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Does Early Post-Treatment Surveillance Imaging Affect Subsequent Management Following Stereotactic Body Radiotherapy for Early Stage Non -Small Cell Lung Cancer?

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Abstract

Purpose/Objectives—Uncertainty exists regarding the optimal surveillance imaging strategy following stereotactic body radiotherapy (SBRT) for early stage non-small cell lung cancer (NSCLC), particularly with respect to timing. We sought to determine how routine use of early (<6 months) post-treatment imaging affects subsequent management.

Methods and Materials—The records of all patients treated with SBRT between January 2007 and January 2013 for early stage NSCLC were reviewed. Eligible patients underwent ≥1 early (defined as within 6 months following SBRT) surveillance imaging study. Radiographic findings and subsequent diagnostic or therapeutic interventions were identified. Proportions and exact 95% confidence intervals (CI) with early post-treatment surveillance findings and altered treatment were calculated, and cases were examined descriptively.

Results—Sixty-two patients with 67 lung tumors underwent 92 early surveillance imaging studies (86 CT and 6 PET/CT) at a median of 2.1 months (range: 0.1–5.9 months). New lung nodules were identified in 8 patients (13%), leading to a diagnosis of metastatic disease treated with systemic therapy in 2 patients and biopsy proven solitary lung recurrence in 2 patients, both treated successfully with local therapy. Tumor growth meeting RECIST criteria was identified in 1 patient, who was followed with subsequent radiographic regression. In aggregate, the treatment of 4 patients (6.5%, 95% CI 1.7% – 15.2%) was altered by early imaging, two (3.2%, 95% CI 0.4% – 10.8%) with a potentially curative intervention. No predictors for utility of early surveillance were identified.

Conclusions—Imaging within 6 months following SBRT for early stage NSCLC resulted in a definitive intervention in approximately 3% of patients. In the era of cost-effective healthcare, a first scan at 6 months post-treatment may be adequate for most patients. Larger-scale prospective studies are needed to address the optimal surveillance regimen following SBRT and identify patients who may benefit from more aggressive surveillance regimens.

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Keywords

Lung Cancer; Stereotactic Body Radiotherapy; Surveillance Imaging

Introduction

Stereotactic body radiotherapy (SBRT) has emerged as standard treatment for early-stage, medically inoperable non-small cell lung cancer (NSCLC). Multiple prospective trials have demonstrated rates of local control exceeding 90% at 3 years [1–3], particularly when a biologic equivalent dose exceeding 100 Gy_{10} is delivered to the tumor periphery [4]. Despite outstanding local control, the rates of regional and distant relapse remain significant, ranging from <5%–11.3% and 11.1%–29.2%, respectively. The majority of recurrences in published prospective trials have occurred beyond 6 months following treatment, although treatment failures within the first six months have been reported. [1, 2, 4]. However, the optimal post-SBRT surveillance strategy to detect local, regional, and/or distant failure remains poorly defined both with regards to timing and modality. A recent patterns of care survey demonstrated considerable variability in surveillance strategies among practicing physicians, with respondents obtaining first post-SBRT imaging anywhere from <4 weeks to >25 weeks post-SBRT, with nearly one-third obtaining a scan within the first 6 weeks following treatment [5]. Moreover, contemporary cooperative group trials evaluating thoracic SBRT mandate a first surveillance computed tomography (CT) scan at a range of time points, generally between 3–6 months post-treatment [1, 2, 6, 7]. While several recent studies have attempted to assess the added utility of positron emission tomography (PET)/CT to CT alone [8, 9], none has yet specifically evaluated the optimal interval to initiate post-SBRT imaging. The difficulties of interpreting evolving post-SBRT CT changes in the lungs have been well-documented [10]. However, the false-positive rate for such scans is poorly defined in the literature, as is the rate of subsequent diagnostic workup and complications from such workup. Several recent studies suggest that incorporation of PET/CT, particularly beyond 6 months post-treatment, may best distinguish consolidation and recurrent tumor [11]. However, use of PET/CT within the first 6 months remains less established given the propensity for false positive results secondary to post-treatment inflammatory changes [11], and the optimal integration of PET/CT into surveillance algorithms remains poorly defined. The aim of the present study is to assess the impact of early (defined as within 6 months of SBRT) surveillance CT on subsequent management in a cohort of patients treated with SBRT for early-stage NSCLC.

