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Sharona Sachs and Thomas V. Bilfinger

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The Impact of Positron Emission Tomography on Clinical Decision Making in a University-Based Multidisciplinary Lung Cancer Practice*

Sharona Sachs, MD; and Thomas V. Bilfinger, MD, ScD, FCCP

Introduction: **Positron emission tomography (PET) scanning has gained increasing application as a diagnostic and staging tool in the evaluation of lung cancer. Although PET scanning has been demonstrated to be a cost-effective adjunct to lung cancer diagnosis, its global impact on clinical decision making has not been assessed.**
Study objectives: **To evaluate the impact of the systematic use of PET scanning on clinical decision making.**
Design: **Retrospective study.**
Setting: **A university-based multidisciplinary lung cancer practice.**
Patients: **All patients undergoing diagnostic or staging PET scans from December 31, 2000, to December 31, 2002.**
Interventions: **None.**
Measurements and results: **One hundred ninety-eight patients underwent PET for diagnosis (161 patients) or staging (37 patients). PET scan results and clinical outcomes were retrospectively reviewed to determine the frequency with which PET scan findings (1) upstaged patients, (2) downstaged patients, (3) changed the diagnostic workup, (4) altered therapy, (5) resulted in a significant additional diagnosis, and (6) triggered evaluations that ultimately proved fruitless. PET upstaged 32 of 198 patients (16.2%) and downstaged 12 patients (6.1%), facilitating curative resection in 4 patients. Overall, PET scan findings changed the stage in 44 patients (22.2%). PET scan findings changed diagnostic management in 105 of 198 patients (53%), among whom biopsy was deferred in 65 patients (61.9%) and was triggered or guided in 40 patients (38.1%). PET scan findings altered treatment decisions in 38 patients (19.2%), leading to neoadjuvant therapy in 6 patients and resection in 5 patients, and forestalling noncurative thoracotomy in 6 patients. PET scan findings prompted or redirected chemotherapy or radiotherapy in the remainder of the patients. Overall, PET scan findings changed management in 143 patients (72.2%). PET scan findings triggered additional diagnostic testing in 32 patients (16.2%), resulting in no new diagnosis in 16 patients (50%) and a critical change in management in 7 patients (21.9%). PET scan findings were solely responsible for a significant non-lung cancer diagnosis in eight patients (4%).**
Conclusions: **Systematically applied PET scanning has a significant impact on patient management, altering diagnostic or therapeutic interventions in 72.2% of patients, changing staging in 22.2% of patients, and identifying serious unsuspected diagnoses in 4.0% of patients, with potentially life-saving consequences in 2.0%.** ***(CHEST 2005; 128:698–703)***

Key Words: diagnosis; lung neoplasms; positron emission tomography

Abbreviations: LCEC = Lung Cancer Evaluation Center; NCN = noncalcified nodule; PET = positron emission tomography; PPV = positive predictive value; SUV = standardized uptake value

Positron emission tomography (PET) scanning has gained increasing application as a diagnostic and staging tool in the evaluation of lung cancer. Although PET scanning has been demonstrated to be a cost-effective adjunct to lung cancer diagnosis,[1] its global impact on clinical decision making has not

*From the Department of Medicine, Division of Pulmonary and Critical Care Medicine (Dr. Sachs), and the Department of Surgery, Division of Cardiothoracic Surgery (Dr. Bilfinger), Stony Brook University School of Medicine, Stony Brook, NY.
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Correspondence to: Sharona Sachs, MD, T17, 040, Health Sciences Center, Stony Brook University School of Medicine, Stony Brook, NY 11794-8172; e-mail: ssachs@mail.som.sunysb.edu

been assessed. As PET scanning becomes incorporated into the standard diagnostic algorithms for identifying potential or proven intrathoracic malignancies, its total "cost," both economic and human, must be assessed with regard to the frequency with which it triggers unnecessary diagnostic maneuvers. Its aggregate "benefit," in a similar fashion, must be viewed as the sum total of the number of tests spared, significant alterations in treatment generated, and significant new diagnoses established. We sought to evaluate the impact of the systematic use of PET scanning on clinical decision making in a university-based multidisciplinary lung cancer practice, and to define the likelihood of a definitive "diagnostically useful" PET scan result in this high-risk population.

