The New Oncology: Cost-effectiveness and Matchless Impactof PET-CT in Cancer Management CME

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Release Date: November 16, 2005; Valid for credit through November 16, 2006

Target Audience

Radiologists, oncologists, and other select referring physicians such as internal medicine specialists with an interest in integrating cost-effective FDG-PET and PET-CT fusion techniques into their clinical armamentarium to refine the diagnosis, staging, and effective clinical management of lung cancer, rectal and colorectal cancers, lymphoma, ovarian cancers, and other malignancies.

Goal

The objective of this activity is to spotlight the clinical impact and cost-effectiveness of advanced imaging studies such as FDG-PET scanning and PET-CT fusion studies in the detection and management of cancer, define the peak clinical applications for the successful use of these technologies, and provide a venue for an expert to detail the benefit of these technologies for the radiology, oncology, internal medicine, and other relevant clinical audiences on Medscape.

Learning Objectives

Upon completion of this activity, participants will be able to:

1. Detail the impact of FDG-PET and PET-CT studies on the detection, staging, and clinical management of a host of cancers.
2. Describe instances in which FDG-PET scanning is cost-effective because the modality can stage disease with precision to determine the best therapies and avoid unnecessary treatments for cancers such as non-small-cell lung cancer and other malignancies.
3. Outline examples in which the use of FDG-PET scanning altered the initial course of clinical management for malignancies such as pancreatic cancer.

Credits Available

Physicians - up to 1.0 AMA PRA Category 1 continuing medical education credits for physicians

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This activity is supported by funding from WebMD.

Contents of This CME Activity

The New Oncology: Cost-effectiveness and Matchless Impact of PET-CT in Cancer Management

Introduction

Anatomic imaging modalities such as computed tomography (CT) and magnetic resonance imaging (MRI) have served radiology well. However, it has become clear that the morphologic diagnostic imaging information can be complemented significantly with the functional imaging information in a synergistic way, leading to increased diagnostic confidence. The impetus for this notion has been facilitated by the rapid emergence of positron emission tomography (PET) in the clinical arena. Supportive evidence now exists to show that hybrid imaging systems, such as PET-CT, are diagnostically more accurate than either system alone or when the corresponding images are viewed side by side. Moreover, PET-CT has an important impact on the clinical management of patients. Hybrid imaging systems have the ability to precisely localize metabolic abnormalities and conversely characterize the metabolic activity of normal and abnormal structures. Hybrid PET-CT imaging systems also allow attenuation correction, thereby facilitating quantitative imaging assessment.

As was stated by Michael E. Phelps, PhD, Norton Simon Professor and Chairman of the Department of Molecular and Medical Pharmacology at the UCLA School of Medicine, during his Eugene P. Pendergrass New Horizons Lecture at the Annual Meeting of the Radiological Society of North America in 2004, current evidence indicates that the commonly used PET radiotracer [F-18]fluorodeoxyglucose (FDG) is 9% to 43% more accurate than morphologic imaging for the diagnosis, staging, detection of recurrence, and evaluation of treatment response for 12 different cancers. PET also affects the clinical management in 15% to 50% of patients.[1] PET has also been found to be cost-effective in many clinical situations and under varying ranges of disease prevalence in different populations. In this clinical update, we highlight those studies that have investigated the cost-effectiveness and the diagnostic and therapeutic impact of FDG-PET in oncology. It must, however, be noted that despite the preponderant evidence for the significant impact of PET in clinical oncology, there remains a critical need for outcomes research on determining whether and to what extent this impact affects the individual patient's long-term outcome.

1. In your oncology practice, you refer patients for PET-CT fusion studies to assess the following types of cancers (check all that apply):

- Lung
- Colorectal
- Gastrointestinal
- Ovarian

- Lymphoma

Occult Malignancy

Rising serum tumor markers may be associated with negative routine imaging in patients with cancer. Israel and colleagues[2] evaluated the incremental role of FDG-PET-CT in 36 patients with cancer with elevated serum level of tumor marker as the sole indicator of potential recurrence. PET-CT was found to be the single imaging modality that directed further treatment planning in 33% of patients. PET-CT had a sensitivity of 100%, specificity of 89%, negative predictive value of 100%, and positive predictive value of 97% in detecting lesion sites in this group of patients.[2]

Brain Cancer

FDG-PET is currently used at many medical centers as the mainstay imaging modality for the management of primary brain tumors. A study from the Massachusetts General Hospital in Boston tabulated the referral indications for 75 patients with glioma.[3] The range of indications included pretherapeutic baseline studies for treatment monitoring (1%), mapping of hypermetabolic regions before surgery or biopsy (2%), mapping of hypermetabolic regions before radiotherapy (2%), postsurgical evaluation for residual tumor (2%), assessment of the malignancy of the mass as a substitute for biopsy (11%), and distinguishing between radiation necrosis and recurrent tumor (87%).