Materials and Methods

Patients

The records of patients treated with SBRT at XX between January 2007 and January 2013 for early stage NSCLC were reviewed following Institutional Review Board approval. A total of 73 consecutive patients were identified, 11 of whom did not have an available surveillance scan performed within the first 6 months following treatment, leaving 62 evaluable patients treated to 67 primary lung tumors. Patients were included in the present study if they underwent at least one post-treatment CT or PET/CT scan of the chest within 6

months of completing SBRT. Patients underwent comprehensive staging prior to treatment including PET/CT, CT of the chest with contrast (unless medically contraindicated), and physical examination. Pathological mediastinal staging via endobronchial ultrasound (EBUS) or mediastinoscopy was performed only for cases of radiographically suspicious (>1 cm) mediastinal nodes. The median age was 76.3 years (range: 48.9–90.5 years). Forty-eight patients (77%) were medically inoperable as determined by a board certified thoracic surgeon, while the remaining 14 (23%) declined operative intervention. Patients were staged according to the American Joint Committee on Cancer 7th Edition. The median tumor diameter was 15 mm (range: 5–61 mm). Two patients underwent 2 sequential courses of SBRT 37 and 69 months and apart, respectively, for separate primary tumors, and 2 patients underwent SBRT targeting 2 and 3 synchronous primary tumors, respectively. Patient and disease characteristics are outlined in Table 1.

Radiotherapy

Treatment planning was performed with CT simulation with patients immobilized in the supine position with a stereotactic body frame or a long vacuum cushion with an abdominal compression plate or belt to limit diaphragmatic respiratory motion. Fluoroscopy was used to ensure diaphragmatic excursion of ≤1 cm. Four-dimensional (4D) CT simulation was performed for 36 tumors (58%). In the absence of 4D planning, 10 mm craniocaudal and 5 mm radial planning margins were used, and with 4D CT planning a circumferential 5 mm planning margin was added to the internal target volume as identified by the maximum intensity projection of the 4D CT dataset. A dose of 48–60 Gy was prescribed in 3–8 fractions. Most plans were generated using 9–15 static non-coplanar beams normalized to the 60–90% IDL, while 5 tumors with challenging adjacent anatomy were targeted with intensity modulated radiotherapy (IMRT) plans.

Surveillance Imaging

Our current institutional approach is to obtain a first surveillance CT scan with intravenous contrast (unless medically contraindicated) and 1–1.5 mm slice thickness at 3 months post-SBRT with PET/CT reserved for further evaluation of worrisome CT findings; however, at physician discretion 6 patients underwent PET/CT as their initial surveillance imaging and were included in the current analysis. Our surveillance strategy has evolved over the past 5 years, and accordingly patients underwent first surveillance scans at 4 weeks to 6 months post-treatment, based on physician preference at the time of treatment. Radiographic findings and subsequent diagnostic or therapeutic interventions were identified for patients with one or more surveillance studies performed within 6 months following SBRT. Local, regional, and distant failures identified by early surveillance imaging were identified. The interval from completion of SBRT to each imaging study was calculated. Tumor response was assessed by the Response Evaluation Criteria in Solid Tumors (RECIST) and was classified as complete response (CR), partial response (PR), stable disease (SD), or progressive disease (PD). However, ultimate interpretation of disease status and management decisions for cases meeting RECIST criteria for PD rested upon consensus opinion and were influenced not only by radiographic findings and interpretation, but also by expected patient tolerance to further invasive workup and treatment. Subsequent patient

outcomes following suspicious radiographic findings were determined from patient medical records.

Statistical Methods

The crude proportions of patients with recurrence detected by early surveillance and patients with potentially curable recurrences were calculated, and exact confidence intervals were calculated for each proportion on a per patient treatment course basis. Factors potentially predicting benefit from early post-treatment surveillance were explored descriptively, but formal statistical predictive modeling was not attempted due to the low total event numbers.

Results

Sixty-seven treated lung tumors were evaluated with a total of 92 imaging studies within 6 months following completion of SBRT, at a median of 2.1 months post-treatment (range: 0.1–5.9 months), including 86 (93%) CT and 6 (8%) PET/CT. Thirty-six treatment courses (56%) were followed by a single surveillance scan within 6 months of treatment, and 28 (44%) by two sequentially performed scans within the first 6 months following SBRT.

