

CT Scans Cut Lung Cancer Deaths by One-Fifth

BY PATRICE WENDLING

A large randomized national trial has provided the first evidence of a significant reduction in lung cancer deaths with a screening test.

The National Lung Screening Trial (NLST) reported a 20.3% reduction in lung cancer mortality among heavy smokers screened with low-dose helical computed tomography (CT), as compared with those given standard chest x-rays. The trial enrolled more than 53,000 older, high-risk individuals.

In addition, deaths from any cause, in-

cluding lung cancer, were 7% lower among participants screened with low-dose helical CT, also known as spiral CT.

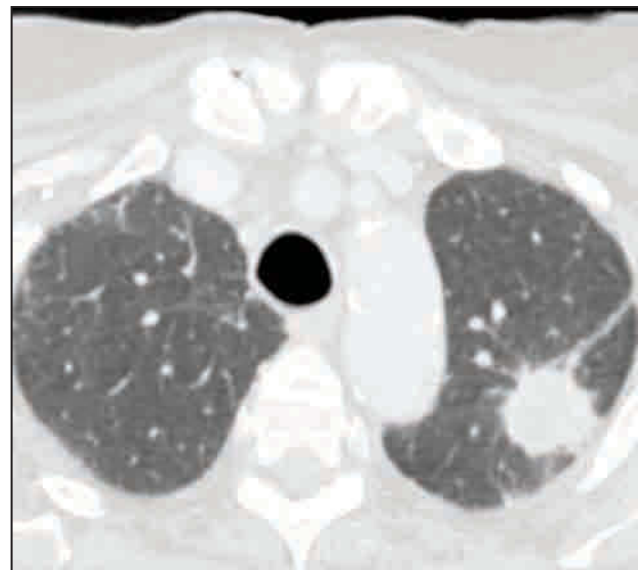
The initial results were released today by the study sponsor, the National Cancer Institute, after the study's independent data and safety monitoring board recommended halting the trial. "The fact that low-dose helical CT provides a decided benefit is a result that will have implications for screening and management of lung cancer for many years to come," Dr. Christine Berg, project officer for the lung screening study at the NCI, said in a statement. Beginning in 2002, the NLST recruited about 53,500 American men and women, aged 55-74 years, who were current or former smokers with a smoking history of at least 30 pack-years. It randomly assigned them to receive three annual screens with low-dose helical CT or chest x-ray. Helical CT uses x-rays to obtain a multiple-image scan of the entire chest during a 7- to 15-second breath-hold, whereas a standard chest x-ray produces only a single image of the chest from a sub-second breath-hold.

At the time of the Oct. 20, 2010 analysis, 354 deaths from lung cancer had occurred in the CT arm vs. 442 in the chest x-ray group. Approximately 25% of deaths in the NLST were due to lung cancer.

NCI director Harold E. Varmus said the well-designed study used rigorous scientific methods and that its findings could spare countless lives.

"Lung cancer is the leading cause of cancer mortality in the U.S. and throughout the world, so a validated approach that can reduce lung cancer mortality by even 20% has the potential to spare very significant numbers of people from the ravages of this disease," he said. "But these findings should in no way distract us from continued effort to curtail the use of tobacco, which will remain the major causative factor for lung cancer and several other diseases."

Like other screening strategies, the use



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Researchers in the National Lung Screening Trial reported a 20.3% reduction in lung cancer mortality among heavy smokers screened with low-dose helical CT.

of low-dose helical CT has disadvantages including the cumulative effects of radiation from multiple CT scans, complications among patients who need additional testing to make a definitive lung cancer diagnosis, and the anxiety and added cost associated with investigating incidental findings picked up on CT.

[Editor's note: In 2009, investigators reported that low-dose CT screening was associated with twice the rate of false positives and more unneeded interventions, compared with chest x-ray, in a randomized feasibility trial that preceded the NLST. But low-dose CT also detected twice as many lung cancers as did chest x-ray screens in that study.]