Head and Neck Tumors

Localization of hypermetabolic abnormalities in the head and neck can be challenging. A recent prospective FDG-PET-CT study of 24 patients with head and neck tumors showed that the PET-CT impacts the degree of confidence in anatomical localization of lesions by 51% and improves interobserver agreement.[4] Wong and colleagues[5] investigated the impact of FDG-PET in the management of occult primary head and neck tumors in 16 patients with cervical adenopathy. PET demonstrated sensitivity, specificity, and positive and negative predictive values of 62%, 66%, 62%, and 62%, respectively, in localizing the primary site. PET affected the treatment plans in 53% of patients.

In another study of 34 patients with squamous cell carcinoma of the oral cavity, PET findings led to a change of treatment in 15% of patients.[6] PET also detected a secondary cancer in 12% of these patients. In a similar study of 48 patients with advanced head and neck cancer, PET was able to assess lymph node involvement, distant metastases, and second primaries in a single imaging study and resulted in changes in clinical management in 8% of patients.[7] PET may then be of value and can be considered as the initial imaging evaluation in patients with head and neck cancer.[8] The cost-effectiveness of FDG-PET has also been investigated.[9] Hollenbeak and colleagues[10] determined whether the use of FDG-PET was cost-effective as part of a treatment strategy for classification of N0 head and neck squamous cell carcinoma. They reported an incremental cost-effectiveness ratio of US$8718 per year of life saved or US$2505 per quality-adjusted life year.

Thyroid Cancer

As Figure 1 illustrates, FDG-PET has been determined to be useful in detecting recurrent and metastatic disease in patients with thyroid cancer after thyroidectomy who present with rising serum thyroglobulin levels and negative radioiodine scans.[11,12] PET findings may impact the clinical management, which can include surgical resection and external radiation therapy.[13] Schluter and colleagues,[14] from Germany, evaluated the impact of FDG-PET on treatment of 64 patients with elevated serum thyroglobulin levels and negative I-131 scans. The positive and negative predictive values of PET were 83% and 25%, respectively. Treatment was changed in 19 of 34 patients with true-positive PET studies. Additionally, PET was true-positive in 11%, 50%, and 93% of patients with thyroglobulin levels of < 10, 10-20, and > 100 microg/L, respectively. PET was considered most promising in the subset of patients with thyroglobulin levels greater than 10 microg/L. Similar findings have been reported for patients with medullary thyroid cancer who present with elevated serum tumor markers.[15] In another investigation that included patients with thyroid carcinoma or biopsy-proven neuroendocrine and neural crest tumors, FDG-PET had an impact on the management of 22% of the patients by demonstrating extensive metastases and canceling therapy, and by detecting recurrence and guiding surgery or radiation therapy.[16]

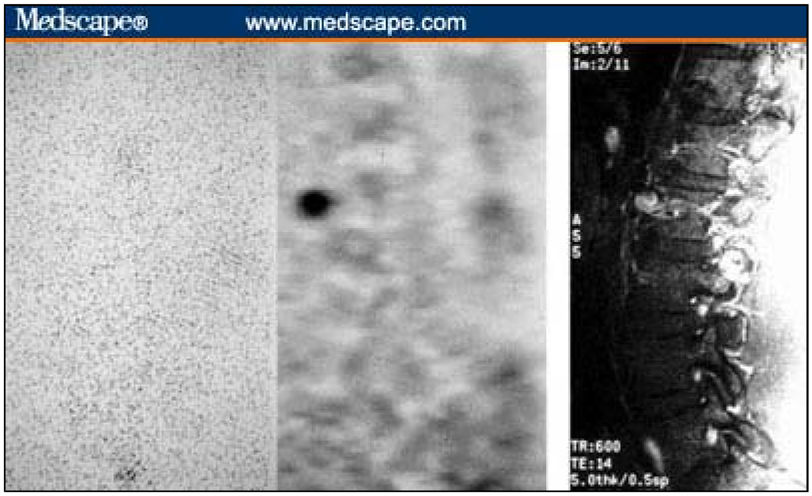

Figure 1. Radioiodine (left panel), FDG-PET (middle panel), and MRI (right panel) of a patient with history of thyroid cancer treated initially with total thyroidectomy followed by radioablation who presented with elevated serum thyroglobulin. Radioiodine scan is negative. PET impacted the management by demonstrating a focal hypermetabolic lesion that was localized on MRI and was then surgically resected. Surgical pathology revealed metastatic papillary thyroid cancer.