Materials and Methods

Patient Selection

The Stony Brook University Hospital Lung Cancer Evaluation Center (LCEC) is a multidisciplinary specialty practice composed of a dedicated pulmonologist (S.S.), a thoracic surgeon (T.V.B.), a medical oncologist, and a radiation oncologist. The spectrum of diagnoses for which patients are referred is outlined in Table 1. There are established algorithms for diagnostic evaluation by category. At the LCEC, diagnostic PET scanning is indicated for the following: noncalcified nodules (NCNs) that are 7 to 9 mm in size if their size is > 8 mm (the minimum size resolution of the scanner) and significant suspicion exists; NCNs are ≥ 10 mm and ≤ 30 mm; lung masses (lesions > 30 mm); and mediastinal lymphadenopathy. PET scanning is not routinely performed for mediastinal masses, which are almost invariably referred for tissue diagnosis. Whole-body PET scanning is routinely performed for unstaged newly diagnosed lung cancer, for reassessment following neoadjuvant therapy, and for treatment follow-up if further therapeutic intervention is feasible. This study is a retrospective analysis of all patients seen at the LCEC from December 31, 2000, to December 31, 2002.

Table 1—*Spectrum of Diagnoses of Patients Seen in the LCEC During the Period Under Study*

Diagnoses	PET Scan Performed	PET Scan Not Performed
PET scan-eligible (n = 252)		
NCN 7–9 mm (n = 34)	16	18
NCN > 10 but < 30 mm (n = 120)	100	20
Lung mass (> 30 mm) (n = 43)	33	10
Mediastinal lymphadenopathy (n = 20)	12	8
Newly diagnosed lung cancer (n = 25)	22	3
Post-neoadjuvant therapy reevaluation (n = 5)	5	0
Posttherapy follow-up (n = 16)	10	6
PET scan-ineligible (n = 110)		
NCN < 6 mm (n = 73)		
Mediastinal mass (n = 8)		
Nonresolving infiltrate (n = 17)		
Pleural effusion (n = 3)		
Calcified nodule (n = 3)		
Palliative care (n = 6)		

PET Scanning

PET scans were performed (Exact 40; Siemens; Munich, Germany) using a dose of 10 to 15 mCi. The radioisotope was generated off-site (Eastern Isotopes; Sterling, VA) and was administered within 6 h of manufacture. The patient was asked to fast for 6 h prior to undergoing the procedure, with a 45-min uptake time resting in a quiet room following injection. Fasting blood glucose measures were obtained. Images were acquired in the two-dimensional mode from the neck to the femur, with an axial field of view of 15 cm. Emission scans were obtained with an acquisition time of 5 min per field of view. Transmission scans were acquired for 3 min with the patient in each bed position. The acquired data were reconstructed using an iterative technique. Axial images were reoriented into coronal and sagittal views, and were viewed on a rotating three-dimensional model. Standardized uptake values (SUVs) were calculated according to standard formulas. PET scans were interpreted by one of two dedicated nuclear radiologists who were blinded to the clinical data.

