Robotic Bronchoscopy



New technology that holds the promise of earlier and more accurate diagnosis of lung nodules

ung cancer is the leading cause of cancer deaths worldwide, with more patients dying every year from the disease than from prostate, breast, and colon cancers combined. Early identification, staging, and diagnosis are critical to improving lung cancer outcomes.

Survival rates in lung cancer largely depend on the stage at diagnosis. According to the American Lung Association's 2014 "Trends in Lung Cancer Morbidity and Mortality" report, from 2004 to 2010, the average five-year survival rate for localized lung cancer was 54.0 percent compared to 16.8 percent overall and 4.0 percent for a distant tumor.¹ However, the report notes that only 15 percent of individuals with lung cancer are diagnosed at an early stage when the cancer is localized.¹

Fox Chase Cancer Center in Philadelphia, Pa., is at the forefront of innovation, so it is not surprising that this former Association of Community Cancer Centers Innovator Award recipient is one of only three institutions in the country to implement a new technology that holds promise for patients with lung cancer and those on the cancer care team who help to treat them and manage their care.

Though a variety of diagnostic options are currently available for lung cancer, "all have limitations in accuracy, safety, or invasiveness," said Christopher J. Manley, MD, director of intervenThe Monarch Platform combines traditional endoscopic views into the lung with computer-assisted navigation based on three-dimensional models of the patient's own lung anatomy, providing physicians with continuous bronchoscope vision throughout the entire procedure.

tional pulmonology at Fox Chase. "These limitations can lead to false positives, false negatives, or side effects such as pneumothorax (collapsed lung) and hemorrhage, which may increase healthcare costs and extend hospital stays." The Monarch Platform could change that.

The new tool, a flexible endoscopic technology developed by Auris Health, Inc., in Redwood, Calif., enables physicians to diagnose, and eventually treat, hard-to-reach, small peripheral



Christopher J. Manley, MD, director of interventional pulmonology at Fox Chase.

lung nodules with greater precision than ever before. It was cleared by the U.S. Food and Drug Administration in March 2018.

How It Works

The Monarch Platform combines traditional endoscopic views into the lung with computer-assisted navigation based on threedimensional models of the patient's own lung anatomy, providing physicians with continuous bronchoscope vision throughout the entire procedure.

"Early detection and diagnosis of lung cancer is critical to improving survival. The Monarch Platform enhances our ability to evaluate, diagnose, and ultimately treat lung cancer by providing improved reach, vision, and control for minimally invasive bronchoscopic procedures," said Dr. Manley, who works with a multidisciplinary cancer care team at Fox Chase to employ minimally invasive techniques for diagnosis and treatment of lung cancers early on in diagnosis and staging and then in the later stages of the disease in palliation of symptoms. Diagnosis and staging includes bronchoscopy, which is the process of navigating through the airways using flexible, fiberoptic cameras to look at lung tumors and lung nodules, in order to diagnose lung cancer. He is one of the first physicians in the country to use the Monarch Platform in a clinical setting.

He describes the process of the biopsy of a lung nodule in detail and what a patient experiences during the procedure itself: "The Monarch is a robotic platform but it's also electromagnetic, meaning we create a magnetic field around the patient, which tells us where the robotic arm is in a space, and if we can link that to a high-quality, high-resolution CT scan, we can then tell where we are in the airways, and that helps us guide the catheter or robotic arm out to the lung nodule for biopsy," said Dr. Manley. "The patient gets a CT scan, which can be done anywhere, and it's loaded into the system; patients come in prior to the procedure and meet with one of us in clinic for consultation, and then the day of the procedure, they're taken off to sleep by the anesthesiologist; we advance our thin robotic camera down through the airways, navigate out to the lung nodule, and then do our biopsies. And at the same time, we can look at the lymph nodes under ultrasound; we can place our fiducial markers or gold seeds to help with delivering radiation, and that sort of thing."

This may sound like business as usual in terms of the process for biopsy and diagnosis of lung nodules; however, the difference is that it provides a level of accuracy not available previously. Although technology has advanced significantly since the development of the earliest robotics platforms used in medicine, the Monarch Platform is designed to address the limitations of current technology.

It is an improvement over endoscopic tools in the past because previous platforms "used the electromagnetic field to help guide us to the nodule, similar to a GPS for your car, but they didn't give us a robotic arm, which offers increased dexterity and movement and freedom to move in 360 degrees through the airways," Dr. Manley said. "Also, because the robotic arm is stable and stationary, it's easy to direct and won't get moved off course or adjusted without us meaning it to. This stability makes our biopsies very consistent, and controlling the catheter is very easy to do."

Training and Implementation

The evolution of these technologies has been ongoing for years, from the first flexible bronchoscopy to the first endobronchial ultrasound, to the first electromagnetic navigational platforms; these skills are taught to interventional pulmonologists at specialty fellowships, which follow critical care training, including all of the different platforms: how they work; what their limitations are; what their benefits are; and how to deploy them safely.

