Sensitivity = 100% Specificity = 56% US Cancer | | + | - | | + | 6 | 7 | | - | 0 | 8 | Sensitivity = 100% Specificity = 50% CA 19-9 Cancer | | + | - | | + | 4 | 4 | | - | 1 | 11 | Sensitivity = 80% Specificity = 73% ECRP Cancer | | + | - | | + | 3 | 1 | | - | 2 | 12 | Sensitivity = 60% Specificity = 92% Prevalence: 6/22 = 27%	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 6** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Rajput **1998** **PROCITE#** 7380 **Cancer Type:** Pancreatic **SOW Question(s) Addressed:** 1a **Fryback et al. Level:** 2	**Dates of data collection:** 3/95 – 8/96 **Geographic Location:** Cleveland, OH **Retrospective Study** **Enrolled Consecutively:** NS **Study Setting:** NS **Patient Incl Crit:** • Clin Pres – possible pancreatic disease **Result led to incl:** • Abnormal only **Comparisons:** • Matched **Use of ref stand:** • Histology	***Patients:*** **N =** 13 **Age Range: 22-83 years** **Gender:** 53.3% Male **Inclusion criteria:** Availability of tissue for final histological diagnosis **Exclusion Criteria:** NS	**Scanner Model:** ECAT EXACT (CTI) **Resolution:** • **Intrinsic:** 6 mm • **Image:** NS **Acquisition Mode:** 2-D **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** NS **Dose of FDG:** 407-802 MBq **Time between injection and performance:** 45 min **Reconstruction Algorithm used:** NS **Glucose Monitoring:** Fasting – overnight	**PET done:** Qualitatively **Criteria used for diagnosis:** Focally increased activity considered malignant, diffuse uptake considered non-malignant inflammation **Comparator Test done:** CT **Criteria used for diagnosis:** NS **Comparator Test done:** ECRP **Criteria used for diagnosis:** NS **Comparator Test done:** EUS **Criteria used for diagnosis:** NS **Gold Standard test done:** Histology **Criteria used for diagnosis:** NS **Blinding:** **Radiologist:** Yes **Gold Standard reader:** NS	PET Cancer | | + | - | | + | 9 | 0 | | - | 2 | 2 | Sensitivity = 82% Specificity = 100% CT Cancer | | + | - | | + | 8 | 2 | | - | 3 | 0 | Sensitivity = 73% Specificity = 0% ERCP Cancer | | + | - | | + | 6 | 1 | | - | 4 | 1 | Sensitivity = 60% Specificity = 50% EUS Cancer | | + | - | | + | 5 | 2 | | - | 0 | 0 | Sensitivity = 100% Specificity = 0% Prevalence: 11/13 = 85%	***Quality Score:*** **Rep.sample: 0** **Setting selection: 0** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 0** **Blinded: 0** **Total Score = 3** **Notes:** First 5 patients did not get the protocol for PET when PET imaging done. Not all patients received all tests since retrospective study. Not mentioned what qualified patients for inclusion in study.

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Rose **1999** **PROCITE#** 7300 **Cancer Type:** Pancreatic **SOW Question(s) Addressed:** 1a, 3 **Frybeck et al. Level:** 2, 4	**Dates of data collection:** 1995 – 1998 **Geographic Location:** Nashville, TN **Prospective Study** **Enrolled Consecutively:** NS **Study Setting:** Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** NS **Comparisons:** • Matched **Use of ref stand:** • Histology – 56 patients • Prolonged follow-up – 9 patients	***Patients:*** **N =** 65 satisfying Fryback 2, Q1A; 9 patients for assessment of response to chemotherapy – Fryback 4 Q3; 8 patients for detection of recurrence after treatment – Fryback 4 Q3 **Mean(Median) Age:** NS **Gender:** NS **Inclusion criteria:** Patients with suspected primary or recurrent pancreatic cancer who had undergone both CT and FDG-PET imaging. **Exclusion Criteria:** NS	**Scanner Model:** Siemens ECAT 933/08/16 **Resolution:** • **Intrinsic:** 4.8mm **Image:** 6.5x6.5x8.0 mm **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** 15 min • **Transmission Scan:** 10 min **Dose of FDG:** 10 mCi **Time between injection and performance:** 60 min **Reconstruction Algorithm used:** NS **Glucose Monitoring:** Fasting > 4 hrs	**PET done:** Qualitatively and Quantitatively **Criteria used for diagnosis:** Focal area uptake in pancreas and SUR ≥ 2.8 considered positive for cancer. **Comparator Test:** CT **Done:** Qualitatively **Criteria used for diagnosis:** Either one considered positive for cancer: 1. Discrete low attenuation mass identified in pancreas. 2. In setting of metastases – enlargement of pancreatic head or uncinate process in the absence of a discrete low attenuation mass. **Gold Standard test done:** Histology (56 patients) or Clinical follow-up for 8 months (9 patients) **Blinding:** **Radiologist:** NS **Gold Standard reader:** NS	PET (Cancer): +: 48, 2 -: 4, 11 Sensitivity = 92% Specificity = 85% CT (Cancer): +: 34, 5 -: 18, 8 Sensitivity = 65% Specificity = 62% Prevalence = 80%	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 6** **Notes:** No description of patient population or recruitment. Several questions were addressed by only sensitivity and specificity of detecting benign vs. malignant lesions had enough patients to include in the study.