Although the NLST trial cohort was ethnically representative of the high-risk U.S. population, the researchers noted that participants were highly motivated and screened at major medical centers. Thus, the results may not accurately predict the effect of CT screening for other populations.

"What has happened here is that the technology shows you can cut down on lung cancer deaths, the leading cause of cancer mortality, and save nearly as many

lives as the number of people who die from breast cancer per year. We as a medical community now need to figure out how to do this in a way that the cost is acceptable to the public," Dr. Bruce E. Johnson, an official with the American Society of Clinical Oncology and director of the Lowe Center for Thoracic Oncology at the Dana-Farber Cancer Institute in Boston, said in a statement.

A more detailed analysis of the NLST results is expected to be published in the coming months, although a paper describing its design and protocol was published by the journal *Radiology*.

The National Cancer Institute sponsored the study. ■

VITALS

Major Finding: Lung cancer deaths were reduced 20% among participants screened regularly with low-dose helical computed tomography vs. standard chest x-ray.

Data Source: The National Lung Cancer Screening Trial in about 53,500 current and former heavy smokers.

Disclosures: The study was sponsored by the National Cancer Institute.

HHS Tobacco Control Strategy Includes Graphic Warnings

BY ALICIA AULT

FROM THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

The Department of Health and Human Services issued a sweeping new tobacco control strategy that would require cigarette makers to place photographs and graphic depictions of the harms of smoking prominently on the packages or in advertising.

The graphic warnings – which will be regulated by the Food and Drug Administration – were part of a proposed rule issued by the agency. They were required by the Family Smoking Prevention and Tobacco Control Act and are the centerpiece of the 66-page strategy released by HHS.

"Every day, almost 4,000 youth try a cigarette for the first time and 1,000 youth become regular, daily smokers," HHS Secretary Kathleen Sebelius said in a statement. "Today marks an important milestone in protecting our children and the health of the American public."

HHS estimates that 443,000 Americans die from tobacco-related diseases each year, with 50,000 of those deaths caused by secondhand smoke. Some 8.6 million Americans have smoking-related chronic diseases.

"When this rule takes effect, the health consequences of smoking will be obvious every time someone picks up a pack of cigarettes," FDA Commissioner Margaret Hamburg said.

The agency is going to require a disturbing photograph or cartoon graphic that takes up half a package of cigarettes or is prominently placed in an ad.

The graphic would depict one of the following warnings: "Cigarettes are addictive," "Tobacco smoke can harm your children," "Cigarettes cause fatal lung disease," "Cigarettes cause cancer," "Cigarettes cause strokes and heart disease," "Smoking during pregnancy can harm your baby," "Smoking can kill you," "Tobacco smoke causes fatal lung disease in non-smokers," and "Quitting smok-

ing now greatly reduces serious risks to your health."

The cancer warning might have a photograph of an obviously terminally ill person in a hospital bed, or a close-up of a mouth riddled with rotting teeth and sores. The heart disease warning might have a photograph of a man clutching his chest, in the throes of a myocardial infarction.

The FDA is seeking the public's input on which graphic depiction to use for each warning. It is accepting comments until Jan. 9, 2011. Then, the agency will select one graphic for each of the nine warnings and publish the choices in a final rule to be issued by June 22, 2011.

Manufacturers would have 15 months from that time – by October 2012 – to come into compliance. If they do not comply, their product will be banned from sale in the United States.

Public health advocacy groups applauded the HHS plan and the FDA proposal. "The new warnings represent the most sig-



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The FDA is seeking comments on what required warnings to include on cigarette packages, including comments on the color graphics that are included in the proposal.

nificant change in U.S. cigarette warnings since they were first required in 1965," Matthew L. Myers, president of the Campaign for Tobacco-Free Kids, said in a statement.

The HHS strategy paper recommended expanding tobacco cessation services and accel-

erating the adoption of smoke-free laws across the country. According to the HHS, if the agency receives funding and all of the initiatives were to go forward, the country could meet the Healthy People 2010 objective to reduce the smoking rate to 12% of American adults. ■