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

Macarena R. Vial, MD, Kashif A. Khan, MD, Oisin O'Connell, MD, S. Andrew Peng, MS, Daniel R. Gomez, MD, Joe Y. Chang, MD, PhD, David C. Rice, MD, Reza Mehran, MD, Carlos J. Jimenez, MD, Horiana B. Grosu, MD, David E. Ost, MD, and George A. Eapen, MD

Department of Pulmonary Medicine, The University of Texas MD Anderson Cancer Center, Houston, Texas; Clínica Alemana de Santiago, Universidad del Desarrollo, Santiago, Chile; Department of Respiratory Medicine, Cork University Hospital/University College Cork, Ireland; and Departments of Biostatistics, Radiation Oncology, and Thoracic Surgery, The University of Texas MD Anderson Cancer Center, Houston, Texas

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 pretreatment 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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Address correspondence to Dr Eapen, Department of Pulmonary Medicine, Unit 1462, The University of Texas MD Anderson Cancer Center, 1515 Holcombe Blvd, Houston, TX 77030; email: geapen@mdanderson.org.

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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.

Standard follow-up of patients after SABR at our institution includes a physical examination and chest CT every 3 months for the first 2 years and then every 6 months in the third year. After 3 years, routine follow-up continues once yearly. If needed, further studies are obtained according to the judgment of the treating physician.

We obtained follow-up data from the medical records and from the Tumor Registry at our institution, which records the vital status of each patient yearly. Patients with no scheduled appointments within 6 months are contacted by mail or telephone calls.

Outcomes

Primary outcome was concordance of PET/CT imaging and EBUS-TBNA for nodal disease in patients with early-stage NSCLC. Secondary outcomes were overall survival, progression-free survival, and locoregional recurrence rate in those who underwent SABR with and without a prior EBUS-TBNA.

Statistics

Summary statistics were calculated as the mean, standard deviation, median, and range for continuous variables and as frequency count and percentage for categoric variables. Wilcoxon rank sum tests were used to compare continuous variables between the two groups. The χ^2 test was used to compare categoric variables. Agreement between two tests was measured using κ statistics. Kaplan-Meier curves were plotted for overall survival and progression-free survival, and log-rank tests were used to compare these end points between patient groups. Gray tests, which accounted for death as the competing risk, were used to compare time-to-progression outcomes between patient groups. The comparison in every time-to-event outcome was also adjusted for age, Eastern Cooperative Oncology Group, forced expiratory volume in 1 second, tumor size, tumor location (central or peripheral), and histologic type (adenocarcinoma or others). A two-tailed p value of less than 0.05 was considered statistically significant. Analyses were performed using SAS 9.3 software (SAS Institute, Inc, Cary, NC).

Results

Study Part 1

For the first part of the study, we reviewed 4,198 patients who underwent an EBUS-TBNA during the specified period and identified 246 potential SABR candidates. The demographics and tumor characteristics of this group are reported in Table 1. By radiographic criteria, 72 of the 246 patients (29%) had clinical N1 disease and 174 (71%) had clinical N0 disease.

On EBUS-TBNA, 644 lymph node stations were biopsied in 246 patients, with a median of 3 lymph nodes per patient (range, 0 to 6). The average size of these lymph nodes was 0.77 cm (minimum, 0.32 cm; maximum, 2.89 cm) with adequate samples, meaning pathologic evidence of lymph node sampling obtained in 95%. There were no immediate complications from EBUS-TBNA.

Table 1. Demographic and Tumor Characteristics of Potential Stereotactic Ablative Body Radiotherapy Candidates Who Underwent Endobronchial Ultrasound-Guided Transbronchial Needle Aspiration

Variable	Result (n = 246)
Age, mean (range) y	69 (44–89)
Male sex, No. (%)	127 (51.6)
Ethnicity, No. (%)	
White	212 (86.2)
Nonwhite	34 (13.8)
Smoking history, No. (%)	
Yes	224 (91.0)
No	22 (8.9)
ECOG performance status, No. (%)	
0	111 (45.12)
1	113 (45.9)
≥2	22 (8.95)
Pulmonary function tests	
FEV_1, mean (SD), %	75 (22.7)[a]
DLCO, mean (SD), %	69.5 (24.5)[b]
Tumor size on CT, mean (range), cm	2.7 (0.7–5)
Tumor location, No. (%)	
Central	55 (22.4)
Peripheral	191 (77.6)
Histology, No. (%)	
Adenocarcinoma	127 (51.6)
Squamous cell carcinoma	91 (37)
NSCLC NOS	21 (8.5)
Others	7 (2.85)
FDG avidity, No. (%)	
SUV ≥2.5	227 (92.3)
SUV <2.5	19 (7.7)

[a] Data were missing for 11 patients. [b] Data were missing for 22 patients.

