Feasibility and Safety of the Transbronchial Access Tool for Peripheral Pulmonary Nodule and Mass

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Background. **Navigational bronchoscopy and other imaging modalities have improved the ability to evaluate pulmonary nodules/mass. Many of these lesions are located outside the bronchial airway and are difficult to access even with these devices. The Transbronchial Access Tool (Medtronic, Minneapolis, MN) allows the bronchoscopist to create a pathway from the bronchial airway, across the lung parenchyma, and into the target lesion. We are reporting the feasibility and safety of this new device.**

Methods. **Patients with peripheral pulmonary nodules/mass with an absence of an air bronchogram on thoracic imaging underwent a navigational bronchoscopy in a hybrid operating room under general anesthesia. A navigational system located predetermined areas in the bronchial tree to deploy the Transbronchial Access Tool, and cone beam computed tomography confirmed that the target lesion was accessed. A standard protocol was developed and followed in the last 7 patients directing cone beam computed tomography use. The ability to enter the target lesion, diagnostic yield, radiation exposure, and procedural complications were recorded.**

Results. **The Transbronchial Access Tool was used in 14 patients who underwent an electromagnetic navigational bronchoscopy–guided biopsy from September 2015 to January 2016. The overall diagnostic yield was 71% (10 of 14) and 100% (7 of 7) when the standard protocol was instituted. Access was achieved in 75% (9 of 12) of the targeted lesions, with a diagnostic yield of 66% (8 of 12). One complication, a pneumothorax, occurred. The average radiation exposure during the procedure was 4.3 mSv (range, 3 to 5 mSv), and fluoroscopic time was 17 minutes (range, 2 to 44 minutes).**

Conclusions. **The Transbronchial Access Tool is safe and permits access to pulmonary nodules/masses with navigational bronchoscopy.**

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Standard bronchoscopy has been limited in the evaluation of the peripheral pulmonary nodules, with diagnostic yields ranging from 19% to 68% [1]. The addition of tools such as electromagnetic navigational bronchoscopy (ENB), radial endobronchial ultrasound (r-EBUS), and advanced radiographic imaging, such as cone beam computed tomography scans (CBCT), have been used to aid bronchoscopy in the evaluation of the solitary pulmonary nodule with variable improvement in diagnostic yield [2–5]. These tools aide bronchoscopy in accessing the pulmonary lesion that is inside or close to the bronchial airway. Some of these nodules may be identified by the absence of an air bronchogram sign and positioned far enough away from the bronchus that sampling techniques by bronchoscopy are not feasible. This may be a significant factor responsible for the inconsistent results of bronchoscopy in the evaluation of the peripheral pulmonary nodule or mass [6–8].

The Transbronchial Access Tool (TBAT; Medtronic, Minneapolis, MN) is a United States Food and Drug Administration–approved device that is used with ENB to help access pulmonary lesions that are located outside the bronchial airway. It has only been described in the porcine lung model and currently has a limited market release [9]. We are reporting the feasibility and safety of using the TBAT combined with ENB and CBCT in the evaluation of pulmonary lesions in humans.

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Patients and Methods

Study Design and Patients

Patients who had undergone a bronchoscopy with ENB-guided biopsies and the TBAT to evaluate pulmonary lesions from September 2015 to January 2016 at one large tertiary medical center were identified in a retrospective fashion. Information was obtained from the institutional medical records and recorded appropriately. Permission to access this information was approved by the University and Medical Center Institutional Review Board (UMCIRB 16-000056).

All patients had been referred to the multidisciplinary thoracic oncology program for suspected lung cancer and underwent ENB-guided biopsy to establish a diagnosis in the hybrid operating room under general anesthesia. Adults with a pulmonary nodule/mass within 5 cm from the pleura and no apparent air bronchogram sign on CT scan of the chest were considered adequate candidates for the TBAT. Patients with centrally located lesions, severe pulmonary hypertension, or lesions near major pulmonary blood vessels were not considered adequate candidates for TBAT use.

For the first 7 patients, standard ENB was performed and a CBCT scan was used to confirm the position of the extended working channel once the TBAT was used. We used our experience with these patients to develop a protocol that specifically addressed the flow of the procedure concerning the use of CBCT scan and when to use the TBAT (see Protocol in the Supplemental Material). All of the patients either preprotocol or postprotocol had the same preprocedural planning. The TBAT and ENB procedures are described below.