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Sendler **2000** **PROCITE#** 7150 **Cancer Type:** Pancreatic **SOW Question(s) Addressed:** 1a **Fryback et al. Level:** 2	**Dates of data collection:** 1/94 – 2/96 **Geographic Location:** Munich, Germany **Prospective Study** **Enrolled Consecutively :** NS **Study Setting:** Academic/ Research **Patient Incl Crit:** • Clin Pres (mass) **Result led to incl:** • Abnormal only **Comparisons:** • Matched **Use of ref stand:** • Histology: N=38 • Prolonged follow-up: N=4	***Patients:*** **N =** 42 **MeanAge:** 54.2 years **Disease:** Adenocarcinoma: N=31 Chronic Pancreatitis: N=11 **Gender:** 50% Male **Inclusion criteria:** 1. Relative good condition (Karnofsky index>80); 2. Able to undergo PET without movement; 3. Underwent helical CT and conventional abdominal US for rutine staging before pancreatic surgery **Exclusion Criteria:** 1. Pregnancy; 2. Poorly controlled diabetes mellitus (blood glucose level > 250 mg/dl prior to PET imaging); 3. Younger than 18 years of age	**Scanner Model:** ECAT 951R/31 (Siemens) **Resolution:** • **Axial:** 5 mm FWHM • **Image:** 8 mm **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** 15 min **Dose of FDG:** 270-390 MBq **Time between injection and performance:** NS **Reconstruction Algorithm used:** Filtered Backposition **Glucose Monitoring:** Fasting overnight; Glucose measured – mean blood glucose level 113±30.4 mg/dl	**PET done:** Qualitatively and Quantitatively **Criteria used for diagnosis:** Qualitatively – visual analysis with a 5-point scale based on uptake relative to background activity: 1=normal (decreased compared to background) 3=equivocal (small focal uptake, low intensity) 5=definite (intense, focal uptake) Quantitatively: Standard ROI of 1.5 cm placed over all tumors. SUVs calculated – average (SUV_{avg}) and maximum (SUV_{max}) activity values of each ROI. Tumor/Non-tumor ratios (T/NT) calculated using normal pancreatic tissue as reference. **Comparator Test done:** Ultrasound **Criteria used for diagnosis:** NS **Comparator Test:** CT **Done:** Qualitatively **Criteria used for diagnosis:** Malignant lesions appear hypodense. Normal pancreas – homogenous arterial enhancement. **Gold Standard test done:** Qualitatively **Criteria used for diagnosis:** Histology and clinical follow-up **Blinding:** **Radiologist:** Yes **Gold Standard reader:** NS	Visual PET Cancer | | + | - | | + | 22 | 4 | | - | 9 | 7 | Sensitivity = 71% Specificity = 64% CT Cancer | | + | - | | + | 23 | 3* | | - | 8 | 8 | Sensitivity = 74% Specificity = 73% US Cancer | | + | - | | + | 18 | 5 | | - | 13* | 6 | Sensitivity = 58% Specificity = 55% * Apparent typographical error in Table 4, pg. 1125 where data is reported. Prevalence: 31/42 = 74% **Using an SUV cutoff of 2.5:** PET Cancer | | + | - | | + | 22 | 3 | | - | 9 | 8 | Sensitivity = 71% Specificity = 73%	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 6** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Sperti **2001** **PROCITE#** 7040 **Cancer Type:** Pancreatic **SOW Question(s) Addressed:** 1a **Fryback et al. Level:** 2, 4	**Dates of data collection:** 2/96 – 1/ 00 **Geographic Location:** Padua, Italy **Prospective Study** **Enrolled Consecutively:** NS **Study Setting:** Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnormal only – all cystic lesions, some (n=16) asymptomatic **Comparisons:** • Matched – CT, CA 19-9 and US (n=56), MRI (n=33) and ERCP (n=3) **Use of ref stand:** • Histology (n=55) • Prolonged follow-up (n=1)	***Patients:*** **Overall:** **N =** 56 **Mean Age:** 60.1 years **Age Range:** 31-86 years **Gender:** 38% Male **Malignant:** **N =** 17 (30%) **Mean Age:** 65.3 years **Age Range:** 31-78 years **Gender:** 23.5% Male **Benign:** **N =** 39 (70%) **Mean Age:** 57.6 years **Age Range:** 31-86 years **Gender:** 43.6% Male **Inclusion criteria:** Suspected cystic tumor of the pancreas or intraductal hypersecreting mucinous neoplasm	**Scanner Model:** ECAT EXACT 47 (Siemens) **Resolution:** • **Transaxial:** 6 mm at FWHM • **Axial:** 5 mm **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** 2 scans, 15 min each • **Transmission Scan:** 2 scans, 15 min each **Dose of FDG:** 444 MBq (12 mCi) **Time between injection and performance:** 60 min **Reconstruction Algorithm used:** NS **Glucose Monitoring:** Fasting – overnight; Glucose measured, < 120 mg/dL permitted	**PET done:** Quantitatively **Criteria used for diagnosis:** Focal uptake with SUV of at least 2.5 **Comparator Test done:** CT **Criteria used for diagnosis:** NS **Gold Standard test done:** Pathologic findings **Criteria used for diagnosis:** Classified according to WHO histologic typing **Blinding:** **Radiologist:** Yes **Gold Standard reader:** Yes	PET Cancer | | + | - | | + | 16 | 1 | | - | 1 | 38 | Sensitivity = 94% Specificity = 97% CT Cancer | | + | - | | + | 11 | 5 | | - | 6 | 34 | Sensitivity = 65% Specificity = 87% CA 19-9 Cancer | | + | - | | + | 11 | 4 | | - | 6 | 35 | Sensitivity = 65% Specificity = 90% Prevalence: 17/56 = 30% **Notes:** Negative PET scans limited pancreatic resection (n=18) or avoided unnecessary splenectomy (n=9) or laparotomy in asymptomatic patients (n=6). In 5 patients with negative PET, percutaneous aspiration biopsy was done without the theoretical risk of seeding malignant cells.	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 1** **Total Score = 7** **Notes:** Limitation of PET – cannot replace anatomic imaging in the assessment of local tumor resectability.

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Zimny **1997** **PROCITE#** 7440 **Cancer Type:** Pancreatic **SOW Question(s) Addressed:** 1a **Fryback et al. Level: 2**	**Dates of data collection:** 1990 – 1996 **Geographic Location:** Aachen, Germany **Retrospective Study** **Enrolled Consecutively:** NS **Study Setting:** Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnormal only **Comparisons:** • Matched – results of comparator not reported in this study **Use of ref stand:** • Histology • Prolonged follow-up	***Patients:*** **N =** 122 **Mean Age:** 56.8 years **Gender:** 65.6% Male **Diabetics:** All: N = 27 IDDM: N = 11 **Inclusion criteria:** NS **Exclusion Criteria:** NS	**Scanner Model:** ECAT 953/15 **Resolution:** • **AxialFOV: 5.2 cm** **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** 15 min • **Transmission Scan:** NS **Dose of FDG:** 190 MBq **Time between injection and performance:** 40 min **Reconstruction Algorithm used:** Iterative **Glucose Monitoring:** Fasting – 12 hours	**PET done:** Qualitatively and Quantitatively **Criteria used for diagnosis:** Visual analysis – focally increased FDG uptake considered positive; SUV calculated, values > 2.9 considered positive **Gold Standard test done:** Histology and/or Clinical follow-up **Criteria used for diagnosis:** NS **Blinding:** **Radiologist:** NS **Gold Standard reader:** NS	**PET (all)** Cancer PET: + 66, 15; - 8, 17 Sensitivity = 89% Specificity = 53% Prevalence = 70% **PET (euglycemia)** Cancer CT/MRI: + 43, 12; - 4, 13 Sensitivity = 91% Specificity = 52% Prevalence = 65% **PET (hyperglycemia)** Recurrence PET: + 23, 2; - 4, 5 Sensitivity = 85% Specificity = 71% Prevalence = 79% PET SUV cutoff: values > 2.9 considered positive	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 0** **Scanner: 0** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 4** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Chin **2002** **PROCITE#** 10470 **Cancer Type:** Lung **SOW Question(s) Addressed:** 1a **Fryback et al. Level:** 2	**Dates of data collection:** 12/1/97 – 3/31/00 **Geographic Location:** Winston Salem, NC **Prospective Study** **Enrolled Consecutively:** Yes **Study Setting:** Academic/ Research **Patient Incl Crit:** • Ref stand result **Result led to incl:** • Abnormal only **Comparisons:** • Matched **Use of ref stand:** • Prolonged follow-up	***Patients:*** **N =** 18 **Mean Age:** NS **Gender:** NS **Inclusion criteria:** NS **Exclusion Criteria:** NS	**Scanner Model:** ECAT 951 (CTI) **Resolution:** • **Intrinsic:** NS • **Image:** NS **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** 7 min per bed position • **Transmission Scan:** 4 min per bed position **Dose of FDG:** 20 mCi **Time between injection and performance:** 60 min **Reconstruction Algorithm used:** Filtered backprojection **Glucose Monitoring:** NS	**PET done:** Qualitatively **Criteria used for diagnosis:** Interpretation by one of two radiologists **Comparator Test done:** CT, MRI, bone scan, bone biopsy **Criteria used for diagnosis:** NS **Gold Standard test done:** Qualitatively **Criteria used for diagnosis:** Survival data obtained from comprehensive cancer center at Wake Forest University **Blinding:** **Radiologist:** No **Gold Standard reader:** No	**Staging results:** Positive Conventional Image: Pathology PET | | + | - | | + | 8 | 0 | | - | 1 | 0 | Sensitivity = 89% Specificity= NA Negative Conventional Image: Pathology PET | | + | - | | + | 2 | 0 | | - | 0 | 7 | Sensitivity = 100% Specificity= 100%	***Quality Score:*** **Rep.sample: 1** **Setting selection: 0** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 0** **Hist or clin confirmation: 0** **Blinded: 0** **Total Score = 3** **Notes:** No definitive outcome (“gold standard”) for determining diagnosis despite presentation of survival data. Multiple conventional imaging tests instead of one used for comparator.

