The Efficacy of Electromagnetic Navigation to Assist With Computed Tomography–Guided Percutaneous Thermal Ablation of Lung Tumors

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Objective: Electromagnetic (EM) navigation is increasingly used to assist with bronchoscopic interventions such as biopsy or fiducial placement. Electromagnetic navigation can also be a useful adjunct to computed tomography (CT)–guided thermal ablation and biopsy of lung tumors. This study compares procedures carried out using an EM navigation system (Veran Medical Technologies Inc, St Louis, MO) with procedures using CT fluoroscopy only.

Methods: Over a 23-month period, 17 patients scheduled for thermal ablation were prospectively enrolled in this study. The mean age was 72 years (range, 60–84 years). Seven patients were women. Patients were randomized to EM navigation (n = 7) or CT fluoroscopy alone (n = 10). In some cases, additional ablation or biopsies were performed with or without EM navigation depending on the randomization arm. All procedures were performed under general anesthesia either by a thoracic surgeon or a radiologist.

Results: A total of 23 procedures were performed in 17 patients: 20 were ablation procedures and 3 were biopsies. Fourteen were performed for non–small cell lung cancer, and 9 for pulmonary metastases from other organs. Despite randomization, patients receiving EM navigation had a trend for smaller tumors (mean diameter, 1.45 vs 2.90 cm; $P = 0.06$). For thermal ablation procedures, the time to complete intervention was significantly less when EM navigation was used (mean, 7.6 vs 19 minutes; $P = 0.022$). Although not statistically significant, there were fewer skin punctures (mean, 1 vs 1.25; $P = 0.082$), fewer adjustments (mean, 5.6 vs 11.8; $P = 0.203$), less CT fluoroscopy time (mean, 21.3 vs 34.3 seconds; $P = 0.345$), and fewer CT scans (mean, 7 vs 15; $P = 0.204$) whenever EM navigation was used.

Conclusions: Electromagnetic navigation reduces the time to successfully place an ablation probe in a target tumor. Further study is required to determine whether EM navigation may also reduce the number of adjustments, skin punctures, and CT scans as well as decrease CT fluoroscopy time.

Key Words: Electromagnetic navigation, Thermal ablation, Pulmonary tumors, Pulmonary metastases, CT-guided biopsy.

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Percutaneous thermal ablation, with either radiofrequency ablation (RFA) or microwave ablation (MWA), of solid organ tumors was originally described for the treatment of hepatic tumors.[1,2] For more than a decade, RFA and MWA have also been used to treat medically inoperable patients with lung cancer or pulmonary metastases.[3,4] Although thermal ablation procedures have traditionally been performed by interventional radiologists, an increasing number of thoracic and hepatobiliary surgeons have also been trained to perform them.

Thermal ablation of lung tumors or pulmonary metastases is performed using computed tomographic (CT) guidance. Initially, a baseline CT scan is acquired, which helps identify both the target lesion for intervention and the optimal trajectory for approach. While in the CT gantry, a suitable axial plane to access the target lesion is marked on the patient's skin using the laser marker of the CT gantry as a guide. The patient is moved out of the CT gantry and an ablation probe is advanced through the skin at the marked entry site and toward the target pulmonary lesion. As the probe is advanced, serial CT scans are acquired to ensure that the probe is not straying off the intended path. These additional CT scans require both the patient to move in and out of the CT gantry and the radiology staff to leave the room between each probe adjustment to avoid radiation exposure. Alternatively, in many centers, CT fluoroscopy is performed to limit the number of CT slices needed to assess each instrument adjustment, but even this approach involves some radiation exposure to both

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the patient and the staff and requires the radiology staff to wear lead shielding to minimize exposure. For this reason, CT fluoroscopy is not uniformly used.

Electromagnetic navigation (EMN) has been previously used in conjunction with bronchoscopy to facilitate the biopsy of peripheral lung lesions or placement of fiducials for stereotactic body radiotherapy.[5] It has also been used in conjunction with image-guided percutaneous interventions.[6,7] We have previously reported our preliminary experience with, and demonstrated the feasibility of, using EMN to aid in the thermal ablation of lung tumors.[7]

In this study, we aimed to determine if there is a benefit to using EMN in patients undergoing CT-guided thermal ablation of lung tumors compared with patients undergoing procedures with CT fluoroscopy alone, which is the standard approach in our center.