Lung Cancer

There is a relatively rich literature on the diagnostic utility of FDG-PET in the imaging evaluation of patients with lung cancer. PET-CT has recently been shown to add incremental diagnostic information by providing precise localization of hypermetabolic lesions that may lead to changes in clinical management. These changes may include eliminating previously planned diagnostic procedures by initiating a previously unplanned treatment option and by inducing a change in the intended therapeutic approach.[17-19] In a prospective study of 142 patients with potentially resectable non-small-cell lung cancer, PET revealed unsuspected distant metastases in 17% of patients, correctly differentiated respectable stages IA through IIIA (N1) from stages IIIA (N2) through IV in 89% of cases, and refined patient selection for curative resection.[20] In a similar study from Australia, FDG-PET changed or influenced management decisions in 67% of patients with non-small-cell lung cancer, frequently avoided unnecessary treatments, and facilitated more appropriate therapies.[21]

Seltzer and colleagues[22] determined the referring physician's perspective on the impact of FDG-PET on staging and management of lung cancer. There was a 37% return rate on the questionnaires. The primary reasons for PET referral were staging in 61%, diagnosis in 20%, and monitoring of therapy response in 6% of patients. Physicians reported that PET altered their decisions on clinical stage in 44% (upstaged in 29%, downstaged in 15%), and caused 39% intermodality change (change from a scheduled therapeutic modality to a different modality) and 15% intramodality change in management.

In a similar study from France that, in addition to patients with lung cancer, also included patients with colorectal cancer, lymphoma, and head and neck cancer, an intermodality management change was noted in 37% and an intramodality change in 9% of patients.[23,24] The prognostic advantage of PET over conventional imaging has also been demonstrated in a study of 63 patients with suspected relapse > 6 months after definitive treatment for non-small-cell lung cancer.[25,26] Using a Cox proportional hazards regression model and a median follow-up of 19 months, it was shown that both presence and extent of relapse on PET are highly significant prognostic factors. The pre-PET stage was significantly associated with survival while the post-PET stage provided strong prognostic stratification and remained significant after adjustment for treatment delivered, which was the case for 63% of the patients.

A recent Canadian study has noted that FDG-PET in combination with CT is cost-saving for the staging of non-small-cell lung cancer when compared to a CT-alone strategy.[27] A Japanese study corroborated this same conclusion in the assessment of the cost-effectiveness of FDG-PET in the work-up of solitary pulmonary nodules.[28] A decision-tree analysis model was used to compare 4 strategies for the diagnosis and management of solitary pulmonary nodules: CT alone, CT plus PET, CT plus PET plus CT-guided needle biopsy, and CT plus CT-guided needle biopsy. The authors concluded that CT-guided needle biopsy and PET were potentially cost-effective strategies in the assessment of solitary pulmonary nodules. The French investigators explored this issue further by performing a decision-tree sensitivity analysis and found that CT plus PET is cost-effective in detecting a malignant solitary pulmonary nodule in patients with a risk of malignancy of at least 5.7% by avoiding inappropriate resections of benign nodules.[29,30] Another related investigation, from Stanford University in California, found that FDG-PET should be used selectively in the evaluation of solitary pulmonary nodules when pretest probability and CT findings are discordant or in patients with intermediate pretest probability who are at high risk for surgical complications.[31]

Separate reports from Japan on the cost-effectiveness of FDG-PET in the management of patients with non-small-cell lung cancer found that the expected cost saving for each patient was US$833 to US$2010 at cancer prevalences ranging from 10% to 90%.[32-35] The UCLA group also reported similar findings with regard to the combined PET and CT strategy - they found it to be the most cost-effective strategy for a wide range of pretest risks for malignancy, with potential cost savings of $91 to $2000 per patient, which translated to a yearly national savings of approximately $62.7 million.[36,37]

A study from Germany employed decision-tree analysis to establish the most cost-effective strategy for management of solitary pulmonary nodules and for potentially operable non-small-cell lung cancer.[38,39] PET demonstrated sensitivity and specificity of 74% and 96%, respectively, for detecting metastasis in normal-sized mediastinal lymph nodes, and 95% and 76%, respectively, for detecting metastasis in enlarged lymph nodes. The study concluded that use of whole-body PET in preoperative staging of patients with non-small-cell lung cancer and normal-sized mediastinal lymph nodes is cost-effective for each life-year saved.