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Pandit **2003** **PROCITE#** 10440 **Cancer Type:** Lung **SOW Question(s) Addressed:** 1a;1b **Fryback et al. Level:** 2	**Dates of data collection:** 1995 – 2000 **Geographic Location:** New York, NY **Retrospective Study** **Enrolled Consecutively:** Yes ("sequentially") **Study Setting:** Inpatient **Patient Incl Crit:** • Clin Pres • Ref stand result – histology **Result led to incl:** • Abnormal only **Comparisons:** • No comp **Use of ref stand:** • Histology • Prolonged follow-up or clinical exam	***Patients:*** **N =** 46 **Mean Age:** 63.8±9.6 years **Age Range:** 43-82 years **Gender:** 41.3% Male **8 patients with initial diagnosis** **38 patients post-treatment** **Inclusion criteria:** NS **Exclusion Criteria:** NS	**Scanner Model:** GE Advance Scanner **Resolution:** • **Transaxial:** 4.8 mm • **Image:** NS **Acquisition Mode:** 2-D **Acquisition time per FOV:** • **Emission Scan:** 4-5 min • **Transmission Scan:** 3-4 min **Dose of FDG:** 370 MBq **Time between injection and performance:** 60 min **Reconstruction Algorithm used:** Iterative **Glucose Monitoring:** Fasting – 4 hours	**PET done:** Qualitatively **Criteria used for diagnosis:** Focal intense uptake considered positive; No uptake or "ill-defined diffuse areas of low grade uptake" considered negative. **Gold Standard test done:** Qualitatively **Criteria used for diagnosis:** Pathology or "clinical follow-up – physical status, performance, radiological data, treatment history and survival history" **Blinding:** **Radiologist:** Yes **Gold Standard reader:** NS	**Initial Diagnosis:** Pathology PET | | + | - | | + | 8 | 0 | | - | 0 | 0 | Sensitivity = 100% **Post-Treatment:** Survival at 1 year PET | | + | - | | + | 23 | 13 | | - | 1 | 9 | Sensitivity = 96% Specificity= 41% **Collapsed across initial or post-treatment diagnosis:** **Histology Reference Standard:** Pathology PET | | + | - | | + | 19 | 4 | | - | 0 | 7 | **Clinical Follow-up Reference Standard:** Pathology PET | | + | - | | + | 19 | 1 | | - | 1 | 11 |	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 0** **Scanner: 1** **Interpretation criteria defined: 0** **Hist or clin confirmation: 1** **Blinded: 1** **Total Score = 5** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Rees **2001** **PROCITE#** 3770 **Cancer Type:** Lung **SOW Question(s) Addressed:** 1c **Fryback et al. Level:** 2	**Dates of data collection:** 1996-2000 **Geographic Location:** London, England **Retrospective Study** **Enrolled Consecutively:** NS **Study Setting:** Inpatient; Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnorm and norm **Comparisons:** • No comp **Use of ref stand:** • Histology • Prolonged follow-up	***Patients:*** **N =** 43 **Mean(Median) Age:** NS **Gender:** 56% Male **Inclusion criteria:** Retrospective study – all patients with suspected paraneoplastic neurological syndrome in whom conventional imaging was negative **Exclusion Criteria:** NS	**Scanner Model:** Siemens/CTI ECAT 951/31R; GE Advance; Siemens ECAT EXACT 47 **Resolution:** • **Spatial:** 4.75-6.0 mm **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** NS **Dose of FDG:** 350 MBq **Time between injection and performance:** 60 min **Reconstruction Algorithm used:** NS **Glucose Monitoring:** NS	**PET done:** NS **Criteria used for diagnosis:** NS **Gold Standard test done:** Qualitatively **Criteria used for diagnosis:** Combination of positive CT, follow-up, surgery and diagnosis of malignancy. **Blinding:** **Radiologist:** Yes **Gold Standard reader:** NS	Cancer PET | | + | - | | + | 9 | 3 | | - | 1 | 26* | Sensitivity = 90% Specificity = 90% Prevalence : 23% to 26% ** * 2 with paraneoplastic syndrome ** unconfirmed counted as negative	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 0** **Scanner: 1** **Interpretation criteria defined: 0** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 4** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Schumacher **2001** **PROCITE#** 4100 **Cancer Type:** Lung **SOW Question(s) Addressed:** 1a **Fryback et al. Level:** 2	**Dates of data collection:** NS **Geographic Location:** Freiburg, Germany **Retrospective/ ProspectiveStudy:** NS **Enrolled Consecutively:** NS **Study Setting:** Academic/ Research **Patient Incl Crit:** • Ref stand result – histology for SCLC **Result led to incl:** • Abnormal only **Comparisons:** • Matched **Use of ref stand:** • Prolonged follow-up	***Patients:*** **N =** 30 **Mean (Median) Age:** 57±13 yrs **Gender:** 77% Male **Inclusion criteria:** NS **Exclusion Criteria:** NS	**Scanner Model:** Siemens ECAT EXACT 921/31 **Resolution:** • **Intrinsic:** 6.0 mm ▪ **Image:** NS **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** 9 min • **Transmission Scan:** 3 min per bed position **Dose of FDG:** 5 MBq/kg **Time between injection and performance:** 90 min **Reconstruction Algorithm used:** Iterative **Glucose Monitoring:** Fasting – 12 hrs	**PET done:** Qualitatively and Quantitatively **Criteria used for diagnosis:** Classified as malignant if: 1. Focally increased tracer uptake exceeds normal limits of regional FDG uptake; 2. Lesion located at a metastatic site; 3. SUV > 4. **Comparator Test done:** CT/ MRI **Criteria used for diagnosis:** Unspecified "standard protocols" **Gold Standard test done:** Follow-up **Criteria used for diagnosis:** Diagnosis is all histologically confirmed. Staging based on follow-up and/or additional tests. **Blinding:** **Radiologist:** Yes **Gold Standard reader:** NS	**Comparisons of PET+ and OE (Other Examination – CT or MRI) for initial staging:** PET Pathology | | + | - | | ED | 20 | 0 | | LD | 0 | 6 | Sensitivity = 100% Specificity = 100% OE Pathology | | + | - | | ED | 13 | 0 | | LD | 7 | 6 | Sensitivity = 65% Specificity = 100% Note: "ED" – extensive disease, "LD" – limited disease. Prevalence: 20/30 = 67%	***Quality Score:*** **Rep.sample: 0** **Setting selection: 0** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 0** **Blinded: 0** **Total Score = 3** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Shen **2002** **PROCITE#** 3160 **Cancer Type:** Lung **SOW Question(s) Addressed:** 1a **Fryback et al. Level:** 2	**Dates of data collection:** NS **Geographic Location:** Taipei, Taiwan **Prospective Study** **Enrolled Consecutively:** NS **Study Setting:** Inpatient; Academic/ Research **Patient Incl Crit:** • Clin pres **Result led to incl:** • Abnormal only **Comparisons:** • Matched **Use of ref stand:** • Histology • Prolonged follow-up	***Patients:*** **N =** 25 **Age Range:** 45-68 years **Gender:** 72% Male **Disease:** Extensive: 60% Limited: 40% **Inclusion criteria:** Histologically confirmed SCLC **Exclusion Criteria:** Any prior radiotherapy or chemotherapy	**Scanner Model:** CTI EXACT HR+ (Siemens); GE Advance PET **Resolution:** • **Intrinsic:** NS • **Image:** NS **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** 7 min per bed position • **Transmission Scan:** 3 min per bed position **Dose of FDG:** 10 mCi **Time between injection and performance:** 40-50 min **Reconstruction Algorithm used:** NS **Glucose Monitoring:** Fasting – 6 hours; Glucose measured, maximum glucose permitted 149 mg/dL	**PET done:** Qualitatively **Criteria used for diagnosis:** Agreement of at least two of three experienced specialists **Comparator Test done:** CT **Criteria used for diagnosis:** NS **Gold Standard test done:** Qualitatively **Criteria used for diagnosis:** Pathological findings from thoracotomy/ mediastinoscopy, other modalities and follow-up of at least one year **Blinding:** **Radiologist:** Yes **Gold Standard reader:** NS	**Results for PET and Conventional imaging** (ED = Extensive disease, LD = Limited disease): PET (Pathology): ED: 15 (+), 0 (-) LD: 0 (+), 10 (-) Sensitivity = 100% Specificity = 100% Conv (Pathology): ED: 14 (+), 1 (-) LD: 1 (+), 9 (-) Sensitivity = 93% Specificity = 90%	***Quality Score:*** **Rep.sample: 0** **Setting selection: 1** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 5** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Zhao **2002** **PROCITE#** 10450 **Cancer Type:** Lung **SOW Question(s) Addressed:** 1a, 1b **Fryback et al. Level:** 2	**Dates of data collection:** NS **Geographic Location:** Bronx, NY **Retrospective Study** **Enrolled Consecutively:** NS **Study Setting:** Academic/ Research **Patient Incl Crit:** • Ref stand result – Histologically confirmed SCLC (3 new patients, 12 past diagnosis) **Result led to incl:** • Abnormal only **Comparisons:** • Matched **Use of ref stand:** • Histology • Follow-up – not prolonged	***Patients:*** **N =** 15 **Mean Age:** 68 years **Age Range:** 50-81 years **Gender:** 53% Male **Inclusion criteria:** NS **Exclusion Criteria:** NS	**Scanner Model:** ADAC Laboratories C-PET PLUS scanner **Resolution:** • **Intrinsic:** NS • **Image:** NS **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** NS **Dose of FDG:** 3.4 – 4.14 mCi **Time between injection and** performance**:** 50 min **Reconstruction Algorithm used:** Iterative **Glucose Monitoring:** Fasting – 4 hours	**PET done:** NS **Criteria used for diagnosis:** NS **Comparator Test done:** CT **Criteria used for diagnosis:** NS **Gold Standard test done:** Qualitatively **Criteria used for diagnosis:** Surgery and Clinical follow-up **Blinding:** **Radiologist:** NS **Gold Standard reader:** NS	**New Patients (N = 3):** N = 3 PET positive N = 0 PET negative Sensitivity: 100% **Patients with previously diagnosed SCLC (N = 12):** Recurrence PET: + 7 1; - 0 4 Sensitivity = 100% Specificity = 80% **Collapsed across new or previously diagnosed patients with SCLC (N = 15):** Pathology PET: + 10 1; - 0 4 Sensitivity = 100% Specificity = 80% CT: + 9 3; - 1 2 Sensitivity = 90% Specificity = 40%	***Quality Score:*** **Rep.sample: 0** **Setting selection: 0** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 0** **Hist or clin confirmation: 0** **Blinded: 0** **Total Score = 2** **Notes:** Data and text do not provide enough data to construct table for CT results by patient type.