Assessment Criteria

PET scan findings were considered to be positive if the SUV was > 2.5, indeterminate if the SUV was > 0 and ≤ 2.5, and negative if the SUV was 0. The primary site was designated as the intrathoracic lesion seen on the CT scan that triggered the PET scan. The extraprimary site was either a noncontiguous intrathoracic site or an extrathoracic site. When false-positive results were being assessed, indeterminate and positive results (*ie*, any nonzero value) were grouped together and were considered to be positive to subject PET scan to the most rigorous standard of accuracy. A patient was considered to be upstaged if the PET scan altered the clinical stage assignment beyond that established on clinical and CT scan findings. The finding of more extensive intrastage disease than had been suspected was not considered to be relevant. A patient was evaluated as downstaged if the PET scan did not reveal hypermetabolic activity in anatomic sites that were considered to be highly suspicious on the CT scan. A change in the diagnostic evaluation was defined as procedure pursued or avoided solely on the basis of PET scan findings, and a change in therapy was documented if the treatment plan was altered because of PET scan findings. The number of additional diagnostic tests triggered by PET scan findings was tracked, as were significant new diagnoses established solely by PET scan findings. A diagnosis was considered to be significant if it (1) had the potential for causing significant morbidity and (2) warranted a specific non-lung cancer-related therapeutic intervention.

Results

Patient Selection

Patients were included for analysis if there was either biopsy confirmation of diagnosis or ≥ 3 months of radiographic follow-up. Of the 405 patients enrolled during the study period, 43 were unevaluable due to a lack of adequate follow-up data. Of the remaining 362 patients, 253 met the established criteria for PET scanning, and 198 underwent PET scanning for diagnosis (161 patients) or staging (37 patients) [Table 1]. The reasons for noncompliance with diagnostic protocols are outlined in Table 2. When PET scanning was deferred because of "no therapeutic implication," the patient was unequivocally staged on the basis of CT scan findings or was medically inoperable, so that treatment choices were constrained by cardiopulmonary reserve, rather than by intrathoracic stage. There were 101 men and 97 women, with a mean age of 62.4 ± 11.8 years.

Changes in Stage

The impact of PET scan findings on patient management is summarized in Figure 1. PET scan findings upstaged 32 of 198 patients (16.2%). Of the 26 patients with true-positive upstaging, 11 had unsuspected N2 disease, 2 had unsuspected N3 disease, and 13 had unsuspected extrathoracic metastases, primarily involving bone or extrathoracic nonscalene lymph nodes. The stage shift was false in 6 of 32 patients (18.8%), with additional confirmatory testing done in 3 patients (*ie*, mediastinoscopy for false-positive N3 nodes, MRI for false-positive thoracic spine uptake, and cervical node biopsy for false-positive N3 uptake), and findings were disproved at resection in 3 patients. No patient was denied potentially curative resection without tissue confirmation of the PET scan findings. PET scan findings downstaged 12 of 198 patients (6.1%), facilitating potentially curative resection in 4 patients. The downshift in stage was false in one patient (8.3%), resulting in an unnecessary thoracotomy. Overall, PET scan findings changed the stage in 44 of 198 patients (22.2%).

Changes in Management

PET scan findings changed diagnostic evaluation in 105 of 198 patients (53.0%). Biopsy was deferred in 65 patients (61.9%), and PET scan findings were instrumental in either triggering a biopsy or guiding selection of the biopsy site in 40 patients (38.1%). Treatment decisions were altered by PET scan findings in 38 of 198 patients (19.2%). PET scan findings led to neoadjuvant therapy in six patients (15.8%), facilitated resection in five patients (13.2%), forestalled noncurative thoracotomy in six patients (15.8%), and prompted or redirected chemotherapy and/or radiotherapy in the remainder of the patients. When diagnostic and therapeutic interventions are combined, PET scan findings changed management in 143 of 198 patients (72.2%).

Additional diagnostic testing was triggered by PET scan findings in 32 of 198 patients (16.2%). Tests consisted of MRI of the spine in four patients, bone scans in two patients, adrenal MRI in one patient, upper endoscopy in two patients, otolaryngology evaluation in four patients, CT scans of the abdomen and pelvis in two patients, mammography and/or breast ultrasound/MRI in four patients, head and neck imaging (CT scan or ultrasound) in five patients, axillary node dissection in one patient, MRI of the liver in one patient, CT scan and needle aspiration of the thigh in one patient, thyroid needle aspiration in two patients, biopsy of an additional extralobar site at thoracotomy in one patient, and additional x-rays in two patients. The net effect of this testing was no new diagnosis in 16 patients (50%), and a critical change in management in 7 patients (21.9%), in whom futile thoracotomy was avoided on the basis of previously unsuspected metastatic disease. PET scan findings were solely responsible for a new, non-lung cancer diagnosis in 8 of 198 patients (4%). These diagnoses are outlined in Table 3.

