After Lung Cancer Screening, Follow-Up Procedures May Be Riskier Than Thought

The cost of treating complications of invasive diagnostic procedures can be substantial.

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Being screened for lung cancer can lead to follow-up diagnostic procedures, including invasive ones. The risk of complications from those invasive procedures may be higher than previously thought, a new study suggests.

By analyzing information from medical insurance claims of more than 300,000 individuals, researchers estimated that, for people treated in community medical practices or hospitals, the complication rates of such procedures were roughly double those reported among participants in the more controlled clinical trial setting of the NCI-sponsored National Lung Screening Trial (NLST). Completed in 2010, NLST was the largest-ever randomized clinical trial of lung cancer screening.

The findings underline an important message for clinicians, said lead investigator Ya-Chen Tina Shih, PhD, a professor of health economics at the University of Texas MD Anderson Cancer Center. They should be sure to discuss the potential benefits and harms associated with lung cancer screening with low-dose computed tomography (low-dose CT) when talking to their patients about screening, she said.

More broadly, the study shows "the importance of going beyond the results from controlled clinical trials [such as NLST] when any new test or intervention is disseminated out into the community," said Barry Kramer, MD, MPH, former director of NCI's Division of Cancer Prevention, who was not involved in the current study.

Published January 14 in JAMA Internal Medicine, the study also found that the medical costs of treating the complications of these invasive diagnostic procedures "can be substantial," Shih said.

Risks and Benefits of Screening

NLST showed that screening with low-dose CT was better than chest x-rays at finding early-stage lung cancers and reduced the risk of dying from lung cancer in current and former heavy smokers.

Reported in 2011, these results led the US Preventive Services Task Force (USPTF) and several

professional societies to recommend annual screening with low-dose CT for people at high risk for lung cancer due to their smoking history.

In 2015, Medicare agreed to cover the costs of lung cancer screening with low-dose CT for beneficiaries ages 55–77 who are considered to be at increased risk. And, under the Affordable Care Act, many private insurers also cover the cost of screening for those at increased risk.

One potential risk of low-dose CT is that it results in many false-positive findings, such as a lung nodule, that, upon further testing, turns out not to be cancer. In NLST, nearly one-fourth of participants had a false-positive result over three rounds of annual screening with low-dose CT.

Although further imaging tests usually suffice to rule out lung cancer, invasive diagnostic procedures are sometimes needed. These invasive procedures, which include needle biopsy, bronchoscopy, and thoracic surgery, carry risks of complications that range from mild to severe.

Concern Over Real-World Complication Rates

Shih estimates that fewer than 5% of people who undergo one round of screening with low-dose CT are likely to have a finding that requires follow-up with an invasive procedure. However, she and her coauthors wrote, “As the number of individuals seeking lung cancer screening with [low-dose CT] increases, so too will the number of individuals undergoing invasive diagnostic procedures as a result of abnormal findings.”

After the NLST results were published, “the high rate of false-positive results and the complication rates in people who had invasive diagnostic procedures following those results were a concern,” said Shih. “So, we were interested in finding out whether the complication rates may be higher when you roll out the screening program to the general population” than they are in a clinical trial setting like NLST, she said.

Real-world complication rates could be higher for numerous reasons. For example, the study authors wrote, “participants in the NLST tended to be healthier than the screening-eligible population in the United States.” And complication rates tend to be lower in academic medical centers and large screening referral centers like those where NLST was conducted, noted Kramer.

Estimating the Risks and Costs of Screening in the Community

To estimate the real-world complication rates, Shih and her colleagues used information from a large national database of medical insurance claims from 2008 to 2013.

They put together a study population, or cohort, consisting of 174,702 individuals 55–77 years old, which is the age group eligible for Medicare coverage of lung cancer screening with low-dose CT. Because lung cancer screening with low-dose CT was not recorded in medical claims until late 2015, the study group consisted of individuals who had undergone the same types of invasive procedures that were reported in NLST to assess lung abnormalities, though not necessarily because they had a positive finding on a low-dose CT scan.

The cohort excluded people who had a lung cancer diagnosis within a year before or after these procedures. Therefore, it was more likely that they had an invasive procedure because of an incidental finding on imaging or a symptom prompting further investigation, rather than as part of follow-up of a pre-existing lung cancer diagnosis.

Because some of the complications could have been due to things other than the invasive procedures, the team subtracted out the complication rates of a comparable group of 169,808 people that did not undergo the procedures.

Using this approach, they estimated a real-world post-procedure complication rate of 22.2% among people ages 55–64 and 23.8% among those ages 65–77. By comparison, the complication rates reported in NLST were 9.8% and 8.5%, respectively.

The average medical costs of these complications, which included insurance payments plus out-of-pocket costs, ranged from $6,320 for minor complications to $56,845 for major complications.

Limitations of the Study

As the study authors noted, their analysis had several limitations. One important limitation, Kramer said, is that "the people in this cohort didn't necessarily have a low-dose CT scan. They may have been identified for workup with an invasive procedure because of a chest x-ray or cough or an incidental CT finding."

Another key limitation is that the claims database does not include information on whether or how much people smoked, whereas all patients screened in NLST were current or former heavy smokers.

Due to these and other limitations, the study authors wrote, "the complication rates estimated in our study are more suggestive than conclusive." Nevertheless, Kramer said, the study "gives us an indication that we should be aware that the complication rates in a community setting could be higher" than those reported in NLST.

Regarding the cost estimates, Kramer said, "It's no surprise that having complications triggered by these procedures can be expensive. But even so, the study authors may have underestimated the financial burden in the community," because they couldn't account for hidden costs such as lost wages due to time missed from work.

Take-Home Messages and Future Research

In addition to the importance of informing patients of the possible harms of screening, one key take-home message of the study, Shih said, is that people who undergo recommended screening and need invasive follow-up procedures should "try to find high-quality providers to perform those procedures" to reduce the risk of complications.

Shih also hopes physicians will convey to patients that "the tradeoff between harms and benefits is going to be worse in people who don't meet the eligibility criteria for screening but want to be

screened anyway," even if that means paying out of pocket for screening.

Her team plans to conduct a follow-up analysis once data are available for a large enough cohort of individuals whose medical claims indicate that they received lung cancer screening with low-dose CT.

"This study is not definitive," Kramer said, "but it's an indicator of the importance of [also] doing prospective studies that look specifically at complication rates and costs incurred in people in community settings who undergo low-dose CT for lung cancer screening.

"It's important to know not only if interventions could work, which is the realm of controlled clinical trials, but also whether they do work the same way in the community and whether they have the same balance of benefits and harms," he continued.

NCI programs such as the NCI Community Oncology Research Program and Population-based Research to Optimize the Screening Process (PROSPR) were set up to facilitate that type of research.

PROSPR is a large research initiative focused on cancer screening delivery in community settings and "aims to look at both harms and costs of cancer screening," including lung cancer screening, said Paul Doria-Rose, Ph.D., chief of NCI's Healthcare Assessment Research Branch. PROSPR includes research centers focused on lung, colorectal, and cervical cancer screening.

Studies designed to find ways to maintain the benefits of screening while reducing the harms are also ongoing, Kramer said. "One important way to do that is to look for noninvasive ways to follow up on abnormalities without resorting to invasive tests," he said.

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http://beta.docker.cancerhealth.com/blog/lung-cancer-screening-followup-procedures-may-riskier-thought