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Albers **1999** **PROCITE#** 9030 **Cancer Type:** Testicular **SOW Question(s) Addressed:** 1a **Frybeck et al. Level:** 2	**Dates of data collection:** **1/95 – 7/97** **Geographic Location:** Bonn, Germany **Retrospective/ Prospective Study: NS** **Enrolled Consecutively:** 37 **Study Setting:** Inpatient; Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnormal only **Comparisons:** • Matched • PET and comp – random • PET and comp – not random • No comp **Use of ref stand:** • Histology • Prolonged follow-up	***Patients:*** **N =** 35 **Stage:** **I: N=25** **II: 12** **Tumor:** N = 24 NSGCT N = 13 seminoma **Mean Age:** NS **Inclusion criteria:** NS **Exclusion Criteria:** NS	**Scanner Model:** Siemens ECAT EXACT **Resolution:** • **Intrinsic:** NS • **Image:** NS **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** 10 min • **Transmission Scan:** 10 min **Dose of FDG:** 5-10 mCi **Time between injection and performance:** 45 min **Reconstruction Algorithm used:** Filtered backprojection **Glucose Monitoring:** Fasting – 12 hours; Glucose measured, maximum amount permitted not specified	**PET done:** Qualitatively and Quantitatively **Criteria used for diagnosis:** Visual analysis; **SUV > 2.0 considered positive** **Comparator Test:** CT **Done:** Quantitatively **Criteria used for diagnosis:** Solitary nodules ≥ 1.0 cm or group of ≥ 5 sub-centimeter nodes considered positive **Gold Standard test done:** Quantitatively **Criteria used for diagnosis:** Histology or clinical follow-up > 6 months **Blinding:** **Radiologist:** Yes **Gold Standard reader:** NS	PET Metastasis | | + | - | | + | 7 | 0 | | - | 3 | 27 | Sensitivity = 70% Specificity = 100% CT Metastasis | | + | - | | + | 4 | 2 | | - | 6 | 25 | Sensitivity = 40% Specificity = 93% Prevalence: 10/37 = 27%	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 1** **Total Score = 7** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Cremerius **1999** **PROCITE#** 9150 **Cancer Type:** Testicular **SOW Question(s) Addressed:** 1a **Frybeck et al. Level:** 2	**Dates of data collection:** NS **Geographic Location:** Aachen, Germany **Retrospective/ Prospective Study: NS** **Enrolled Consecutively:** NS **Study Setting:** Inpatient; Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnorm and norm **Comparisons:** • Matched **Use of ref stand:** • Histology • Prolonged follow-up	***Patients:*** **N =** 50 **Median Age:** 31 years **Age Range:** 20-76 years **Inclusion criteria:** NS **Exclusion Criteria:** NS	**Scanner Model:** ECAT EXACT 922/47; ECAT 953/15 **Resolution:** • **Intrinsic:** NS • **Image:** NS **Acquisition Mode:** 2-D **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** NS **Dose of FDG:** 221±62 MBq **Time between injection and performance:** 30-60 min **Reconstruction Algorithm used:** Cited in references **Glucose Monitoring:** Glucose measured, maximum amount allowed not specified	**PET done:** Qualitatively **Criteria used for diagnosis:** Visual analysis – foci of unphysiologic FDG uptake considered positive. SUV calculated **Comparator Test:** CT **Done:** Quantitatively **Criteria used for diagnosis:** Node > 10 mm in size considered positive **Gold Standard test done:** Histology and/or clinical follow-up **Criteria used for diagnosis:** All available sources of clinical data used to determine gold standard diagnosis **Blinding:** **Radiologist:** Yes **Gold Standard reader:** No	PET Metastasis | | + | - | | + | 13 | 2 | | - | 2 | 33 | Sensitivity = 87% Specificity = 94% CT Metastasis | | + | - | | + | 11 | 2 | | - | 4 | 33 | Sensitivity = 73% Specificity = 94% Tumor Markers Metastasis | | + | - | | + | 10 | 0 | | - | 5 | 35 | Sensitivity = 67% Specificity = 100% Prevalence: 15/50 = 30%	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 6** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Cremerius **1998** **PROCITE#** 9380 **Cancer Type:** Testicular **SOW Question(s) Addressed:** 1a, 1b **Fryback et al. Level:** 2	**Dates of data collection:** 9/90 – 8/96 **Geographic Location:** Aachen, Germany **Retrospective/ Prospective Study: NS** **Enrolled Consecutively:** NS **Study Setting:** Inpatient; Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnormal only **Comparisons:** • Matched **Use of ref stand:** • Histology • Prolonged follow-up	***Patients:*** **N =** 33 **Mean Age:** 30 years **Age Range:** 19-71 years **Disease:** N = 14 seminoma N = 18 non-seminoma **Inclusion criteria:** Histopatho-logically proven germ cell tumor **Exclusion Criteria:** NS	**Scanner Model:** Siemens ECAT 953/15 **Resolution:** • **In-plane:** 7 mm • **Image:** NS **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** 45-80 min • **Transmission Scan:** 12-15 min per bed position **Dose of FDG:** 120-309 MBq **Time between injection and performance:** 40-60 min **Reconstruction Algorithm used:** Iterative **Glucose Monitoring:** Fasting – overnight (n=42) or 3-6 hours (n=12)	**PET done:** Qualitatively and Quantitatively **Criteria used for diagnosis:** Visual analysis, hypermetabolic lesion considered positive; SUV values calculated **Comparator Test:** CT **Done:** Qualitatively **Criteria used for diagnosis:** Stable or progressive disease considered positive, complete response or partial response considered negative. Tumors greater than 1.5 cm considered positive. **Gold Standard test done:** Histology or clinical follow-up more than 180 days **Criteria used for diagnosis:** Residual viable tumor if: Lesions documented by CT and either tumor markers positive at time of PET, or Progression found in CT during follow-up **Blinding:** **Radiologist:** No **Gold Standard reader:** NS	**Initial Staging:** PET (Metastasis): + 5, - 1; + 1, - 5 Sensitivity = 83% Specificity = 83% CT (Metastasis): + 5, - 1; + 1, - 5 Sensitivity = 83% Specificity = 83% **Less than 2 weeks after chemotherapy:** PET (Metastasis): + 4, - 0; + 5, - 4 Sensitivity = 44% Specificity = 100% CT (Metastasis): + 7, - 2; + 2, - 2 Sensitivity = 78% Specificity = 50% **More than 2 weeks after chemotherapy**: PET (Metastasis): + 7, - 2; + 2, - 18 Sensitivity = 78% Specificity = 90% CT (Metastasis): + 6, - 9; + 3, - 11 Sensitivity = 67% Specificity = 55%	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 6** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