A similar finding has been reported with regard to a strategy employing PET after a negative CT; it was shown to be a cost-effective alternative to a CT-only strategy ($25,286 per life-year saved).[40] FDG-PET may then be cost-effective for preoperative staging of non-small-cell lung cancer when compared to CT alone due to the greater staging accuracy of PET, which often prevents futile surgeries.[41-44]

In patients with small-cell carcinoma, FDG-PET changes the stage of disease (upstage or downstage) in comparison to CT, which then can lead to significant changes in the treatment protocol.[45,46] Kamel and colleagues[47] evaluated the impact of whole-body FDG-PET on staging and managing 42 patients with small-cell lung cancer. PET changed the clinical management in 29% of the patients, including changes in radiation therapy planning and in decision making for surgery and for chemotherapy.

Breast Cancer

FDG-PET contributes significantly to the clinical management of women with breast cancer. Eubank and colleagues [48] retrospectively reviewed the treatment decisions for 125 women with recurrent and metastatic breast cancer who were referred for imaging evaluation with FDG PET. Compared with conventional imaging, FDG-PET changed the extent of disease in 67% of patients and altered the therapeutic plan in 32% of patients. In another study, the investigators sent questionnaires to the referring physicians to evaluate the impact of FDG-PET on management. Overall, the rate of change in management was 44%, with intermodality changes more frequent than intramodality changes.[49] A similar survey from the UCLA group demonstrated a change in clinical stage in 36% (28% upstaged, 8% downstaged), intermodality management change in 28%, and intramodality change in 30% of patients with breast cancer.[50] In another report, the clinical impact of FDG-PET was retrospectively evaluated in 30 patients with suspected recurrent breast cancer based on asymptomatic elevated serum tumor marker levels.[51] PET demonstrated a sensitivity of 96% and a specificity of 90% in this group of patients, representing a significant impact on their clinical management.

Esophageal Cancer

In a retrospective study by the Danish group of investigators, it was determined that FDG-PET was the only imaging modality that predicted unnecessary surgery in patients with esophageal cancer, primarily due to its ability to detect otherwise unknown distant metastases.[52] Figure 2 delineates the use of PET in this regard. In another similar study of 84 patients with esophageal cancer, PET upstaged 17% of patients to M1 disease, which avoided previously planned surgery with curative intent.[53]

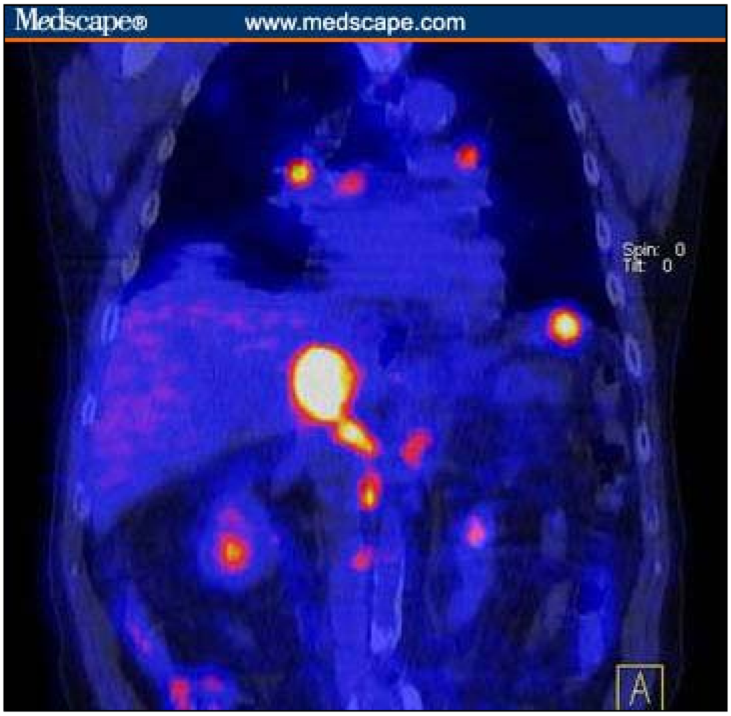

Figure 2. A patient with metastatic esophageal carcinoma involving the caudate lobe of the liver as well as hilar, subcarinal, left subdiaphragmatic, and retroperitoneal nodal basins. PET impacted the management (initiation of chemotherapy) by demonstrating extensive metastatic disease, which was underestimated by CT scanning alone.