By RECIST criteria, tumor response was classified as follows: 2 CR (3%), 20 PR (32%), 26 SD (42%), and 10 initially concerning for PD (19%). Among scans concerning for PD, indeterminate new lung nodules were identified in 7 patients (11%), enlargement of the primary >20% for 1 patient (1.6%), nodal enlargement was noted in 1 patient (1.6%) and overt metastatic disease in 1 patient (1.6%). No findings suggestive of progressive disease were identified in the 6 patients evaluated with up-front PET/CT.

The finding of indeterminate new lung nodules led to additional workup with PET/CT for 3 patients, identifying obvious disseminated metastatic disease for one patient. Another patient underwent immediate biopsy of a new lung lesion, with confirmation of a solitary NSCLC. He was managed with subsequent thermal ablation, and is now without evidence of disease at 36 months post-SBRT. An additional patient with a suspicious new lung lesion at 1.4 months underwent serial thoracic CT surveillance demonstrating slow growth of a solitary lung nodule, with biopsy at 7 months confirming NSCLC and subsequent SBRT to the new lesion and is currently without evidence of disease. The other 5 patients with non-specific new lung nodules have been followed with ongoing surveillance CT and none has progressed radiographically or clinically. The patient with significant enlargement of the treated primary tumor was followed by serial CT demonstrating subsequent tumor regression suggestive of treatment effect. The patient with suspicious hilar nodal enlargement was also evaluated by PET/CT, which did not suggest recurrent disease. However, this patient died from interstitial pneumonitis (idiopathic versus treatment-related) shortly thereafter; thus, long-term follow up to assess disease status was not available. Both patients developing early metastatic disease proceeded to systemic therapy and ultimately died at 10.2 and 17.2 months post-SBRT, respectively. Subsequent interventions and outcomes for patients with concerning findings on early scans are outlined in Table 2.

In aggregate, the treatment course of 4 patients (6.5%, exact 95% CI 1.7% – 15.2%) was altered by early post-treatment imaging, two (3.2%, exact 95% CI 0.4% – 10.8%) with a

potentially curative intervention. Descriptive analysis of variables potentially predictive of utility of early surveillance imaging suggested that neither T- stage nor histology predicted for detection of early treatment failure. The cross-section of the lesions was similar for the 4 patients to those who had no early treatment failure. The small number of events precluded formal multivariate statistical assessment of potential predictive factors for early failure. The median interval from staging PET/CT to initiation of treatment was 3.3 months (range: 0.1–11.7 months) for the entire patient cohort, and 2.1 months among the 4 patients with failures detected by early surveillance, suggesting no relationship between timeliness of pre-treatment staging and early-post-treatment failure.

Discussion

Post-SBRT surveillance imaging guidelines remain poorly defined. In a recent patterns-of-care survey, 32% of surveyed radiation oncologists reported obtaining a first surveillance scan within 6 weeks following SBRT, and 96% reported imaging their patients within 16 weeks of treatment. By contrast, only 2% reported obtaining a first post-treatment scan at >25 weeks [5]. To further illustrate the lack of consensus, cooperative group trials have recommended first imaging at a variety of time points after completion of SBRT. For instance, Radiation Therapy Oncology Group (RTOG) 0236 and 0915 mandated a first screening CT at 12 weeks [1, 7]. However, the currently accruing RTOG 0813, evaluating SBRT for centrally located NSCLC in medically inoperable patients, mandates a first CT scan at 6 months [6]. Despite the increasing popularity of SBRT for early-stage NSCLC, evidence based and/or consensus guidelines outlining detailed guidelines for post-SBRT surveillance are noticeably lacking. Several recent studies have specifically evaluated the impact of the integration of PET/CT on detection of post-SBRT failure [9, 12] but none have focused on optimal timing of the initiation of surveillance imaging. Post-treatment imaging guidelines after surgical management of early stage non-small cell lung cancer are better defined by consensus panels, although prospectively studies are still lacking. Consensus guidelines from the European Society for Medical Oncology (ESMO), the National Comprehensive Cancer Network (NCCN), the American Society for Clinical Oncology (ASCO), and the American College of Chest Physicians (ACCP) recommend post-treatment CT at 6–12 month intervals, with most acknowledging lower-level evidence in support of these guidelines [13–16].