DeSantis **2001** **PROCITE#** 8230 **Cancer Type:** Testicular **SOW Question(s) Addressed:** 1b **Fryback et al. Level:** 2	**Dates of data collection:** NS **Geographic Location:** Austria and Germany **Prospective Study** **Enrolled Consecutively:** Yes – prospective study **Study Setting:** Inpatient; Academic/ Research **Patient Incl Crit:** • Clin Pres • Comp test result **Result led to incl:** • Abnormal only • Abnorm and norm **Comparisons:** • Matched **Use of ref stand:** • Histology: N=9 • Prolonged follow-up: N=28	***Patients:*** **N =** 33 patients (37 scans) **Median Age:** 37 years **Age Range:** 22-59 years **Inclusion criteria:** Patients with metastases of pure testicular or extragonadal seminomas who had negative tumor markers on completion of platinum-containing first-line or salvage chemotherapy, but showed CT evidence of clearly defined and measurable residual masses > 1 cm diameter **Exclusion Criteria:** Patients not meeting inclusion criteria, along with those scheduled for radiotherapy at the site of the residual lesions	**Scanner Model:** GE Advance (N=32); ECAT ART – Siemens/CTI (N=1) **Resolution:** • **Axial:** 4.0 mm • **Transaxial:** 3.8 mm **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** NS **Dose of FDG:** 10 mCi (370 MBq) **Time between injection and performance:** ≥ 45 min **Reconstruction Algorithm used:** Filtered Backprojection; Iterative **Glucose Monitoring:** Fasting – 4 hours	**PET done:** Qualitatively **Criteria used for diagnosis:** Visual interpretation – localization, shape, intensity of increased uptake **Comparator Test:** CT **Done:** Quantitatively **Criteria used for diagnosis:** Size >3cm considered positive **Gold Standard test done:** Quantiatively **Criteria used for diagnosis:** Histology or clinical follow-up ≥ 2 years or other imaging study **Blinding:** **Radiologist:** NS **Gold Standard reader:** NS	**Results reflect N = 37 lesions (scans):** Viable Residual Tumor PET | | + | - | | + | 8 | 0 | | - | 1 | 28 | Sensitivity = 89% Specificity = 100% Viable Residual Tumor CT | | + | - | | + | 7 | 7 | | - | 2 | 21 | Sensitivity = 78% Specificity = 75% Prevalence: 9/37 – 24%	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 6** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Ganjoo 1999 **PROCITE#** 10500 **Cancer Type:** Testicular **SOW Question(s) Addressed:** 1b **Frybeck et al. Level:** 2	**Dates of data collection:** 2/96 – 3/98 **Geographic Location:** Indianapolis, IN **Prospective Study** **Enrolled Consecutively:** Yes – prospective enrollment **Study Setting:** Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnorm and norm **Comparisons:** • Matched **Use of ref stand:** • Histology	***Patients:*** **N =** 29 – all seminoma patients **Median Age:** 38 years **Age Range:** 24-67 years **Chemotherapy:** Initial: n=19 Salvage: n=10 **Primary Tumor:** Testicular I: n=12 Testicular II: n=7 Retroperitoneal: n=6 Mediastinal: n=4 **Residual Mass:** < 3 cm: n=8 ≥ 3 cm: n=18 Unknown: n=3 **Inclusion criteria:** NS **Exclusion Criteria:** NS	**Scanner Model:** NS **Resolution:** • **Intrinsic:** NS • **Image:** NS **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** NS **Dose of FDG:** 10 mCi **Time between injection and performance:** NS **Reconstruction Algorithm used:** NS **Glucose Monitoring: NS**	**PET done:** Quantitatively **Criteria used for diagnosis:** SUV ≥ 4 **Comparator Test:** CT **Done:** Quantitatively **Criteria used for diagnosis:** size ≥ 3 cm considered abnormal (positive) **Gold Standard test done:** Quantitatively **Criteria used for diagnosis:** Histology or prolonged follow-up **Blinding:** **Radiologist:** NS **Gold Standard reader:** NS	PET (Cancer) | | + | - | | + | 0 | 1 | | - | 5 | 23 | Sensitivity = 0% Specificity = 96% CT (Cancer) | | + | - | | + | 2 | 14 | | - | 2 | 10 | Sensitivity = 50% Specificity = 42%	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 1** **Scanner: 0** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 5** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Hain **2000a** **PROCITE#** 8730 **Cancer Type:** Testicular **SOW Question(s) Addressed:** 1a **Fryback et al. Level:** 2, 3	**Dates of data collection:** 1994 – 1998 **Geographic Location:** London, UK **Retrospective Study** **Enrolled Consecutively:** No – retrospective review **Study Setting:** Inpatient; Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnorm and norm **Comparisons:** • Matched **Use of ref stand:** • Histology • Prolonged follow-up	***Patients:*** **N =** 31 **Tumor Type:** N=13 seminomas N=18 NSGCT **Mean Age:** 31.6 years **Age Range:** 17-51 years **Inclusion criteria:** None **Exclusion Criteria:** None	**Scanner Model:** Siemens ECAT 951 **Resolution:** • **Spatial:** 8 mm FWHM **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** 5 min • **Transmission Scan:** 5 min **Dose of FDG:** 320 MBq **Time between injection and performance:** NS **Reconstruction Algorithm used:** **Glucose Monitoring:** Fasting – 6 hours	**PET done:** NS **Criteria used for diagnosis:** Scans reported by two nuclear medicine physicians blinded to CT/MRI reports **Comparator Test done:** CT/ MRI **Criteria used for diagnosis:** NS **Gold Standard tests done:** Qualitatively and Quantitatively **Criteria used for diagnosis:** Histology or clinical follow-up ≥ 18 months **Blinding:** **Radiologist:** Yes **Gold Standard reader:** NS	PET Metastasis | | + | - | | + | 10 | 0 | | - | 5 | 16 | Sensitivity = 67% Specificity = 100% CT Metastasis | | + | - | | + | 13 | 7 | | - | 2 | 9 | Sensitivity = 87% Specificity = 56% Prevalence: 15/31 = 48%	***Quality Score:*** **Rep.sample: 1** **Setting selection: 0** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 0** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 4** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Hain **2000b** **PROCITE#** 8640 **Cancer Type:** Testicular **SOW Question(s) Addressed:** 1c **Frybeck et al. Level:** 2, 3, 4	**Dates of data collection:** 1994-1998 **Geographic Location:** London, UK **Retrospective Study** **Enrolled Consecutively:** Yes **Study Setting:** Academic/ Research **Patient Incl Crit:** • Clin Pres – abnormal CT or increased markers **Result led to incl:** • Abnormal only **Comparisons:** • Matched **Use of ref stand:** • Histology • Prolonged follow-up	***Patients:*** **N =** 55 patients 70 total PET scans: 23 scans for patients with increased markers and normal CT; 47 scans (in 39 patients) for abnormal CT **Mean Age:** 30 years **Age Range:** 15-55 years **Inclusion criteria:** Patients with previous germ cell tumor(s) **Exclusion Criteria:** NS	**Scanner Model:** Siemens ECAT 951 **Resolution:** • **Spatial:** 8 mm FWHM • **Image:** NS **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** NS **Dose of FDG:** 320 MBq **Time between injection and performance:** NS **Reconstruction Algorithm used:** NS **Glucose Monitoring:** Fasting – 6 hours	**PET done:** NS **Criteria used for diagnosis:** NS **Comparator Test:** CT **Done:** NS **Criteria used for diagnosis:** NS **Comparator Test:** Tumor Markers **Done:** Quantitatively **Criteria used for diagnosis:** BHCG > 5 ku/l and AFP > u/l **Gold Standard test done:** Qualitatively and Quantitatively **Criteria used for diagnosis:** Histology or extended clinical follow-up **Blinding:** **Radiologist:** NS **Gold Standard reader:** NS	Patients with residual masses after chemotherapy (N=47 scans): PET: Cancer + 25, Cancer - 1, Non-cancer + 3, Non-cancer - 18 Sensitivity = 89% Specificity = 95% CT: Cancer + 28, Cancer - 19, Non-cancer + 0, Non-cancer - 0 Sensitivity = 100% Specificity = 0% Prevalence: 28/47 = 60% Patients with elevated tumor markers (N=41 scans): PET: Cancer + 27, Cancer - 1, Non-cancer + 6, Non-cancer - 7 Sensitivity = 82% Specificity = 88% CT: Cancer + 18, Cancer - 0, Non-cancer + 15, Non-cancer - 8 Sensitivity = 55% Specificity = 100% Prevalence: 33/41 = 80% Patients with elevated tumor markers and negative CT (N=23 scans): PET: Cancer + 11, Cancer - 1, Non-cancer + 4, Non-cancer - 7 Sensitivity = 73% Specificity = 88%	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 0** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 5** **Notes:** Therapy was changed in 57% (27/47) of patients based on PET compared with care plan established based on CT alone.