The operating physician using endobronchial ultrasound in all cases staged the mediastinum. Three physicians with varying degrees of experience (an interventional pulmonologist and 2 thoracic surgeons) performed the procedures. Radial ultrasound was not available in the hybrid operating room.

The diagnostic yield (defined as a definitive diagnosis or resolution of the lung abnormality on a 6-month follow-up imaging), ability for the TBAT to access the target lesion (as visualized by chest CT scan), and procedural complications were recorded.

Procedure Planning

All patients underwent a noncontrast thoracic CT scan. As indicated by the software recommendations, these scans were completed with 2- to 3.5-mm slice thickness and intervals of 1 to 2.5 mm. The resulting images were then imported into the superDimension software (superDimension, Inc, Minneapolis, MN) for virtual reconstruction and processing. During this planning phase, the target lesions were identified and marked in standard fashion, as previously reported [10].

Because the TBAT will exit outside of the bronchial airway and through the lung parenchyma, we instituted two additional targets: the point on the airway where the TBAT will exit out of the bronchial airway (exit point) and any vascular structures within the lung parenchyma that need to be avoided (danger zones), as shown in Figure 1.

Exit Point

The three-dimensional reconstructions of the bronchial tree and the axial, sagittal, and coronal CT images were

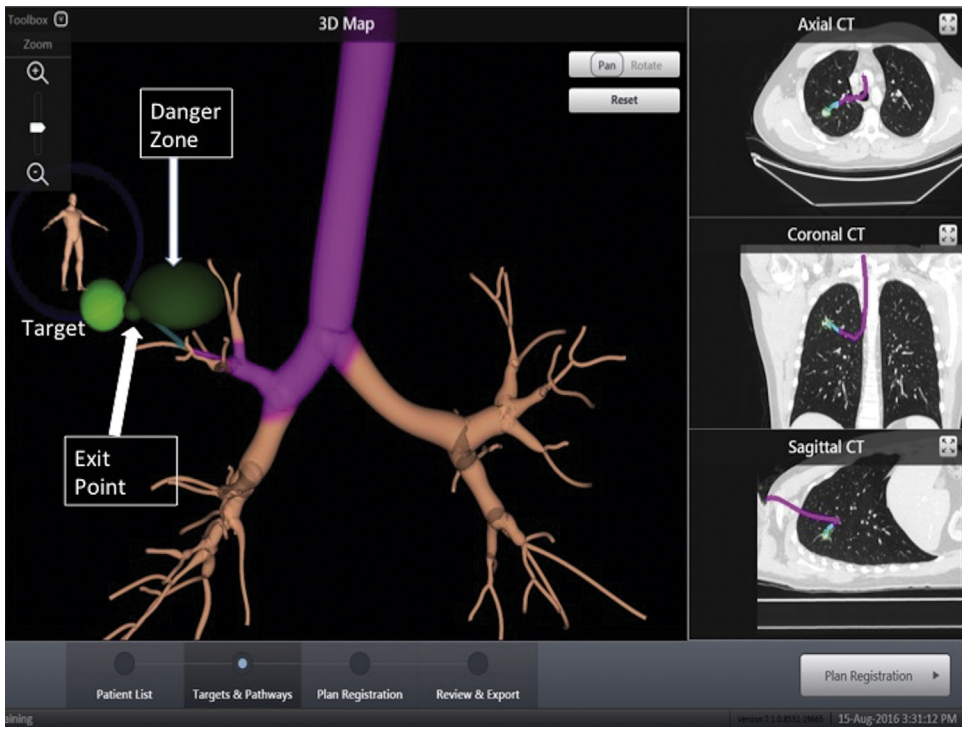

Fig 1. Three-dimensional (3D) map shows the danger zones and exit point, and the target lesion are demonstrated. (CT = computed tomography.)

used to identify a location that would allow the most direct route from the exit point, through the lung parenchyma, to the target lesion. To create the exit point, we simply planned this area as if it were a target and renamed it the exit point. At the time of the procedure, we navigated to this exit point, and the TBAT could be deployed.