Pancreatic Cancer

In a recent prospective study from Switzerland involving 59 patients with presumed resectable pancreatic cancer after routine staging, PET-CT findings changed the management in 16% of patients. PET-CT was considered cost-effective by avoiding unnecessary surgeries.[54]

Colorectal Cancer

There is now abundant evidence that FDG-PET has a significant effect on the clinical management of patients with colorectal cancer.[55-57] A group of Czech investigators performed prospective preoperative staging with FDG-PET in 38 patients with colonoscopy-guided histologically proven colorectal carcinoma.[58] The sensitivity and specificity of PET were 29% and 88%, respectively, for detection of lymph node metastases, and 78% and 96%, respectively, for detection of liver metastases. PET changed the method of treatment for 16% of patients.

Simo and colleagues[59] assessed the influence of FDG-PET on the management of 120 patients with suspected recurrent colorectal cancer, of which 58 patients were referred because of elevated serum carcinoembryonic antigen (CEA) levels. The authors tabulated management changes as major (medical treatment to surgery or vice versa), minor (intramodality changes), or as a change to no treatment. PET resulted in major management changes in 48%, minor changes in 3%, and no change in 45% of patients. FDG-PET also frequently resulted in surgical intervention with curative intent.

In a similar survey study of referring oncologists, PET altered management in 59% of patients primarily by avoiding unnecessary local therapies upon PET documentation of widespread disease.[60] Meta and colleagues[61] surveyed the referring physicians to determine the impact of PET on the management of patients with colorectal cancer. The referring physicians indicated that PET changed the clinical stage in 42% of patients (upstaging in 80% and downstaging in 20%). PET also resulted in intermodality (eg, medical to surgical, surgical to radiation, medical to no treatment) management change in 37% of patients. There was also intramodality (eg, altered medical, surgical, or radiotherapy approach) in 18% of patients. A combination of management changes occurred in 7% of patients. PET avoided major surgery in 41% of patients for whom surgery was the intended treatment.

FDG-PET has also been shown to be cost-effective in the management of patients with recurrent colorectal cancer. Park and colleagues[62] employed a decision-tree analysis to assess the cost-effectiveness of a combined PET and CT strategy in comparison to a CT-alone strategy. The combined PET and CT strategy was found to be cost-effective for managing patients with elevated CEA levels who were candidates for hepatic resection. Although the PET and CT strategy was higher in mean cost by $429 per patient, this strategy also resulted in an increase in the mean life expectancy of 9.5 days per patient.

Ovarian Cancer

A Spanish study of 43 women with suspected recurrent ovarian cancer found that FDG-PET impacted the clinical management in some manner in 90.7% of patients, with an intermodality management change rate of 63% and intramodality change rate of 7%.[63,64]

Testicular Cancer

A prospective multicenter trial from an Austrian investigation of the predictive impact of FDG-PET in 33 patients with residual post chemotherapy masses ≥ 1 cm demonstrated a sensitivity of 89%, specificity of 100%, positive predictive value of 100%, and negative predictive value of 97% for detecting viable tumor.[65]

Lymphoma

Many studies have demonstrated the crucial role of FDG-PET in the management of patients with lymphoma. FDG-PET has high diagnostic accuracy for restaging lymphoma after initial treatment, in the early prediction of response to chemotherapy, and in the evaluation of residual masses after chemotherapy or radiation therapy.[66-68] In a prospective investigation of 88 patients with Hodgkin's lymphoma, PET suggested a change to a different clinical stage in 20% of patients and a change in management in 18% of patients.[69] Similar results have been reported for patients with non-Hodgkin's lymphoma. Blum and colleagues,[70] from Australia, evaluated the diagnostic utility of FDG-PET in 47 patients with indolent non-Hodgkin's lymphoma. PET downstaged the disease in 30% and upstaged the disease in 16% of patients in comparison to CT. Clinical management was changed in 34% of patients as a result of PET findings.