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Kollmannsberger **2002** **PROCITE#** 7870 **Cancer Type:** Testicular **SOW Question(s) Addressed:** 1b **Fryback et al. Level:** 2	**Dates of data collection:** 9/95 – 10/99 **Geographic Location:** Tuebingen, Germany **Prospective Study** **Enrolled Consecutively:** Yes **Study Setting:** Inpatient; Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnorm and norm **Comparisons:** • Matched **Use of ref stand:** • Histology • Prolonged follow-up	***Patients:*** **N =** 45 **Median Age:** 33 years **Age Range:** 21-57 years **Tumor localization:** N=37 Gonadal N=8 Extragonadal **Inclusion criteria:** Newly diagnosed, metastatic, poor prognosis NSGCT OR recurrent disease after cisplatin-based chemotherapy and at least one residual mass ≥ 1 cm on a CT scan **Exclusion Criteria:** NS	**Scanner Model:** GE Advance **Resolution:** • **Intrinsic:** NS • **Image:** 8 mm **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** 5-15 min per FOV • **Transmission Scan: 3-20 min per FOV** **Dose of FDG:** 250 MBq **Time between injection and performance:** 45-60 min **Reconstruction Algorithm used:** Filtered backprojection; Iterative **Glucose Monitoring:** Fasting – 12 hours; Glucose measured, maximum amount allowed not specified	**PET done:** Qualitatively and Quantitatively **Criteria used for diagnosis:** Visual analysis; SUV ≥ 2 **Comparator Test:** CT **Done:** Quantitatively **Criteria used for diagnosis: Less than** 50%decrease in tumor size, and persistent/increased contrast medium uptake considered positive **Comparator Test:** MRI/Serum tumor marker **Done:** NS **Criteria used for diagnosis: NS** **Gold Standard test done:** Histology or survival **Criteria used for diagnosis:** Histological results or survival > 6 months **Blinding:** **Radiologist:** Yes **Gold Standard reader:** No	Results reported for lesions (not patients) Visual analysis: PET (Cancer): | | + | - | |---|---|---| | + | 29 | 3 | | - | 20 | 33 | Sensitivity = 59% Specificity = 92% CT/ MRI (Cancer): | | + | - | |---|---|---| | + | 27 | 5 | | - | 22 | 31 | Sensitivity = 55% Specificity = 86% CT/ MRI/ Serum (Cancer): | | + | - | |---|---|---| | + | 38 | 3 | | - | 11 | 33 | Sensitivity = 77.5% Specificity = 92% Prevalence: 49/85 = 57.6%	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 6** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Nuutinen **1997** **PROCITE#** 9600 **Cancer Type:** Testicular **SOW Question(s) Addressed:** 1b **Fryback et al. Level:** 2	**Dates of data collection:** 5/95 – 5/96 **Geographic Location:** Turku, Finland **Retrospective/ Prospective Study: NS** **Enrolled Consecutively:** No **Study Setting:** Inpatient; Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnormal only – abnormal CT after chemotherapy **Comparisons:** • No comp **Use of ref stand:** • Histology • Prolonged follow-up	***Patients:*** **N =** 15 **Median Age:** 32 years **Age Range:** 21-54 years **Inclusion criteria:** Abnormal CT after chemotherapy for metastatic testicular cancer **Exclusion Criteria:** NS	**Scanner Model:** Siemens ECAT 931/08-12 **Resolution:** • **Intrinsic:** NS • **Image:** NS **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** 15 min • **Transmission Scan:** NS **Dose of FDG:** 311-446 MBq **Time between injection and performance:** 45 min **Reconstruction Algorithm used:** NS **Glucose Monitoring:** Fasting – 6 hours; Plasma glucose level measured.	**PET done:** Qualitatively and Quantitatively **Criteria used for diagnosis:** Visual analysis: ++ = clearly positive + = suspect – = normal; SUV calculated. **Gold Standard test done:** Histology and clinical follow-up **Criteria used for diagnosis:** Morphological studies, serum tumor markers and length of event-free follow-up time (median 16 months, range 8-20 months). **Blinding:** **Radiologist:** NS **Gold Standard reader:** NS	Analysis based on N = 13 (rather than N = 20 scans). Patients 1 and 11 eliminated due to conflicting secondary results. Cancer PET | | + | - | |---|---|---| | + | 3 | 2 | | - | 1 | 7 | Sensitivity = 75% Specificity = 78%	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 6** **Notes:**