Danger Zones

Any identifiable vascular structures near the target lesion were marked using the central targeting tool so that we could determine whether the TBAT would transect any of these structures as it exited out of the airway through the lung parenchyma, to the target lesion. During the procedure, once the exit point is reached, we used the three-dimensional bronchial tree screen on the ENB tower, and by toggling between the exit point and danger zone target setting (by pushing the direction button on the ENB tower keyboard), we could determine whether the TBAT pathway would encroach upon any of these danger zones.

CBCT Scan

The CBCT protocol is available in the Supplemental Material. During the procedure, imaging was performed using a robotic angiographic system (Artis Zeego; Siemens Healthcare, Forchheim, Germany) equipped with a 30 × 40 flat-panel detector. In each patient, noncontrast C-arm CT was performed during suspended respiration using a 6-second acquisition protocol with 400 projection images acquired over a 200-degree rotation. Cross-sectional images were then reconstructed automatically on a dedicated workstation (Syngo X Workplace, Siemens). On cross-sectional images, the target lesion was manually contoured in multiple orthogonal planes using dedicated software (Syngo iGuide Toolbox, Siemens), and the contours were displayed on live fluoroscopy for intraprocedural guidance. These contours follow along during all C-arm and table movements.

Electromagnetic Navigational Bronchoscopy

The superDimension navigation system 7.0 (Medtronic, Inc), the Edge extended working channel catheter (EWC; Medtronic, Inc) with the 180- or 90-degree angles, and the standard locatable guide (LG) were used in all cases. We attempted to access all target lesions with the standard approach, as previously reported [11]. If the lesion could not be accessed (Fig 1), we navigated to the exit point and used the TBAT. Once the lesion was accessed by the TBAT, samples were taken which included at least 7 fine-needle aspiration samples and 7 forceps biopsy samples. Rapid on-site evaluation by pathology was used at every case to confirm whether adequate tissue had been collected.

Transbronchial Access Tool

The TBAT is composed of a guidewire and dilation catheter and is inserted through the EWC used with navigational bronchoscopy. The guidewire is used to pierce a hole through the bronchial wall (Fig 2A), traversing the lung parenchyma into the targeted lesion, and does not contain an electromagnetic sensor. The dilation catheter is advanced over the guidewire by the Seldinger technique (Fig 2B) and introduced into the target lesion. The EWC is then guided over the dilation catheter (Fig 2C), and the TBAT is removed (Figs 2 and 3).

Results

From September to December, 14 patients met the inclusion criteria and underwent the ENB-guided biopsy with TBAT use (Table 1). The overall diagnostic yield was 71% (10 of 14), with 3 lesions being malignant and 7 being nonmalignant (Table 2). The 4 remaining nondiagnostic samples were confirmed malignant by other methods. Once the standard protocol was instituted, the diagnostic yield was 100% (7 of 7). The TBAT was able to access 75% (9 of 12) of the targeted lesions (2 lesions did not require TBAT for the diagnosis), with a diagnostic yield of 66% (8 of 12). One complication was noted, a pneumothorax postprocedure, which required drainage by a small-gauge pleural drainage catheter. The average radiation exposure during the procedure was 4.3 mSv (range, 3 to 5 mSv), and the average fluoroscopic time was 17 minutes (range, 2 to 44 minutes, Table 1). One physician performed 57% (8 of 14) of the procedures.