METHODS

Technology

The EMN system (Veran Medical Technologies Inc, St Louis, MO USA) is an accessory device that uses electromagnetic navigation to identify an instrument (in this study, a percutaneous ablation probe or a biopsy needle) and track its position relative to a CT-based image of the patient's anatomy. This technology uses real-time positioning information, acquired from the movement of a probe within a magnetic field, which is overlaid onto an existing CT or positron emission tomography (PET)–CT image. The system works analogously to a commercial GPS system and provides the interventional radiologist or surgeon with a reconstructed CT image as she/he manipulates a tracked ablation probe relative to other chest structures during device placement. The image is considered "near" real time—as opposed to "true" real time—because the technology uses a previously obtained CT reference image (typically acquired just before the procedure). The EMN system consists of an electromagnetic (EM) tracking accessory placed on the proximal end of a rigid needle or probe, a matrix of thoracic markers placed on the chest wall, an EM field generator, and the tracking system. The matrix of thoracic markers placed on the chest allows the system to track respiratory motion.

Patients

Our institutional review board approved this prospective randomized trial, and informed consent was obtained from all patients. There were 17 patients with lung cancer or pulmonary metastases who were prospectively enrolled and underwent a total of 23 procedures under general anesthesia. All patients were considered high risk for pulmonary resection (based on poor pulmonary function, high cardiac risk, or other comorbidities), and percutaneous ablation was selected as the primary therapy. Patients with tumors that were suspicious for either a primary lung cancer or pulmonary metastases were included, and patients with central lung tumors were excluded.

The EM interventions included biopsy, RFA, or MWA. All patients scheduled to undergo these interventions, who could provide informed consent, were offered participation in this study. Patients undergoing biopsy were offered participation only if the biopsy was scheduled during the same procedure as the thermal ablation.

Preferably, biopsies are performed before scheduling ablation. However, in patients where either the risk of biopsy or the potential impact of a pneumothorax is considered to be high, the biopsy is performed immediately before ablation so that patients are subjected only once to the risk of pneumothorax, in a controlled situation in which the airway is secured and a pigtail catheter or chest tube can be placed if required.

Procedural Details

All procedures are performed using a 16-slice CT scanner with CT fluoroscopy (Lightspeed VCT, GE Healthcare, Waukesha, WI USA). After induction of general anesthesia and endotracheal intubation, patients are optimally positioned for the ablation procedure (most commonly in the lateral decubitus position). The tracking pads—consisting of an array of three pads placed in an L-shaped configuration—are placed on the patient's chest, typically away from where the pathology exists (and where the percutaneous ablation probe would be placed or a tube thoracostomy would be performed if required). A reference CT scan is performed, and the images are imported into the EMN system.

The EM field generator and tracking system are a portable unit with an articulating mechanical arm than can be wheeled up to the scanner and positioned over the operative field during needle or probe placement. After reviewing the target lesion on the CT scan, an entry point for the percutaneous probe is selected, and the point is marked on the skin using the CT laser marker system on the CT gantry. The patient is then slid out of the gantry, and the EMN device is positioned over the patient. The EMN device is used when advancing the ablation probe or biopsy needle to the target lung tumor. In this process, images are automatically reconstructed by the EMN system in the axial, sagittal, coronal, and oblique planes—using data from the previously acquired CT imaging—that correlate to the position of the advancing probe or needle. Eventually, CT fluoroscopy is obtained to confirm final placement of the ablation probe or biopsy needle and also to achieve optimal positioning within the lung tumor through fine adjustments if necessary.

For procedures performed without the use of EMN, an initial CT scan is obtained and the patient is marked as described above. The ablation probe or biopsy needle is then advanced into the target tumor using CT fluoroscopy alone. Computed tomographic fluoroscopy differs from standard fluoroscopy because it requires moving the patient into the CT gantry and then acquiring a scan of three successive images in the axial plane. Needle or probe manipulations are then made, and additional three-image scans acquired until successful deployment is achieved.

Outcomes Measured

Each EM-guided procedure (biopsy or ablation) was defined as an EM intervention. The following data were obtained: tumor diameter, distance from skin to tumor, body mass index, pathology of tumor, time for each intervention, number of readjustments, number of CT scans for intervention, number of skin punctures, CT fluoroscopy time, postoperative pneumothorax and the need for a tube thoracostomy, total days requiring a chest tube, and hospital length of stay. Statistical analysis was undertaken using SPSS (Windows, Version 11, SPSS Inc, Chicago, IL USA). A P value <0.05 was considered significant.