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Stephens 1996 **PROCITE# 10490** **Cancer Type:** Testicular **SOW Question(s) Addressed:** 1b **Frybeck et al. Level:** 2	**Dates of data collection:** NS **Geographic Location:** Indianapolis, IN **Retrospective/ Prospective Study: NS** **Enrolled Consecutively:** NS **Study Setting:** Academic/ Research **Patient Incl Crit:** • Clin Pres – residual post-chemotherapy mass **Result led to incl:** • Abnormal only **Comparisons:** • Matched – no SN or SP reported for CT, all patients had abnormal CT **Use of ref stand:** • Histology: n=30	***Patients:*** **N =** 30 **Median Age:** 31.5 years **Age Range:** 16-46 years **Chemotherapy status:** 1st line: n=22 Salvage: n=8 **Inclusion criteria:** All patients non-seminoma Tumor markers normal in all patients **Exclusion Criteria:** NS	**Scanner Model:** Siemens 951/31R **Resolution:** • **Intrinsic:** NS • **Image:** NS **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission Scan:** NS • **Transmission Scan:** NS **Dose of FDG:** 10 mCi **Time between injection and performance:** 60 min **Reconstruction Algorithm used:** NS **Glucose Monitoring:** NS	**PET done:** Quantitatively **Criteria used for diagnosis:** SUV > 5 considered positive **Comparator Test:** CT **Done:** Quantitatively **Criteria used for diagnosis:** NS – inferred criteria for abnormality was mass > 1 cm **Gold Standard test done:** Quantitatively **Criteria used for diagnosis:** Histological results **Blinding:** **Radiologist:** NS **Gold Standard reader:** NS	PET Cancer | | + | - | | + | 3 | 1 | | - | 16 | 10 | Sensitivity = 16% Specificity = 91% CT Cancer * | | + | - | | + | 12 | 2 | | - | 13 | 11 | Sensitivity = 48% Specificity = 85% * Teratoma scored as "cancer"	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 6** **Notes:**