CT = computed tomography; DLCO = diffusion capacity of the lung for carbon monoxide; ECOG = Eastern Cooperative Oncology Group; FDG = [^{18}F]Fluoro-2-deoxy-2-D-glucose; FEV_1 = forced expiratory volume in 1 second; NOS = not otherwise specified; NSCLC = non-small cell lung cancer; SUV = standardized uptake value.

Compared with clinical radiographic staging, EBUS-TBNA led to a stage shift in 48 of the 246 patients (19%; Fig 1). Among clinical N0 patients, nodal metastases were identified in 6 of 174 (3.4%; 95% confidence interval, 0.013 to 0.074) by EBUS-TBNA, and 2 were upstaged to N2 and 4 to N1 (Table 2). Among the 72 clinical N1 patients, 6 were upstaged to N2 (8%), 36 (50%) were downstaged to N0, and the nodal stage after EBUS-TBNA remained unchanged in 30 patients (42%). Concordance of EBUS-TBNA and PET/CT for nodal metastasis was 83% with a κ coefficient of 0.53 (95% confidence interval, 0.41 to 0.65; Table 3).

Study Part 2

For the second part of the study, we identified 81 patients who underwent SABR after staging with EBUS-TBNA.

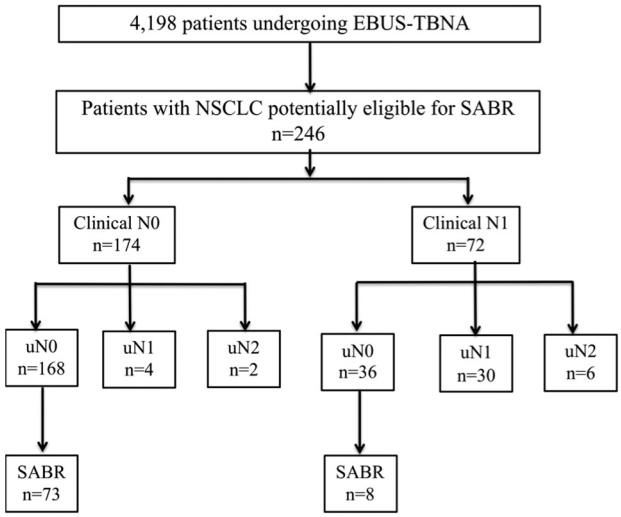

Fig 1. Flow diagram of patients with non-small cell lung cancer (NSCLC) undergoing endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA).
(SABR = stereotactic ablative body radiotherapy; uN0 = ultrasound N0; uN1 = ultrasound N1; uN2 = ultrasound N2.)

Most of these patients were clinical N0, but 8 (10%) were initially clinical N1 and subsequently downstaged by EBUS-TBNA to N0, and as such received SABR. This EBUS-TBNA–staged cohort of 81 patients was compared with a separate cohort of 88 clinical N0 patients who underwent SABR treatment after clinical radiographic staging alone.

Most of the patients in both cohorts received a dose of 50 Gy delivered in 5 fractions, with a few patients receiving 70 Gy in 10 fractions. Treatment was well tolerated in 78% of the patients, with only minor complications reported on follow-up visits, consisting mainly of dermatitis, fatigue, cough, and chest pain. Radiation pneumonitis that required steroid treatment developed in 2 patients. We did not observe any significant differences in overall survival, progression-free survival, or locoregional recurrence between the groups, even after adjusting for age, Eastern Cooperative Oncology Group status, forced expiratory volume in 1 second, tumor size, tumor location, and histologic type (Fig 2).

Comment

Patients with NSCLC undergoing SABR have traditionally been staged by imaging. PET/CT, although highly sensitive for metastatic disease in patients with enlarged lymph nodes, is a conditional test, and the sensitivity in settings with low prevalence of nodal disease is estimated at 62% [12]. This is the first study to assess concordance of PET/CT and EBUS-TBNA in assessing nodal metastasis among patients, potentially SABR-eligible patients, and to describe the incremental value of performing an EBUS-TBNA. We found an 83% concordance rate with only a moderate agreement ($\kappa = 0.53$) between the PET/CT and EBUS-TBNA findings. As such, incorporating EBUS-TBNA as part of the staging work-up changed the N descriptor in a substantial fraction (19%) of patients. These findings are consistent with the previously reported performance of PET/CT in surgical patients with "negative mediastinum" [7, 8].