RESULTS

Over a 23-month period, 17 patients were prospectively enrolled. The mean age was 72 years (range, 60–84 years). Seven patients were women. The mean body mass index was 29.8 kg/m^2 (range, 22–36.1 kg/m^2). The mean tumor diameter was 2.33 cm (range, 0.6–7.9 cm). The mean (range) of the pulmonary function tests for these patients are as follows: forced expiratory volume in one second (FEV1) 1.69 (0.66–3.22) liters; FEV1 percentage predicted, 69.9% (25%–177%); force vital capacity (FVC), 2.73 (1.31–3.94) liters; FCV, percentage predicted, 78.5% (51–144%); and diffusing capacity of the lung for carbon monoxide percentage predicted, 52.6% (34%–89%). In addition, 8 of 17 patients (47%) had emphysema. Patients were randomized to EMN (n = 7) or CT fluoroscopy alone (n = 10). For some patients, additional ablation or biopsy procedures were performed and included in the study, and EMN was used based on the randomization arm.

In total, 23 procedures were performed under general anesthesia by either a thoracic surgeon or a radiologist. Twenty were ablation procedures and 3 were biopsies. Fourteen were performed for non–small cell lung cancer (4 with EMN, 10 with CT only), and 9 for metastases from other organs (4 with EMN, 5 with CT only). Despite randomization, patients receiving EMN had a trend for smaller tumors (mean diameter, 1.45 vs 2.90 cm; P = 0.06).

For the thermal ablation procedures, 11 lung tumors were located in the right upper lobe, 1 in the right middle lobe, 2 in the right lower lobe, 3 in the left upper lobe, and 3 in the left lower lobe. The mean and median distance from the skin to the lesion, in the axial plane, was 8.45 and 8.2 cm, respectively (range, 2.5–14.2 cm). The mean time to complete intervention was significantly less when EMN was used (mean, 7.6 vs 19 minutes; P = 0.022). Although not statistically significant, there were fewer skin punctures (mean, 1 vs 1.25; P = 0.082), fewer instrument adjustments (mean, 5.6 vs 11.8; P = 0.203), less CT fluoroscopy time (mean, 21.3 vs 34.3 seconds; P = 0.345), and fewer CT scans (mean, 7 vs 15; P = 0.204) whenever EMN was used.

Among all 17 patients, 14 developed a pneumothorax and 13 required placement of a pleural (pigtail) catheter. No patient required a large-bore chest tube or sclerosis. The median number of days with a pigtail catheter was 1 day (range, 1–4 days). In addition, the median length of stay was 2 days (range, 1–4 days) and was not different between the two groups.

DISCUSSION

Although CT guidance is the typical approach used in the thermal ablation of lung tumors, there is a concern regarding radiation exposure to both the patient and radiology staff. The theoretical risks associated with increased radiation exposure are difficult to prove, yet this matter is a topic of intense debate.[8,9] For these reasons, strategies to reduce radiation exposure, which include selecting low-dose CT scans, reducing the time of radiation exposure, increasing the distance between the CT scanner and the radiology staff, and routinely using lead shielding, are commonly used.

CT fluoroscopy is used in many centers to guide interventional procedures because it allows the radiology staff to remain in the CT room while the intervention is performed and confirmatory imaging is acquired. Procedural times are faster because there is less movement both of the patient in and out of the CT gantry and the staff walking in and out of the room, and minimal waiting to review the acquired image at the CT workstation. CT fluoroscopy is particularly useful for more lengthy procedures that require general anesthesia. However, although the radiation exposure is less when a three-image CT fluoroscopy scan is acquired for the interval assessment of device positioning than with a standard CT scan for the same purpose, the additional exposure still remains a concern, so many radiologists continue to use standard CT imaging alone without CT fluoroscopy.