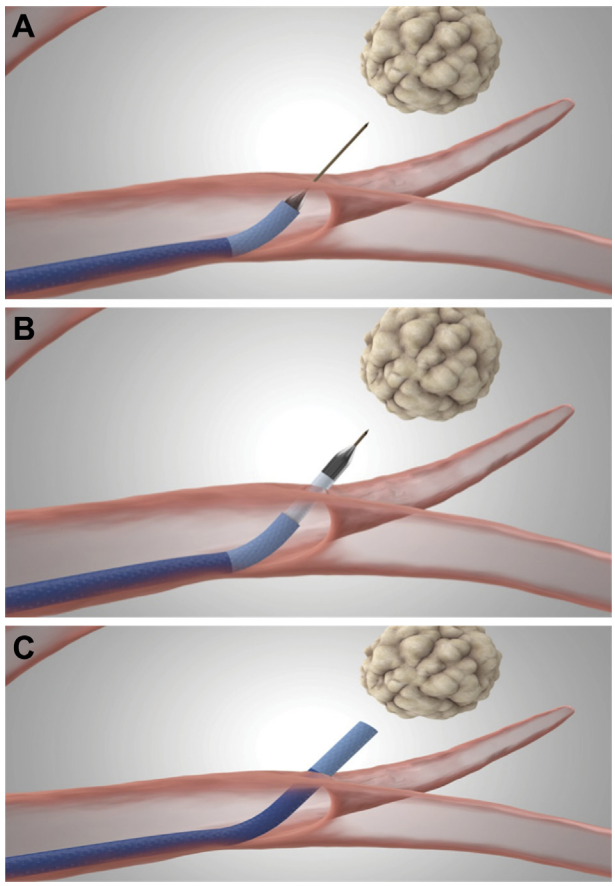

Fig 2. (A, B, and C) How the Transbronchial Access Tool is used is demonstrated. (All rights reserved. Used with the Permission of Medtronic, 161 Cheshire Lane, Suite 100, Minneapolis, MN 55441.)

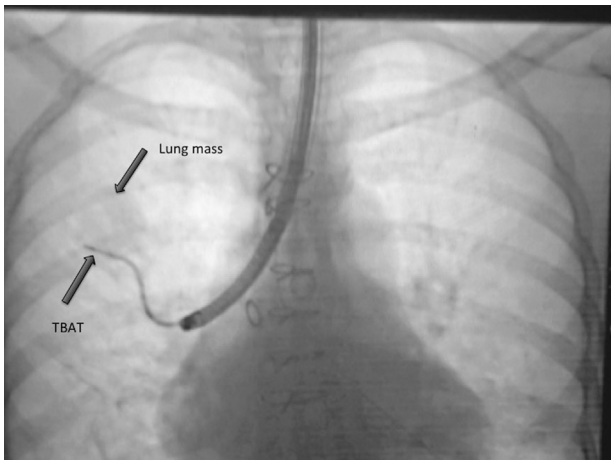

Fig 3. Fluoroscopic imaging demonstrates the Transbronchial Access Tool (TBAT; Medtronic, Minneapolis, MN) being deployed into a right upper lobe lung mass.

Comment

We have reported the first case series on the use of ENB-guided biopsies for the evaluation of the pulmonary nodule/mass using the TBAT and CBCT scan. One complication required minimal intervention, and the overall diagnostic yield was 71% (10 of 14), with 75% (9 of 12) of the targets successfully accessed with the TBAT and a diagnostic yield of 66% (8 of 12). This is lower than the data reported by Herth and colleagues [12], where they described a similar technique using fluoroscopy and the Archimedes Virtual Bronchoscopy Navigation virtual bronchoscopic system (Broncus Medical, Mountain View, CA) to access lesions located away from the bronchial airway. The diagnostic yield in that study was 83% (10 of 12), and no complications were reported. To our knowledge, this system is not yet commercially available.

We were unable to use the TBAT in 3 of the 4 patients in whom we failed to obtain a definitive diagnosis. Two nodules were located in the superior segment in an extreme posteromedial location, and the third was located in apical posterior segment of the left upper lobe abutting the major fissure. In all 3 cases, the EWC would straighten as soon as the TBAT was deployed, thus deflecting the catheter enough to miss the exit point. We were unable to locate a safe suitable alternative in these patients. This is consistent with our experience with standard ENB-guided biopsies. Owing to the rigidity of various biopsy tools, the EWC may change in a manner that can alter the pathway to the nodule enough to cause sampling error [11]. This may be particularly true when the target is located in the superior segment where an acute angle may be required to reach the target lesion. The TBAT may not be useful when the nodules are located in the superior segment of the lower lungs or if the pathway to the target is at a severe angle. Further evaluation needs to be done concerning the optimal nodule location to use the TBAT.

The patient in the fourth nondiagnostic case was not a surgical candidate and had undergone a previous CT-guided transthoracic needle biopsy and a separate ENB procedure, both of which resulted in a histologic diagnosis of necrosis. We successfully accessed the mass (4 cm) with three different pathways using the TBAT. We were able to confirm that the EWC was in the target lesion each time with CBCT, but the final histologic diagnosis was extensive necrosis. Perhaps the biology of this tumor made it difficult to obtain a definitive diagnosis from any cytologic specimen from the lung. A diagnosis of adenocarcinoma was established 1 month after the bronchoscopy by a fine-needle aspiration of a bone metastasis.