The Monarch system is similar to previous platforms, but there are also many differences. For 12 months, Dr. Manley traveled to the Monarch headquarters in California for formalized training, working first in rubber and foam models and then in human cadavers, until he was able to use the machine, travel out to simulated nodules, perform biopsies, and perform ultrasounds effectively. After that, Dr. Manley and his team felt that it was safe to move forward and institute this technology at Fox Chase.

In order to implement the Monarch Platform, there were many moving parts, yet Dr. Manley said that the process was seamless. The Monarch and Auris team flew out to Philadelphia from California, bringing with them a large technical team who worked closely with Fox Chase staff, including its technology team, endoscopy staff, endoscopy nursing staff, nurse educators, and physical plant staff over the course of a week-long installation and education process.

The Monarch is used to assess lung nodules that cannot be reached by traditional bronchoscopy. Even the very first cases were extremely successful. "We did six cases in our first two days. They went very smoothly, and we've been off and running since," Dr. Manley said.

Patient Safety and Outcomes

The top priority is ensuring safety for patients, and that means measuring outcomes and feedback. The team at Fox Chase is looking closely at how the machine works, whether it is doing what it is intended to do safely and effectively, and analyzing the large amount of data that it provides, such as nodule size and location, time of navigation, biopsy results, and whether there were any complications. "In these early cases, there's been significant concentration on patient safety and moving through the airways with good effect," Dr. Manley said. "The next step is looking at how quickly we're able to get out to the nodule that we're trying to biopsy, and whether we're able to do that faster, with a high level of safety, because the benefit of this device is that it will make the procedures shorter so it's less anesthesia for the patient, hopefully fewer biopsies for the patient, and complete diagnosis and staging in one short anesthetic period."

What's the Cost?

The price tag on such an investment is expensive, and the Monarch Platform was funded by donors at Fox Chase. Although there was a large capital purchase upfront, the return is seen in the level of patient-centered care Fox Chase is able to provide, which does not exactly have a price tag.

"In terms of a return on our investment, it's always hard to measure what the benefit is and what in terms of a dollar amount we should expect," said Dr. Manley. "The one aspect that we are concentrating on is trying to determine what the benefit is to our patient, and so despite the high initial cost to acquire the machine, if we can provide superior care with a shorter anesthetic period, a safer procedure, and better outcomes, then the cost will be worthwhile."

The procedure is covered by insurance, and no pushback is anticipated from insurers, Dr. Manley said.

Use at the Community Level

Whether this technology can be implemented outside of an academic setting remains to be seen, but it is possible with the right support. "I think that technologies like these are best used at high-volume centers," Dr. Manley said. "Our success comes from our consistency, and we have a dedicated team that performs bronchoscopies every day; we have dedicated respiratory therapists; specialized cytologists, specialized pathologists; technicians; an anesthesia team that's familiar with how the procedure works; how long it should be; what complications can occur; and so, to me, the more important thing is the team behind me." In other words, yes, it is replicable, but only within certain parameters namely, a specialized multidisciplinary team of cancer care providers.

Impact on Patients, Cancer Care as a Whole

The impact on patient-centered care is the bottom line. "What's important to remember is that early diagnosis of lung cancer is very, very important, so diagnosing a nodule when it's very small and easy to remove or easy to treat will give us better outcomes for our patients. Having a robust lung cancer screening program combined with a platform like this, which provides rapid and safe diagnoses with a high diagnostic yield, really helps us make an intervention early in our patients' lives," said Dr. Manley. "The significant benefit, the significant improvement in outcomes, is going to be from that early diagnosis and staging, so I think that's going to have sweeping changes on the cancer care for a



User touching the Monarch Tower's displays touch screen.



Full view powered on with stowed arms on Monarch Cart.



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User holding Monarch controller.

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Scope coming out of lung model.

lot of our patients because they're going to be treated earlier and their outcomes should be better."

What, then, does this mean for the future of lung cancer care, and how does it change the dialogue around lung cancer diagnosis and patient outcomes? "The landscape of cancer care is changing very rapidly, and we're finding out that we can institute technologies to have an impact early, and the earlier we can have the impact, the more it's felt, and the better the outcomes, so I think that the landscape of cancer care as I see it will have more robust screening programs, earlier interventions, more tailored therapies," Dr. Manley said. "All of these technologies that have come out in the last five years and especially the new robotic platform that we're using at Fox Chase, I think it enables us to make those early impacts in a noninvasive way, and as the landscape continues to evolve, we're going to be trying to bring technologies that benefit our patients."

Amy Hindman is a freelance writer with more than 10 years of experience writing in technology, healthcare, and oncology.

Reference

1. American Lung Association. Trends in lung cancer morbidity and mortality. Available online at: lung.org/ assets/documents/research/lc-trend-report.pdf. Last accessed January 3, 2019.



Full view of Monarch Platform.

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