Electromagnetic navigation is a relatively new modality that is becoming increasingly popular as an adjunct to bronchoscopy to aid in the transbronchial biopsy of peripheral lung lesions, the placement of fiducials to help guide stereotactic body radiation therapy, and the dye marking of small lung lesions before thoracoscopic resection.[10] Previously, the feasibility of using EMN for the CT-guided percutaneous ablation of lung tumors had been established.[7,11]

When EMN is not used, the interventionalist advances a needle or probe without the benefit of real-time (or near real-time) imaging. This may require additional smaller incremental steps and adjustments, particularly for more deeply located or smaller lesions. Because more interval images are typically needed to confirm the position of the percutaneous device, the overall time for completing the intervention is likely to be higher with CT guidance alone. This was confirmed in our study, where the use of EMN led to both a faster time and a trend toward fewer skin punctures to the completion of an intervention compared with CT fluoroscopy alone. In addition, these outcomes were achieved in patients who tended to have a smaller target lesion diameter.

However, EMN should not be used without CT confirmation of the device's position. As the device is introduced, the patient's anatomy may change from the baseline scan used for registering the EMN system. For instance, a pneumothorax may develop, which changes the relative location of the lung tumor from the baseline imaging. These factors can cause a deviation in the trajectory that must be accounted for by final confirmation of the device's position with CT imaging.

Another potential benefit is reduction of radiation exposure to the patient, interventionalist, and the radiology staff. In our study, the mean overall CT fluoroscopy time and number of CT scans needed were smaller for the EMN group; however, this difference was not statistically significant. It may be that our study was underpowered to demonstrate any difference because of the small sample size and will need to be investigated in future studies.

In conclusion, EMN seems to be a useful adjunct to assist with percutaneous pulmonary interventions such as the thermal ablation of lung tumors or pulmonary metastases.

Electromagnetic navigation reduces the amount of time needed for the completion of CT-guided thermal ablation of lung tumors. More study is required to conclusively determine if a benefit exists in terms of reduced radiation exposure compared with standard CT-guided approaches alone.

REFERENCES

1. Curley SA, Izzo F, Delrio P, et al. Radiofrequency ablation of unresectable primary and metastatic hepatic malignancies: results in 123 patients. *Ann Surg*. 1999;230:1–8.
2. Lu MD, Chen JW, Xie XY, et al. Hepatocellular carcinoma: US-guided percutaneous microwave coagulation therapy. *Radiology*. 2001;221:167–172.
3. Dupuy DE, Zagoria RJ, Akerley W, et al. Percutaneous radiofrequency ablation of malignancies in the lung. *AJR Am J Roentgenol*. 2000; 174:57–59.
4. Feng W, Liu W, Li C, et al. Percutaneous microwave coagulation therapy for lung cancer. *Zhonghua Zhong Liu Za Zhi*. 2002;24:388–390.
5. Lamprecht B, Porsch P, Pirich C, et al. Electromagnetic navigation bronchoscopy in combination with PET-CT and rapid on-site cytopathologic examination for diagnosis of peripheral lung lesions. *Lung*. 2009; 187:55–59.
6. Wood BJ, Locklin JK, Viswanathan A, et al. Technologies for guidance of radiofrequency ablation in the multimodality interventional suite of the future. *J Vasc Interv Radiol*. 2007;18:9–24.
7. Santos RS, Gupta A, Ebright MI, et al. Electromagnetic navigation to air radiofrequency ablation and biopsy of lung tumors. *Ann Thorac Surg*. 2010;89:265–268.
8. Brenner DJ, Hall EJ. Computed tomography—an increasing source of radiation exposure. *N Engl J Med*. 2007;357:2277–2284.
9. Tubiana M. Correspondence: computed tomography and radiation exposure. *N Engl J Med*. 2008;358:850–853.
10. Arenberg D. Electromagnetic navigation guided bronchoscopy. *Cancer Imaging*. 2009;9:89–95.
11. Dupuy DE, Morrell E, Mayo-Smith WW. Preliminary experience with a novel electromagnetic tracking system for CT-guided ablation procedures. Paper presented at the World Conference in Interventional Radiology; 2008; Los Angeles, CA.

CLINICAL PERSPECTIVE

Electromagnetic navigational bronchoscopy (ENB), a technology that provides us the ability to reproducibly reach peripheral pulmonary parenchymal nodules and masses for diagnostic and therapeutic indications, has continued to evolve over the last several years. There have been few prospective, especially randomized, trials that demonstrate superiority of ENB to other available technologies. In this article, Narsule and colleagues at Boston University performed a small trial that demonstrated to us that ENB has an efficient role to play in the performance of thermal ablation of malignant lung lesions. Perhaps, larger trials will better identify the role of this new technology.