<table>
<tr><th>Study, Year/ General Inclusion Criteria</th><th>Study Design</th><th>Patients/ Subject Characteristics</th><th>PET Technical Characteristics</th><th>Criteria for Abnormality</th><th>Results</th><th>Quality Score/Notes</th></tr>
<tr>
<td>
Sugawara

1999

PROCITE# 9040

Cancer Type: Testicular

SOW Question(s) Addressed: 1b

Frybeck et al. Level: 2
</td>
<td>
Dates of data collection: NS

Geographic Location: Ann Arbor, MI

Retrospective/ Prospective Study: NS

Enrolled Consecutively: NS

Study Setting: Inpatient; Academic/ Research

Patient Incl Crit:
• Clin Pres

Result led to incl:
• Abnormal only – all patients had abnormal CT results

Comparisons:
• No comp

Use of ref stand:
• Histology, or increased mass with positive biomarkers
</td>
<td>
Patients:

N = 21 overall

N = 15 patients

Tumors
Primary: n=15
Retroperitoneal or mediastinal: n=6

Mean Age: 29 years

Age Range: 19-42 years

Inclusion criteria: NS

Exclusion Criteria: NS
</td>
<td>
Scanner Model: Siemens ECAT 931

Resolution:
• Intrinsic: 120 mm
• Image: NS

Acquisition Mode: NS

Acquisition time per FOV:
• Emission Scan: 2-10 min per FOV
• Transmission Scan: 10 min

Dose of FDG: 370 MBq

Time between injection and performance: 0 min

Reconstruction Algorithm used: NS

Glucose Monitoring: Fasting – 4 hours
</td>
<td>
PET done: Qualitatively and Quantitatively

Criteria used for diagnosis:
Grading scale:
0 = no uptake
1 = equivocal uptake
2 = intense uptake; SUV calculated by dividing decay-corrected tissue activity by injected dose per patient body weight corrected by predicted lean body mass.

Gold Standard test done: Quantitatively

Criteria used for diagnosis:
Histology results

Blinding:
Radiologist: No
Gold Standard reader: NS
</td>
<td>
Equivocal PET results (Visual Grade 1) reported for N = 3 patients.

Data reflecting Visual Grade 1 results as PET positive:
<table>
<tr><td></td><td>Viable Tumor</td><td></td></tr>
<tr><td></td><td>+</td><td>-</td></tr>
<tr><td>PET</td><td>+</td><td>8</td><td>1</td></tr>
<tr><td></td><td>-</td><td>4</td><td>8</td></tr>
</table>
Sensitivity = 67%
Specificity = 89%

Data reflecting Visual Grade 1 results as PET negative, and teratomas considered positive Viable Tumors:
<table>
<tr><td></td><td>Viable Tumor</td><td></td></tr>
<tr><td></td><td>+</td><td>-</td></tr>
<tr><td>PET</td><td>+</td><td>10</td><td>0</td></tr>
<tr><td></td><td>-</td><td>6</td><td>11</td></tr>
</table>
Sensitivity = 67%
Specificity = 100%
</td>
<td>
Quality Score:

Rep.sample: 1

Setting selection: 1

Design minimizes diffs: 1

Scanner: 1

Interpretation criteria defined: 1

Hist or clin confirmation: 1

Blinded: 0

Total Score = 6

Notes:
</td>
</tr>
</table>

Study, Year/ General Inclusion Criteria	Study Design	Patients/ Subject Characteristics	PET Technical Characteristics	Criteria for Abnormality	Results	Quality Score/Notes
Tsatalpas **2002** **PROCITE#** 7990 **Cancer Type:** Testicular **SOW Question(s) Addressed:** 1a, 1b **Fryback et al. Level:** 2	**Dates of data collection:** NS **Geographic Location:** Dresden, Germany **Retrospective/ Prospective Study: NS** **Enrolled Consecutively:** NS **Study Setting:** General outpatient clinics/ physician office; Academic/ Research **Patient Incl Crit:** • Clin Pres **Result led to incl:** • Abnorm and norm **Comparisons:** • Matched **Use of ref stand:** • Histology • Prolonged follow-up	***Patients:*** **N =** 21 patients scanned for staging **N =**11 patients scanned to assess for response to therapy **Mean(Median) Age:** NS **Inclusion criteria:** Patients with diagnosed testicular cancer **Exclusion Criteria:** NS	*Set 1 = 15/21 scans* **Scanner Model:** Siemens ECAT EXACT HR+ **Resolution:** • **Intrinsic:** NS • **Image:** 4-5 mm FWHM **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission:** 50-60 min • **Transmission:** NS **Dose of FDG:** 266-390 MBq **Time between injection and performance:** 60 min **Reconstruction Algorithm used:** Filtered Backposition **Glucose Monitoring:** Fasting – 6-12 hours *Set 2 = 6/21 scans* **Scanner Model:** Solus EPIC MCD (ADAC) **Resolution:** • **Intrinsic:** NS • **Image:** 4 mm FWHM **Acquisition Mode:** NS **Acquisition time per FOV:** • **Emission:** 60-90 min • **Transmission:** NS **Dose of FDG:** 100-140 MBq **Time between injection and performance:** 60 min **Reconstruction Algorithm used:** Iterative **Glucose Monitoring:** Fasting – 6-12 hours	**PET done:** Qualitatively Quantitatively **Criteria used for diagnosis:** Area determined to be "Hot or not", SUV calculation, cutoff not mentioned. **Comparator Test:** CT Scan **Done:** Quantitatively **Criteria used for diagnosis:** Node> 1.5 cm. Contrast-enhancement of suspected organ metastasis. **Gold Standard test done:** Quantitatively **Criteria used for diagnosis:** Histology gold standard for n= 7. Clinical follow-up (6-11 mos after last PET) gold standard for n=16. **Blinding:** **Radiologist:** Yes **Gold Standard reader:** NS	**SOW Question 1a** Metastasis PET: + 9, - 0; + 1, - 11 Sensitivity = 90% Specificity = 100% Metastasis CT: + 6, - 0; + 4, - 11 Sensitivity =60% Specificity = 100% Prevalence = 10/21 = 48% **SOW Question 1b** Viable Tumor PET: + 1, - 4; + 0, - 6 Sensitivity = 100% Specificity = 60% Viable Tumor CT: + 1, - 4; + 0, - 6 Sensitivity = 100% Specificity = 60% Prevalence = 1/11 = 9%	***Quality Score:*** **Rep.sample: 1** **Setting selection: 1** **Design minimizes diffs: 1** **Scanner: 1** **Interpretation criteria defined: 1** **Hist or clin confirmation: 1** **Blinded: 0** **Total Score = 6** **Notes:**

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Appendix G – TA References

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