Operating Characteristics

Primary Site: The distribution of PET scan results by diagnostic category is outlined in Table 4. We analyzed the performance of PET scanning based on

Table 2—*Reasons PET Scanning Was Not Performed*

Diagnostic Category	Reasons PET Scanning Not Performed: Refused	Size < 8 mm	Stability on Prior Studies	No Therapeutic Implication
NCN 7–9 mm (n = 18)	1	13	4	0
NCN 10–30 mm (n = 20)	6	0	4	10
Lung mass (n = 10)	0	0	0	10
Mediastinal adenopathy (n = 8)	1	0	0	7
Staging				
New Dx Lung Ca (n = 3)	0	0	0	3
Post-Neoadjuvant F/U (n = 0)	0	0	0	0
Posttreatment F/U (n = 6)	0	0	0	6

Dx = diagnosis; F/U = follow-up; No Therapeutic Implication = patients for whom available clinical and imaging data provided sufficient staging information to define treatment plan (*ie*, patients who were stage IV by CT scan or were medically inoperable); Ca = cancer.

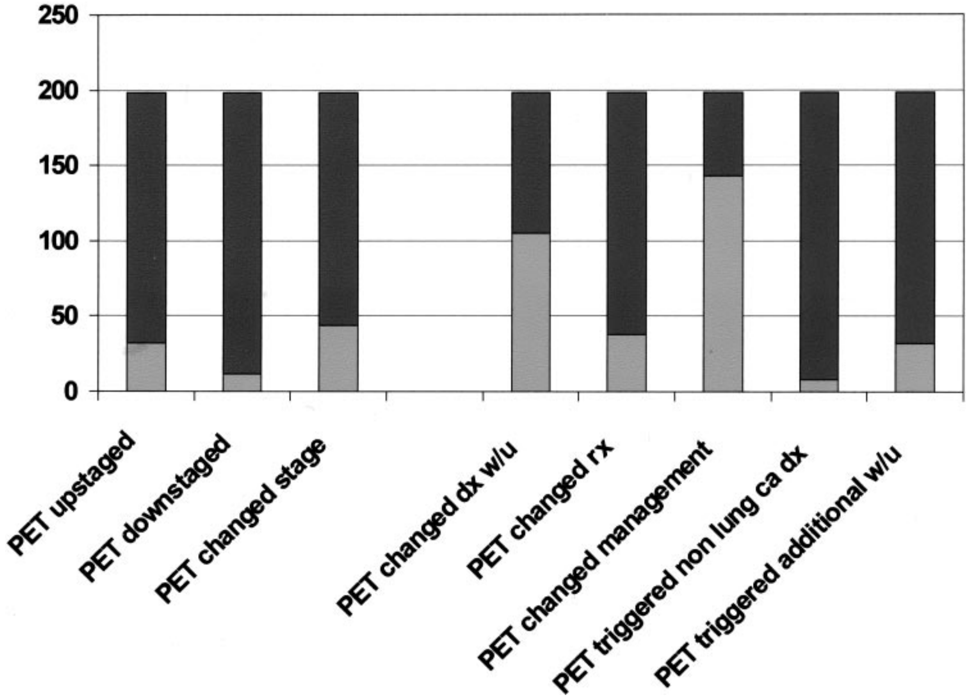

FIGURE 1. The relative frequencies with which PET scan findings changed the stage, changed the diagnostic evaluation, changed treatment, changed management (*ie*, summed the data on diagnostic and therapeutic manipulations), established a previously unsuspected significant diagnosis, and triggered additional testing in the 198 patients studied. dx = diagnosis; rx = treatment; w/u = work-up.