Post-SBRT imaging for early-stage NSCLC poses particular challenges. The frequency of progressive scarring and mass-like consolidation on CT at the treated site has been well-documented in this setting [10], making assessment of in-field response and recurrence particularly difficult. The challenges of interpreting PET images in the early post-treatment setting are also well-established; however, recent data suggests residual FDG avidity at ≥6 months strongly correlates with local recurrence [11]. The utility of enhanced CT imaging metrics for detecting local recurrence, such as perfusion imaging and textural analysis, are active areas of investigation in lung cancer but are not yet a part of standard clinical practice [17, 18]. Furthermore, as SBRT is primarily used for medically inoperable patients, salvage treatment options are often limited. Isolated local failure is a rare occurrence, reported in 3–5% of patients treated with SBRT. In the medically inoperable population, re-irradiation or other ablative approaches such as radiofrequency or microwave ablation provide the only

potentially curative salvage options, with only scant retrospective data to support these approaches in the setting of post-SBRT recurrence [19]. Failure patterns following SBRT are predominantly distant [1, 4], and particularly in the frail population typically undergoing SBRT further systemic treatment options for disseminated disease may be limited. As the majority of the included patients were medically inoperable, these results cannot be extrapolated to the medically operable population, who may have more robust salvage treatment options.

A recent publication by Ebright and colleagues suggested surprisingly high rates of regional nodal failure detected by PET/CT at a median of only 4.5 months [12], in contrast to other studies suggesting modest regional failure rates and relatively few failures within 6 months of treatment [1, 2, 6]. The authors acknowledge that, in part, their results may stem from inadequate pre-treatment staging, but are nonetheless provocative and suggest a possible role for early PET/CT surveillance in detecting isolated regional failures.

In the present study, only two patients underwent subsequent definitive treatment for disease identified on surveillance imaging within 6 months of SBRT. One developed a highly suspicious new lung nodule noted on the first post-treatment scan at 1.2 months, underwent biopsy confirming NSCLC, and was subsequently treated with local microwave ablation with definitive intent. This patient is now without evidence of disease at more than 3 years following SBRT, suggesting this represented a new primary malignancy rather than a metastasis. A second patient similarly developed a new lung nodule at 1.4 months, and was followed with serial imaging that showed gradual progression without development of other sites of disease. Biopsy at 7 months confirmed NSCLC. She underwent a second course of SBRT and is currently without disease recurrence at 3 months post-salvage SBRT. Other patients with non-specific nodules have been followed with subsequent stabilization or resolution, suggesting false-positive findings. Two additional patients developed widely metastatic disease identified on early surveillance imaging (at 2.6 and 4.3 months, respectively). Both proceeded to systemic therapy but ultimately succumbed to metastatic lung cancer at 10.2 and 17.2 months, respectively.

The early development of parenchymal, out-of-field lesions (whether metastatic or de novo primary tumors) suggests a need for improved detection of regional and distant disease at the time of staging. In the present study, all but one patient underwent staging PET/CT as part of the initial workup; however, the median interval from PET/CT to SBRT was 3.3 months (range: 0.1–11.7 months), as patients were often referred from outside facilities and repeat PET/CT was often limited by insurance coverage difficulties. Ebright and colleagues describe similarly varied timing of pre-treatment staging in their analysis of PET/CT surveillance following SBRT [12], and suggest timeliness of pre-treatment staging may have contributed to their unexpectedly high rate of early distant failure. However, in the present analysis, the 4 patients with early failures underwent staging PET/CT at a median of 2.1 months, compared to a median PET-to-start interval of 3.3 months among the entire patient cohort. Nonetheless, the long median interval from staging to treatment may have contributed to the noted early failures, and in light of these findings we now attempt to perform staging within 6 weeks of treatment for all patients.