For the first 7 patients, CBCT was used once the TBAT was used to confirm the positioning of the EWC (Fig 4).

Table 1. Demographics, Target Characteristics, and Radiation Exposure of the 14 Patients Studied

Age (y)	Race	Sex	Current Smoker	Lesion Size (mm)	Lesion Location	Lesion Class	Distance From Pleura (mm)	Lesion Borders	PET SUV	Effective Radiation Dose (mSv)	Fluoroscopy Time (min)
56	W	F	Yes	21 × 24	LUL	Solid	0 to 20	Smooth	12	4.4–4.6	25
71	W	M	Yes	24 × 18	RUL	Solid	0 to 20	Spiculated	2	3.3, 3.4, 3.5	2
65	W	F	Yes	25 × 13	RLL	Solid	0 to 20	Smooth	12	4.9	44
64	W	M	Yes	12 × 11	RLL	Solid	0 to 20	Smooth	9	4.3, 4.4	25
49	AA	M	Yes	27 × 36	LUL	Solid	0 to 20	Spiculated	7	3.9, 4.0	25
19	AA	M	No	12 × 11	RLL	Solid	0 to 20	Lobulated	NA	None	10
61	W	M	Yes	24 × 20	LLL	Solid	0 to 20	Spiculated	7	4.9	15
48	W	F	No	13 × 26	RUL	Solid	0 to 20	Lobulated	3	3.9, 4.0	16
70	AA	F	Yes	20 × 24	RUL	Solid	0 to 20	Smooth	12	4.1, 4.2, 4.2	16
89	W	M	No	19 × 9	LUL	Solid	20 to 50	Spiculated	4	3.9, 3.9	6.3
74	W	M	No	18 × 19	LUL	Semisolid	0 to 20	Lobulated	9	4.4, 4.4	7
56	W	F	Yes	30 × 47	RLL	Solid	0 to 20	Smooth	NA	5.0, 5.0, 5.0	11
27	W	M	Yes	11 × 9	LUL	Solid	0 to 20	Spiculated	NA	4.4, 4.4	9.8
72	W	M	Yes	30 × 27	RLL	Cavity	0 to 20	Smooth	5	4.9, 4.9	11

AA = African American; F = female; LLL = left lower lobe; LUL = left upper lobe; M = male; NA = not applicable; PET = positron emission tomography; RLL = right lower lobe; RUL = right upper lobe; SUV = standard uptake value; W = White.

Table 2. The Histology of Electromagnetic Navigational Bronchoscopy–Guided Samples

		Biopsy Tools and No. of Samples Collected With ENB Biopsies and TBAT Use			
ENB	Histology	FNA (No.)	Forceps (No.)	Needle Brush (No.)	TBAT (No.)
No diagnosis	Malignant				
	Adenocarcinoma FNA of bone[a]	10	15	0	3
	Adenocarcinoma EBUS[a]	0	0	0	0[b]
	Squamous cell operation[a]	0	0	0	0[b]
	Adenocarcinoma FNA lung[a]	0	0	0	0[b]
Diagnosis	Malignant				
	Lymphoma	7	7[c]	0	NA
	NSCLCA-NOS	7	7[c]	0	1
	Adenocarcinoma	7	7	7[c]	3
	Nonmalignant				
	Organizing pneumonia[d]	7	10[c]	0	1
	Noncaseating granuloma[d]	7	10[c]	0	1
	Acute inflammation with necrosis[d]	7[c]	7[c]	0	1
	Organizing pneumonia[d]	7	10[c]	0	1
	Noncaseating Granuloma	7	10[c]	0	NA
	Noncaseating Granuloma	7	10[c]	0	1
	Acute inflammations with necrosis[d]	7[c]	7[c]	0	1

[a] Diagnosis not obtained by ENB. [b] TBAT could not be used. [c] Tool that obtained the diagnosis. [d] Resolved on previous imaging of the chest.

EBUS = endobronchial ultrasound; ENB = electromagnetic navigational bronchoscopy; FNA = fine-needle aspiration; NA = not applicable; NSCLCA-NOS = non-small cell lung carcinoma not otherwise specified; TBAT = Transbronchial Access Tool (Medtronic, Minneapolis, MN).