the function it was serving in the clinical evaluation. If PET scanning was used both to establish the presence of malignancy and to define the stage, the metabolic uptake in the primary lesion was evaluated. If the tissue diagnosis was already established and PET scanning was being used only to define the clinical stage, then PET scan staging accuracy was assessed. If only diagnostic PET scans (161 scans) are considered for the analysis of discriminative ability in the primary site, 79 of 161 scan results (49.1%) were positive. Fifty-two of 161 scan results (32.3%) were negative in the primary site, and 30 of 161 scan results (18.7%) were indeterminate. Positive PET scan findings prompted an invasive diagnostic evaluation in all patients who were medically amenable to undergo biopsy. Because some centers do not subscribe to SUV-based interpretation and base decisions on a visual analog "positive" or "negative" result, any nonzero SUV was considered when evaluating the false-positive rate, subjecting PET scan findings to the most rigorous possible standard. PET scans yielded false-positive results (defined as an SUV of > 0) in the primary site in 15 of 161 scans (9.3%). These false-positive results resulted in five unnecessary thoracotomies, two unnecessary mediastinoscopies, and one unnecessary median sternotomy.

Table 3—*PET Scan-Triggered Non-Lung Cancer Diagnoses*

Patient	Diagnosis	Treatment
1	*Helicobacter pylori* gastritis	Endoscopy/antibiotics
2	Stage II breast cancer	Surgery/radiotherapy, and adjuvant chemotherapy
3	Recurrent head and neck cancer	Resection
4	Stage II breast cancer	Resection/radiotherapy
5	Recurrent head and neck cancer	Palliative chemotherapy
6	Uterine leiomyoma	Arteriographic embolization
7	Thyroid cancer	Resection
8	Head and neck cancer	Resection

PET scanning yielded a false-negative result in the primary site in 7 of 161 scans (4.3%). In four of these patients, a neoplastic diagnosis would have been missed if PET scanning had guided therapy (metastatic colon cancer, one patient; metastatic renal cell carcinoma, one patient; early-stage primary adenocarcinoma with bronchoalveolar features, one patient; and carcinoid tumor, one patient). PET scanning is known to have a lesser diagnostic sensitivity in the setting of metastatic disease and slow-growing disease. All of these lesions were in a size range (*ie*, > 1 cm) in which spatial resolution should not have

Table 4—*Distribution of PET Results by Indication**

Indication	PET Scan Result: Positive	Indeterminate	Negative	Total
NCN 7–9 mm	0 (0)	1 (0.6)	15 (9.3)	16 (9.9)
NCN 10–30 mm	41 (25.5)	27 (16.8)	32 (19.9)	100 (62.1)
Lung mass	32 (19.9)	0 (0)	1 (0.6)	33 (20.5)
Mediastinal adenopathy	6 (3.7)	2 (1.2)	4 (2.5)	12 (7.5)
Total	79 (49.1)	30 (18.6)	52 (32.3)	161 (100)

*Values given as No. (%).

contributed to diagnostic error. In an additional three patients who underwent resection for primary non-small cell cancer, the extent of nodal disease (N2) was underestimated. PET scanning is also known to have lesser sensitivity and specificity in the mediastinum. Sixty-nine patients had biopsy-proven malignancies, so that the positive predictive value (PPV) of a PET scan in this population was 87.3%. An additional two patients who were not medically amenable to undergoing biopsy had compelling collateral evidence of malignancy, with both having interval tumor growth evident on serial CT scans. One of those patients had a history of non-small cell cancer and a highly characteristic lesion that was irradiated without biopsy on the basis of PET scan and clinical findings. If these additional patients are considered for analysis, the PPV becomes 89.9%.