In a similar Japanese study of 46 patients with lymphoma, PET changed the clinical management in 17% of patients.[71] Schoder and colleagues[72] performed a survey-based study of referring physicians and found that PET changed the clinical stage in 44% (21% upstaged, 23% downstaged), the intermodality management in 42%, and the intramodality management in 10% of patients. PET has also been determined to be cost-effective in managing patients with lymphoma with great potential for cost savings primarily due to more accurate staging of disease with PET in comparison to conventional imaging.[73]

Melanoma

Malignant melanoma can metastasize to almost any site. Imaging evaluation for metastatic disease is therefore valuable before contemplating surgery with curative intent.[74,75] Harris and colleagues,[76] from Australia, investigated retrospectively the effect of FDG-PET on the clinical management of 92 patients with advanced melanoma (stage III or IV) over a 6-year period. PET correctly affected the clinical decision-making process in 32% of patients, particularly in the selection of patients for surgery.

In another study of 49 patients with known or suspected metastatic melanoma, FDG-PET led treatment changes in 24 (49%) patients; planned surgery was canceled in 12 cases, an additional previously unplanned surgery was performed in 6 cases, and in the remaining 6 cases, chemoradiation therapy or immunotherapy was employed.[77]

The referring physician's perspective was assessed in a study performed by the UCLA investigators.[78] A questionnaire was sent to the referring physicians to investigate whether and how PET altered clinical decision in treatment planning. The response rate for the questionnaires was 35%. The referring physicians indicated that whole FDG-PET changed the clinical stage in 29% of patients (20% upstaged, 9% downstaged), affected an intermodality change in 29%, and brought about an intramodality change in 18%. Overall, PET had a major impact on the management of 53% of patients with melanoma (Figure 3).

Figure 3. A patient with history of melanoma of the upper back presented with palpable left supraclavicular nodal mass that was initially planned for surgical excision. PET-CT finding of widespread metastatic disease impacted the management by avoiding futile surgery.

2. Approximately how many patients per month do you refer for radiation therapy as part of your treatment protocol?:

- 5
- 10
- 20
- 40
- > 40

Radiation Therapy Planning

PET and PET-CT have important impact on tumor staging, treatment strategy, and treatment planning for radiotherapy.[79-83] PET may lead to cancellation of previously planned radiotherapy to specific sites, administration of treatment to new sites, change in intention for treatment (curative vs palliative), change in radiation dose, and change in radiation volume.[84]

Gabriele and coworkers,[85] from Italy, analyzed the contribution of PET to patient selection and radiation therapy planning in 87 patients with a variety of cancers. In 26 patients with lung cancer, PET modified the tumor stage in 39%, the clinical management in 50%, and the radiotherapy planning in 23% of patients. In 24 patients with hematologic malignancy, the stage was changed in 33%, the treatment strategy was impacted in 38%, and radiotherapy planning was affected in 13% of patients. These same parameters for the 15 patients with gastrointestinal tumors were 13%, 27%, and 53%, respectively. The authors concluded that overall PET changes the tumor stage in 30%, the treatment strategy in 43%, and the radiation treatment planning in 30% of patients with cancer.

Another similar study, from Germany, investigated the diagnostic and therapeutic impact of FDG-PET in a total of 176 patients (222 scans) with a variety of tumors (37 lung, 15 gastrointestinal, 38 head and neck, 30 lymphoma, 37 breast, 19 sarcoma, and 16 other) at the time of initial staging (148 patients) and restaging (74 patients).[86] FDG-PET yielded additional important diagnostic information in 47% of the scans, which directly induced modifications of the radiotherapeutic treatment plan (target volume) in 26% of these scans. The Queen's Medical Center in Honolulu, Hawaii, has also reported comparable results after determining the impact of PET from polling 463 referring physicians who had referred patients with a variety of tumors for imaging evaluation with PET.[87] PET changed the management in 45% of all patients, which included addition of chemotherapy or radiation therapy in 17%, elimination of chemotherapy or radiotherapy in 8%, and surgical intervention in 58% of these patients.

Bradley and colleagues,[88] from Washington University in St. Louis, investigated the impact of FDG-PET on the radiation therapy volume in non-small-cell lung cancer. PET resulted in alterations in radiation targeting in over 50% of patients in comparison with CT. In another similar study utilizing FDG-PET coregistered with CT, management strategy was changed from radical to palliative in 23% of cases. PET reduced the geographical misses of CT-alone information, leading to a reduction in planning target volume in 24%-70% of cases and an increase in 30%-76% of cases.[89] The alteration may include both increases and decreases in the target volume. The more accurate tumor volume targeting allows delivery of the radiation dose to the relevant tissue while reducing the dose to the normal tissue and decreasing the risk for the development of toxicity.[90,91]

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Disclosure: Robert Chevrier has disclosed no relevant financial relationships.

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