Based on our experience, we developed a standard protocol, and the diagnostic yield improved to 100% for the next 7 patients (Table 2). We made two significant changes to our approach (see the Cone Beam Protocol in the Supplemental Material): First, we noticed that once the TBAT was used or biopsy samples were collected, or both, the target lesion would be difficult to visualize by fluoroscopy or CBCT because of distortion of the image from bleeding around the lesion (there have been similar reports that bleeding can also distort r-EBUS images as well). This inability to clearly delineate the nodule/mass made it challenging to access a different pathway to the target lesion. Therefore, we instituted a preprocedural CBCT scan, and used the Syngo iGuide Toolbox to outline and display the target lesion on the fluoroscopic image throughout the procedure (Fig 5).

Second, after navigating to the target lesion/exit point, a CBCT was done to confirm whether the positioning of the LG/EWC was adequate to deploy the TBAT. Interestingly, CBCT established that the LG/EWC was located at the target/exit point 100% (7 of 7) of the time. This suggests that the navigation system is accurate. In 2 patients the postnavigation CBCT confirmed that the LG/EWC was in the target and correlated with the overlay images on the live fluoroscopy. Biopsy samples were obtained from this area, and the preliminary diagnosis by rapid onsite evaluation was acute inflammation. Given that the LG was in the target by CBCT imaging and corresponded to the live fluoroscopic imaging, we felt this sample was representative of the pathology, and TBAT was not used. The patient was treated with steroids, and the lesion resolved on subsequent radiologic studies. Perhaps the absence of an air bronchogram sign is not the best preprocedural indicator for the potential need of the TBAT. Further investigation needs to be done concerning the best preprocedural predictor for the potential use of this device.

The lack of real-time imaging during sampling is a significant limitation to ENB. The combination of the CBCT imaging confirming the LG location and the fused appearance (the Syngo iGuide Toolbox) of the target lesion during live fluoroscopy move us closer to real-time

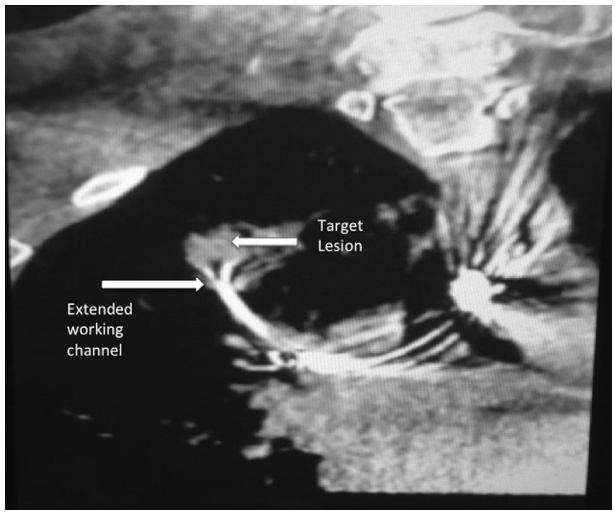

Fig 4. Cone beam computed tomography imaging demonstrates the extended working channel in the target lesion.

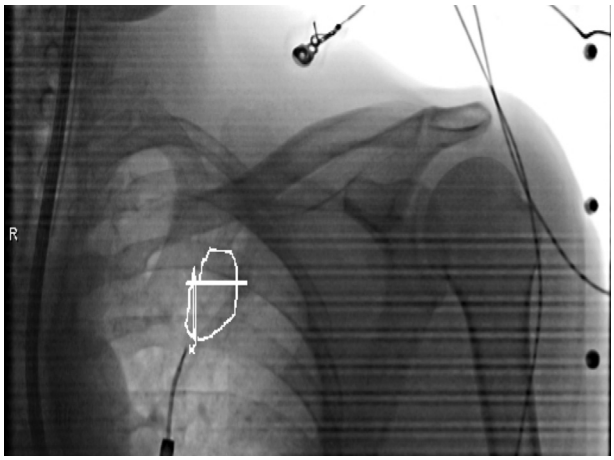

Fig 5. Fluoroscopic imaging with the target lesion marked (white line) with the Syngo iGuide Toolbox (Siemens Healthcare, Forchheim, Germany).

image-guided sampling. However, the use of CBCT to help guide the TBAT is unique and has certainly helped us to understand the best approach to using this device, but it may not be practical to most ENB users. Perhaps thoughtful procedural planning, use of appropriate fluoroscopic images (left anterior oblique, right anterior oblique), and other tools such as r-EBUS to confirm EWC positioning relative to the target lesion are adequate to safely use the TBAT. Further investigation needs to be done to help clarify what other factors aid in the utility and safety of the TBAT.