Nonprimary Site: PET scan findings were positive in a nonprimary site in 52 of 161 patients (32.3%) and were indeterminate in 18 of 161 patients (11.2%). If these are considered together in an analysis of false-positive results, PET scan results proved to be false-positive in 21 of 161 patients, and triggered additional testing in 15 of 21 patients (71.4%). This additional testing was confined to either noninvasive radiologic investigation or consultation with additional specialists in seven patients; however, an invasive evaluation was triggered in 8 of 21 patients (38.1%). Patients who did not undergo confirmatory testing had a clear history of trauma or nonmalignant disease in the index area that clearly explained the findings (*eg*, mandibular uptake due to a dental abscess, chest wall uptake postthoracotomy, or multiple joint uptake due to a rheumatoid flare-up).

Discussion

Several studies have been published to date that outline the impact of PET scanning on individual aspects of lung cancer care. Over the past decade, the overall sensitivity, specificity, and accuracy of PET scanning for the evaluation of solitary pulmonary nodules have averaged 96%, 88%, and 94%, respectively.[2–5] For nodal staging, the sensitivity has ranged between 67% and 100%, the specificity has ranged between 76% and 100%, the PPV has ranged between 64% and 96%, and the negative predictive value has ranged between 81% and 100%.[6–17] Many authors have developed theoretical models using PET scanning as a standard adjunct to diagnosis and staging. These models have suggested that, as theoretically incorporated, PET scanning is a cost-effective measure, with most cost savings achieved through the prevention of unnecessary surgical procedures.[18,19] Kalff and colleagues[20] have reviewed the impact of PET scanning on the management of patients with proven lung cancer, demonstrating that PET scanning changed overall management in 70 of 105 patients. In their study, PET scanning upstaged 36% of patients (21 of 59 patients) undergoing initial staging, shifting care from curative to palliative, and downstaged 12% of patients. In patients whose disease was restaged by PET scanning after potentially curative treatment (n = 29), PET scanning altered the treatment intent or modality in 72%. In the small subgroup of patients undergoing PET scanning for the evaluation of suspected early-stage non-small cell lung cancer (n = 12), PET scanning rendered 3 of 12 cancers unresectable, and altered radiation delivery in 1 patient. Pieterman and colleagues[21] have reported the impact of PET on preoperative staging in 102 patients. They determined that PET scan findings altered staging compared with standard radiographic techniques in 62 of 102 patients, upstaging in 42 patients and downstaging in 20 patients.[21] In another study[22] of 50 patients with histologically proven non-small cell lung cancer who were being considered for resection, PET scan results changed management decisions in 24%, with curative-intent therapy delivered as a result of downstaging in 9 of 12 patients. Our study demonstrated similar results with regard to management decisions but incorporates the broader impact of PET scanning when it is used as a tool to guide decisions regarding biopsy in indeterminate nodules. Our results support those suggested by questionnaire-based studies[23] that PET scan findings alter decision making regarding both diagnostic and therapeutic interventions in a significant proportion of patients. Although many studies[1,18,19] have modeled PET scan-inclusive diagnostic plans in determining cost-effectiveness, this study addresses actual rather than theoretical global patient impact.

Conclusions

Overall, systematically applied PET scanning had a significant impact on patient management. In our population, the results of PET scanning altered the diagnostic or therapeutic intervention in 72.2% of patients, changed staging in 22.2% of patients, triggered additional diagnostic testing in 16.2% of patients, and identified serious unsuspected diagnoses in 4.0% patients, with potentially life-saving consequences in 2.0% of patients. A definitive result (*ie*, a positive or negative result) in the site prompting PET scanning was found in the majority of patients (81.4%). In the primary site, the PPV of PET scanning was at minimum 87.3%; however, our results indicated that unanticipated positive results in extraprimary sites merit careful individualized assessment. Even when diagnostic evaluation was undertaken selectively, unnecessary testing was prompted in 9.3%, with invasive testing in 5.0% of the population studied. The false-positive rate in extraprimary sites was 40% (21 of 52 patients). Both negative and indeterminate results in the primary site benefit from analysis in the context of clinical suspicion, since cancer was diagnosed in 6 of 52 patients with negative PET scan findings and in 5 of 30 patients with indeterminate PET scan findings.

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