

Endobronchial Ultrasound-Guided Transbronchial Needle Aspiration in the Nodal Staging of Stereotactic Ablative Body Radiotherapy Patients

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Background. Patients with non-small cell lung cancer (NSCLC) being evaluated for stereotactic ablative body radiotherapy (SABR) are typically staged noninvasively with positron emission tomography/computed tomography (PET/CT). Incorporating endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) into the staging workup of these patients has not been evaluated. Our primary objective was to compare the performance of PET/CT with EBUS-TBNA for intrathoracic nodal assessment among SABR-eligible patients.

Methods. This was a retrospective study consisting of two parts. First, we assessed the concordance for nodal metastasis of PET/CT and EBUS-TBNA. Second, we evaluated clinical outcomes among patients who underwent SABR with and without a prior EBUS-TBNA.

Results. We identified 246 eligible patients. Compared with PET/CT, EBUS-TBNA led to a stage shift in 48 of 246

patients (19%). Of 174 N0 patients by PET/CT, 6 (3.4%) had nodal metastasis on EBUS-TBNA. Among 72 clinical N1 patients, 36 (50%) were downstaged to N0 after EBUS-TBNA, therefore becoming eligible for SABR. Concordance between PET/CT and EBUS-TBNA for nodal metastasis was 83% ($\kappa = 0.53$). Clinical outcomes of patients who underwent SABR with or without a prior EBUS-TBNA did not differ significantly.

Conclusions. Concordance of PET/CT and EBUS-TBNA for nodal disease was only moderate. Incorporating EBUS-TBNA into the staging workup was beneficial in identifying occult nodal metastasis that would otherwise be left untreated with SABR and in expanding the pool of potentially SABR-eligible patients.

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Stereotactic ablative radiotherapy (SABR) is emerging as an effective therapeutic alternative for early-stage non-small cell lung cancer (NSCLC), with response rates exceeding 90% [1, 2]. Given that reported response rates are higher than those obtained with conventional radiotherapy and comparable with surgical resection [3], SABR is no longer being limited to those at high surgical risk. Furthermore, as the median age of patients with lung cancer increases [4], there is an associated increase in the number of patients in whom a less invasive option may be preferred.

Despite the excellent initial tumor response rates, locoregional recurrence at 2 years is approximately 15%,

and rates appear to be higher than those reported for surgical resection [5, 6]. This may be partly explained by the presence of occult lymph node metastasis at the time of the initial treatment, because SABR only targets the primary tumor. Eligibility criteria for SABR includes the absence of known nodal metastasis; however, the lack of routine nodal sampling in SABR patients limits the pre-treatment evaluation of nodal involvement, and undiagnosed nodal disease might therefore remain undetected and untreated.

Patients with NSCLC being evaluated for SABR are typically staged noninvasively with positron emission tomography/computed tomography (PET/CT). Nodal metastasis can be found in up to 22.3% of patients who have no evidence of mediastinal disease on PET/CT [7]. PET/CT

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can also demonstrate false-positive results in intrathoracic lymph nodes, particularly among patients from regions with endemic granulomatous diseases, potentially preventing these patients from being considered for SABR [8].

To improve the diagnostic accuracy of intrathoracic nodal staging, some centers have incorporated minimally invasive sampling with endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) as part of the standard workup before SABR. EBUS-TBNA is a safe procedure [9] with superior diagnostic accuracy compared with imaging modalities alone for assessing nodal stage in patients with radiographic evidence of nodal metastases [10]; however, the added benefit of EBUS-TBNA over noninvasive staging methods has not been evaluated in SABR-eligible patients with no radiographic evidence of nodal disease because prior studies did not have a primary tumor size limitation.

The primary objective of this study was to assess the performance of PET/CT compared with EBUS-TBNA in nodal staging among potentially SABR-eligible patients by evaluating the concordance between the two tests. We also postulated that optimizing patient selection for SABR by improving pretreatment staging accuracy would improve outcomes; hence, we also examined the rates of progression-free survival and overall survival among patients who underwent SABR after EBUS-TBNA compared with patients who received SABR without a prior EBUS-TBNA.

Patients and Methods

The MD Anderson Cancer Center Institutional Review Board approved the study (protocol PA14–0591) along with a waiver of consent.

Study Design

This was a retrospective study of patients with early-stage NSCLC who were evaluated at MD Anderson Cancer Center from January 2007 to January 2013. The study consisted of two parts involving two distinct cohorts. The first part assessed the concordance of PET/CT with EBUS-TBNA for intrathoracic nodal assessment among potentially SABR-eligible patients. The second part evaluated clinical outcomes among patients who underwent SABR after an EBUS-TBNA compared with those who underwent SABR without a prior EBUS-TBNA.

Study Population

For the first part of the study, we included all potentially SABR-eligible patients aged 18 years or older with a diagnosis of NSCLC proven by biopsy specimen who underwent PET/CT and EBUS-TBNA for mediastinal staging. Criteria for potential SABR eligibility was defined as a primary tumor sized smaller than 5 cm, without clinical radiographic evidence of mediastinal nodal disease or distant metastasis. Patients in this group were included if they were potential candidates for SABR, independent of the final treatment.

The second part of the study consisted of two distinct cohorts:

1. Patients with early-stage NSCLC treated with SABR for curative intent whose stage was established by clinical and radiographic criteria (PET/CT), without a prior EBUS-TBNA.
2. Patients with early-stage NSCLC treated with SABR for curative intent whose stage was established by a combination of PET/CT and EBUS-TBNA.

For both parts of the study, we excluded patients with synchronous malignancies, prior mediastinal radiotherapy or chemotherapy because of an intrathoracic malignancy, those who did not have an available PET/CT, and those who were planning to receive definitive treatment at another institution.

Definitions and Procedures

Study patients were identified using billing codes for EBUS-TBNA and the Radiation Oncology database. The medical records were screened to identify patients meeting inclusion criteria. Two study investigators used a standardized form to abstract study data. A lesion was classified as positive on PET/CT if the standardized uptake value (SUV) was 2.5 or higher. Lymph nodes were considered enlarged on CT if the short-axis diameter was 10 mm or more. Central tumor was defined as located within the inner third of the hemithorax and peripheral if within the outer two-thirds.

Patients were considered to have a recurrence if imaging showed evidence of progressive soft-tissue abnormalities over time that corresponded to (fluorodeoxyglucose)-avid (SUV > 5) areas on PET/CT at least 6 months after SABR. Confirmation by a biopsy specimen was not necessary for the purposes of this study. Time to recurrence was defined as time from the end of treatment to the time at which the follow-up imaging first showed the abnormalities.

EBUS-TBNA was performed under general anesthesia in the standard fashion. We use a linear-array ultrasound bronchoscope to systematically examine the accessible intrathoracic lymph nodes and identify those that met any of the following criteria on ultrasound for sampling: a short-axis diameter exceeding 0.5 cm or a combination of features that are associated with malignancy (sharp margins, heterogeneity, central necrosis sign, absence of a central hilar structure, and rounded shape), or both.

The size of the lymph node on ultrasound imaging is measured on static images. Nodal sampling begins at the contralateral hilum to avoid the possibility of specimen cross-contamination and potential staging inaccuracies. A minimum of 3 passes are performed for each node by passing a 22-gauge needle through the working channel of the bronchoscope. Rapid on-site cytologic evaluation was available for all procedures. The lymph node stations were described according to the International Association for the Study of Lung Cancer classification.

The SABR technique has been described previously [11]. Treatment is delivered in 4 fractions over consecutive days if the total dose is 50 Gy or in 10 fractions if the total dose is 70 Gy.

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