The use of CBCT was helpful in developing a safe approach to the TBAT but can be challenging and may not be necessary when sampling tissue. One of the more trying aspects was securing the bronchoscope when the CBCT was used to determine the location of the EWC to the target. There is not a commercially available bronchoscope holder, and various techniques were tried such as taping the bronchoscope to the anesthesia circuit tree. This was clumsy and burdensome but did secure the bronchoscope enough to allow safe use of the CBCT.

The CBCT does seem to increase the time of the procedure. The total procedure time was not formally evaluated, but in our experience, ENB procedures, under general anesthesia, rarely take more than 1 hour. In some instances when using the TBAT and CBCT, the case lasted up to 3 hours. More investigation needs to be done to determine the best practices for CBCT and bronchoscopy.

The radiation exposure during the procedure was consistent with the reported literature, which averaged 4.3 mSv per CBCT use (range, 3.3 to 5.0 mSv) [13–15]. The fluoroscopic time was considerably longer in the first 7 patients, with an average of 20 minutes (range, 2 to 44 minutes) compared with 10 minutes (range, 6 to 16 minutes) in the last 7 patients. This may have been because of inexperience or the initiation of a standard approach decreased the overall use of fluoroscopy. The radiation exposure for the use of the CBCT and fluoroscopy are similar to a standard thoracic CT scan of the chest and endoscopic retrograde cholangiopancreatography, respectively [13, 15].

Finally, an unexpected finding in our small cohort was the low diagnostic yield of fine-needle aspirate samples. We believe that this may have resulted from how the samples were prepared at the bedside. Our surgical technicians and nurses prepare the slides for immediate evaluation, and upon review of their technique, we have made the appropriate corrections to their method.

We have presented the first case series describing the feasibility and safety of the TBAT to access peripheral pulmonary nodules/mass with ENB guidance. Our experience suggests that this tool is safe and feasible. Targets should be avoided that are near major pulmonary vasculature. We recommend marking danger zones during planning of the procedure, and immediate access to thoracic surgeons, vascular interventionalists, and the tools necessary to control significant hemorrhage (ie, double-lumen endotracheal tubes, and balloon bronchial blockers) are mandatory.

The use of CBCT may not be necessary to use the TBAT to obtain a biopsy sample, but we do recommend that confirmation that the EWC is in the target lesion should be done with tools like r-EBUS. If CBCT is to be used, a standard approach, as we have suggested, may help with procedure flow and efficiency and decrease radiation exposure.

The effect of the use of the TBAT for the thoracic surgeon includes not only obtaining a definitive diagnosis in those lesions difficult to access with standard bronchoscopic methods but also avoiding unnecessary lung resections in patients with poor pulmonary reserve, without compromising adequate diagnosis and sufficient tissue procurement for driver mutations. It offers these same benefits in cases of multifocal metastatic disease, negating the need for surgical intervention and unnecessary parenchymal loss in these frequently debilitated patients.

In the setting of lesions of uncertain pulmonary vs metastatic origin, TBAT allows for diagnostic certainty before undertaking a surgical intervention, with the entire range of cytologic and immunologic stains being available. An oncologically sound nonanatomic metastasectomy or an anatomic resection are thus planned preoperatively, diminishing operative time, and reducing the need for multiple resections for frozen section analysis, intraoperative pathology consultations, and the interpreter bias they introduce, and avoidable pulmonary parenchymal loss in the metastatic setting.

The ability to ensure access to the primary tumor with tools like the TBAT and CBCT opens the door to future therapeutic applications such as thermal ablation or the implantation of a virus or chemotherapeutic agent. However, given our small analysis, more investigation needs to be done in identifying the optimal approach of using the TBAT, lesion selection, the role of CBCT with ENB and other imaging modalities like r-EBUS.

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