Recent publications evaluating the integration of PET/CT into the surveillance algorithm suggest a potential role for metabolic imaging in the early detection of regional recurrence, and the present study, which used almost exclusively CT as the first imaging modality does not address the utility of PET. Our data does, however, suggest, imaging within the first 6 months post-treatment is of limited value for the detection of recurrent or residual disease. The potential for early post-treatment CT to provide a baseline comparison to future studies remains a possible benefit, and should be explored in larger datasets and/or prospective trials. Our event numbers are too limited for meaningful statistical analysis of predictors of early failure. However, similar analyses of larger datasets could allow development of robust, evidence-based prospective surveillance protocols. The development of nuanced surveillance algorithms accounting for both patient and tumor-specific predictive factors as well as prior imaging findings could ultimately reduce unnecessary imaging while allowing for expedient detection of recurrences.

Significant limitations of the present study include the relatively small patient numbers, the retrospective, single institution nature of the study, heterogeneity of the treated population including several patients with synchronous primary cancers, inconsistent timing of early surveillance imaging studies, and use of PET/CT as the initial surveillance study for several patients at physician discretion. Nonetheless, our data suggest that if CT is used as the primary screening modality, early surveillance imaging within the first 6 months following SBRT for early stage NSCLC affects subsequent management for a small subset of patients.

Conclusions

CT Imaging within the first 6 months following SBRT for early stage NSCLC results in a potentially curative intervention in 3% of patients in the present series and alters oncologic management for a small minority of patients. In the era of cost-effective healthcare, a first surveillance study at 6 months post-treatment may be adequate for most patients. Robust predictors to identify the small subset of patients who will develop an early, treatable recurrence are currently lacking. The potential role of PET/CT in surveillance algorithms should also be further studied. Larger analyses of multi-institution databases and prospective studies are needed to better address the optimal surveillance regimen following SBRT

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Table 1

Patient and Treatment Characteristics

Patient Characteristics	Patients (%)
Age	76.3 years (range: 48.9–90.5 years)
Stage	
T1a	44 (66%)
T1b	11 (16%)
T2a	9 (13%)
T2b	3 (4%)
Histology	
Adenocarcinoma	40 (60%)
Squamous cell carcinoma	17 (25%)
Other	7 (10%)
No histologic diagnosis	3 (5%)
Number of Treated Tumors	
1	58 (94%)
2	3 (5%)
3	1 (2%)
Medically Inoperable?	
Yes	48 (77%)
No	14 (23%)
Dose/Fractionation	
54–60 Gy in 3 fractions	29 (43%)
48–50 Gy in 4 fractions	23 (34%)
50–60 Gy in 5 fractions	12 (18%)
56–60 Gy in 8 fractions	3 (4%)

Table 2

Interventions and Outcomes Among Patients with Findings Suggestive of Progressive Disease on Early Surveillance Imaging after SBRT

	Stage/histology	Treatment to scan interval (months)	Findings	Action	Outcome
1	T2bN0M0 adeno	0.9	New lung nodule	PET/CT→not suggestive of recurrence	NED at 6 months
2	T1bN0M0 scc	2.6	New lung nodule	PET/CT→confirmed metastatic disease	Chemotherapy
3	T1bN0M0 scc	3.9	New lung nodule	Ongoing routine surveillance	NED at 27 months
4	T1bN0M0 adeno	1.2	New lung nodule	Biopsy confirming NSCLC, thermal ablation	NED at 36 months
5	T1bN0M0 Carcinoma NOS	2.5	New lung nodule	Ongoing routine surveillance	NED at 5 months
6	T2aN0M0 Adenosquamous	2.5	Enlarged hilar node	PET/CT, then surveillance	Deceased at 5 months secondary to progressive pneumonitis (idiopathic vs radiation)
7	T1aN0M0 Scc	1.4	New lung nodule	Surveillance CT at 4.3 and 7.0 months, then biopsy confirming NSCLC. Additional staging negative. SBRT to new lesion.	NED at 14 months after first SBRT and 3 months after second SBRT course
8	T1aN0M0 Adeno	4.3 (CT at 2.1 months partial response)	Gross metastatic disease	Chemotherapy	Deceased at 10 months
9	T1aN0M0 Adeno	4.2	Enlargement of primary	Ongoing routine surveillance	NED at 17.5 months
10	T1aN0M0 Scc	4.1	New lung nodule	Ongoing routine surveillance	Ongoing surveillance at 6.6 months

Abbreviations: Adeno: Adenocarcinoma; SCC: squamous cell carcinoma; AS: Adenosquamous carcinoma; NOS: not otherwise specified; NED: no evidence of disease