Among patients staged as N0 by PET/CT, 3.4% had nodal metastasis on EBUS-TBNA. This is relatively low compared with recent studies reporting nodal disease in up to 22% of patients with clinical N0 disease [7]. Our findings may be partly explained by differences in the study population, with smaller tumor sizes in our patients, but may also be a result of the inherent limitations of EBUS-TBNA in this particular population, with reported sensitivities of 35% to 37% [7, 13]. In a more comparable population of SABR-eligible patients who underwent surgical resection and lymphadenectomy, the prevalence of occult nodal metastasis was found to be lower (9%) [14] but, nonetheless, higher than in this study. This suggests that the reliability of current minimally invasive staging modalities, including EBUS-TBNA, is still an open question in this population.

Although EBUS-TBNA can clearly identify some additional patients with occult nodal disease compared with PET/CT, the comparative effectiveness of incorporating EBUS-TBNA in the staging workup before SABR is unclear, and risk-stratification studies are likely needed to improve patient selection. In addition, strategies to enhance the incremental value of EBUS-TBNA in this setting may include a revision of lymph node size thresholds for sampling or incorporation of biomarker assays to increase the sensitivity for detecting occult nodal metastasis [13].

Table 2. Characteristics of Clinical N0 Patients With Nodal Metastasis Identified on Endobronchial Ultrasound-Guided Transbronchial Needle Aspiration

Patient	Age (y)	Tumor Lobe	Tumor Centrality	Histology	Size (cm)
1	49	RUL	Peripheral	Adenocarcinoma	2.5
2	69	RLL	Peripheral	Adenocarcinoma	3.2
3	73	RLL	Peripheral	Squamous cell	2.3
4	62	RLL	Peripheral	Adenocarcinoma	3.2
5	55	RML	Central	Adenocarcinoma	2.3
6	86	RLL	Peripheral	Adenocarcinoma	3.3

RLL = right lower lobe; RML = right middle lobe; RUL = right upper lobe.

Table 3. Concordance of Endobronchial Ultrasound-Guided Transbronchial Needle Aspiration and Positron Emission Tomography/Computed Tomography for Nodal Metastasis

	Nodal Metastasis on EBUS/TBNA		
Nodal metastasis on PET/CT	Present, No.	Absent, No.	Total No. of Patients
Present, No.	36	36	72
Absent, No.	6	168	174
Total, No.	42	204	246

EBUS/TBNA = endobronchial ultrasound-guided transbronchial needle aspiration; PET/CT = positron emission tomography/computed tomography.

A very intriguing finding in this study was that the use of EBUS-TBNA in the clinical N1 population downstaged a significant number of patients. This is consistent with a recent study where 47 of 69 patients with N1 disease by CT or PET/CT were downstaged by EBUS [8]. Among patients with clinical N1 or greater disease, whether EBUS downstaging to N0 disease is sufficiently robust to permit treatment with SABR is an important question that deserves additional investigation. Given the lower sensitivity of EBUS in this setting, it is unlikely that a negative EBUS in the setting of PET/CT-positive nodal disease will provide enough evidence to confidently proceed with SABR therapy; however, it is more plausible that patients who are clinical N1 by CT criteria but not by PET criteria and are subsequently found to be node negative by EBUS may be considered for SABR. Such a strategy could potentially increase the pool of SABR eligible patients.

Failure to identify nodal disease before SABR might result in poorer outcomes, but whether outcomes would improve by incorporating EBUS-TBNA as part of the

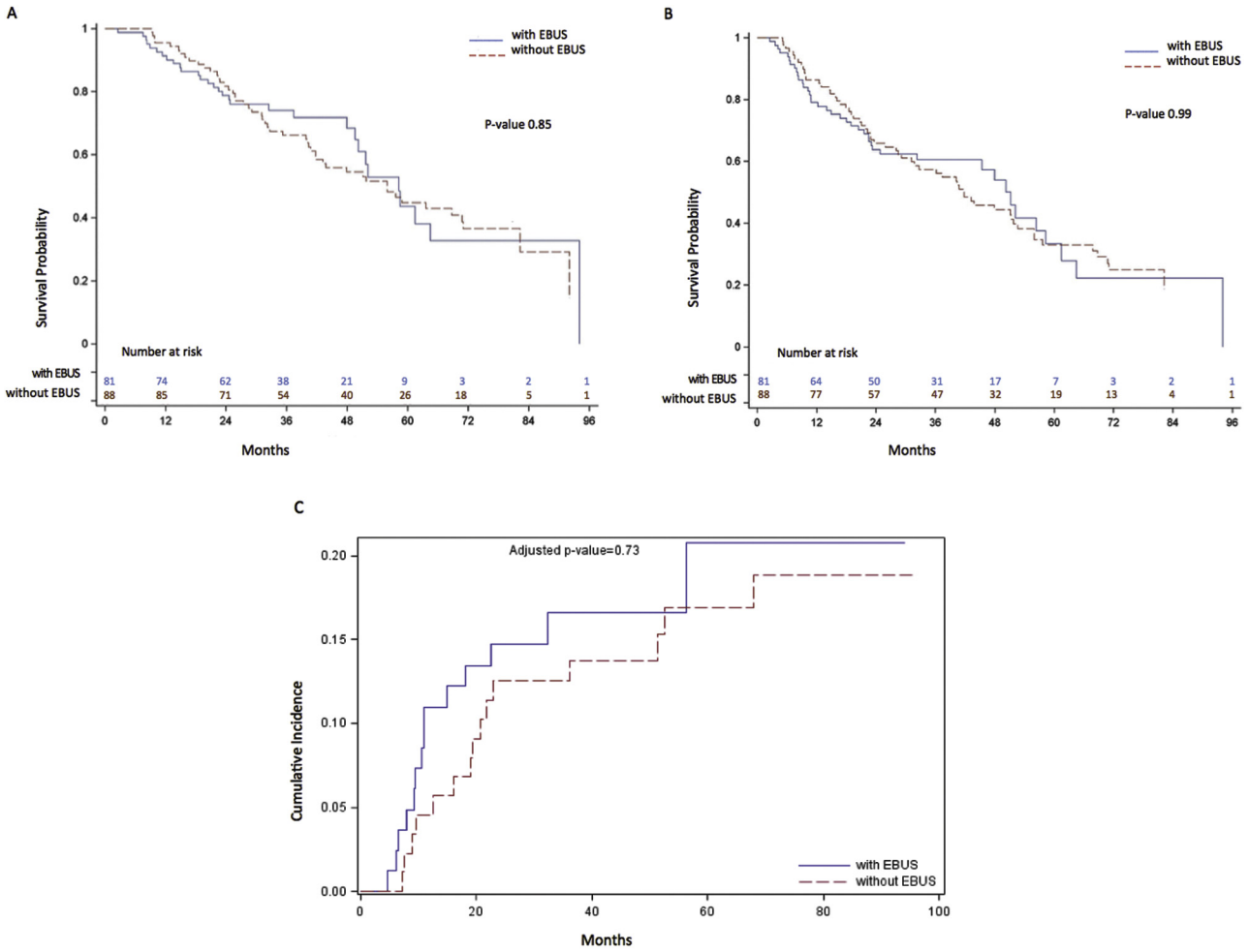

Fig 2. (A) Overall survival, (B) progression-free survival, and (C) locoregional recurrence comparing patients with endobronchial ultrasound (EBUS)-detected N0 disease (uN0) vs clinical N0 disease.

routine staging strategy remains unclear. We did not detect any differences in overall survival, progression-free survival, or locoregional recurrence between those staged with EBUS-TBNA compared with PET/CT staging alone. Our study, however, was underpowered to address this question fully, and additional studies are warranted.

A limitation of our study is that patients who underwent EBUS-TBNA before SABR might have been intrinsically different from those who did not. As with most retrospective studies, we do not have enough information about what determined the physician's choice for an EBUS-TBNA and cannot therefore correct for these variables.

Also, our findings were obtained from a single cancer referral center where all procedures are performed by highly experienced interventional pulmonologists with rapid on-site cytology. Results might differ significantly in other settings, limiting the generalizability of our findings.

In summary, we found that EBUS-TBNA was beneficial in identifying occult nodal disease that would have been untreated with SABR and in downstaging some clinical N1 patients, thereby potentially expanding the pool of patients eligible for SABR. Whether routinely incorporating EBUS-TBNA as part of the staging strategy before SABR could improve outcomes remains unclear and should be the subject of prospective studies.

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INVITED COMMENTARY

Endobronchial ultrasound–guided transbronchial needle aspiration (EBUS-TBNA) is recommended as test of first choice for invasive mediastinal lymph node (LN) evaluation in primary lung cancer [1].

While surgical resection is the standard of care for management of early stage lung cancer, approximately 25% of patients with surgical disease are not surgical candidates. These patients may be candidates for local therapies, including stereotactic ablative body therapy (SABR). Currently, a majority of patients managed with local therapies are staged with CT or positron emission tomography (PET). However, the false-negative rate of PET can be as high as 25% [1]. The reported 15% SABR failure could, therefore, be due to occult nodal metastasis. These developments suggest a role for invasive staging of the cT1N0Mo lesions.

In the current issue of *The Annals of Thoracic Surgery*, Vial and coworkers [2] report the results of their retrospective study aimed at evaluating the concordance between PET/CT and EBUS-TBNA for detection of nodal metastasis in SABR-eligible patients. Their second goal was to compare progression-free and overall survival between SABR patients staged with EBUS-TBNA and those staged only with PET/CT.

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