

A Closer Look—Who Are We Screening for Lung Cancer?

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Abstract

Objective: To evaluate the characteristics of individuals receiving lung cancer screening (LCS) and identify those with potentially limited benefit owing to coexisting chronic illnesses and/or comorbidities.

Patients and Methods: In this retrospective study in the United States, patients were selected from a large clinical database who received LCS from January 1, 2019, through December 31, 2019, with at least 1 year of continuous enrollment. We assessed for potentially limited benefit in LCS defined strictly as not meeting the traditional risk factor inclusion criteria (age <55 years or >80 years, previous computed tomography scan within 11 months before an LCS examination, or a history of nonskin cancer) or liberally as having the potential exclusion criteria related to comorbid life-limiting conditions, such as cardiac and/or respiratory disease.

Results: A total of 51,551 patients were analyzed. Overall, 8391 (16.3%) individuals experienced a potentially limited benefit from LCS. Among those who did not meet the strict traditional inclusion criteria, 317 (3.8%) were because of age, 2350 (28%) reported a history of nonskin malignancy, and 2211 (26.3%) underwent a previous computed tomography thorax within 11 months before an LCS examination. Of those with potentially limited benefit owing to comorbidity, 3680 (43.9%) were because of severe respiratory comorbidity (937 [25.5%] with any hospitalization for coronary obstructive pulmonary disease, interstitial lung disease, or respiratory failure; 131 [3.6%] with hospitalization for respiratory failure requiring mechanical ventilation; or 3197 [86.9%] with chronic obstructive disease/interstitial lung disease requiring outpatient oxygen) and 721 (8.59%) with cardiac comorbidity.

Conclusion: Up to 1 of 6 low-dose computed tomography examinations may have limited benefit from LCS.

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Lung cancer is the second most diagnosed cancer and remains the leading cause of cancer-related death, accounting for approximately 25% of cancer deaths in the United States.¹ Results from the landmark National Lung Screening Trial (NLST) demonstrated a 20% reduction in lung cancer mortality with an annual low-dose computed tomography, which led to recommendations by the United States Preventive Services Task Force (USPSTF) and coverage for lung cancer screening (LCS).²⁻⁴

The focus of LCS has been to identify the highest risk population who develop lung cancer. However, this strategy also tends to identify individuals with severe and often life-limiting comorbidity. Hence, benefits of LCS are highly variable and may lead to

unnecessary diagnoses, testing, and treatments in specific populations. Highly comorbid and older populations were shown to experience higher complications during the evaluation of LCS examination findings.⁵ Given a <0.33% absolute risk reduction for LCS, careful patient selection is necessary to ensure that the benefits outweigh the harms.⁶

Criteria for LCS inclusion are based on objective risk factors that predispose individuals to the development of lung cancer (age 50-80 years, a 20-pack year smoking history, and have smoked within the past 15 years).³ These criteria were initially based on the NLST and were recently revised from 30- to 20-pack years, with a starting age of 55-50 years, after modeling studies reported an increase in life-years gained, with a decrease in

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overdiagnosis in this expanded population.⁷ Criteria for LCS exclusion are based on elements that may indicate risks that outweighs the benefits but are not clearly defined. The USPSTF generalizes exclusions to individuals with health problems that substantially limits life expectancy or the ability or willingness to undergo curative lung operation—both are areas for subjective interpretation.⁸⁻¹¹

To date, most studies characterized patient demographics and outcomes of those receiving LCS with an assumption that LCS is appropriate in these cohorts. In particular, few studies evaluated potentially life-limiting comorbidities, that is, competing cause of death in those screened. We used the national administrative health claims to identify individuals aged older than 18 years, who underwent LCS to characterize and identify patients and evaluate risk factors and/or comorbidities, which may potentially limit benefit from LCS.

PATIENT AND METHODS

This is a retrospective study of LCS use in the United States using Optum deidentified Clinformatics Data Mart. This study was approved by the University of Texas Medical Branch institutional review board, and informed consent was not obtained owing to the nature of the study.

We included all patients who received LCS from January 1, 2019, through December 31, 2019, and had at least 1 year of previous continuous enrollment. Lung cancer screening was identified by current procedural terminology code G0297 or 71271. Non-CT thorax were identified by current procedural terminology codes 71250, 71260, 71270, and 71275. The variables assessed were age, sex, race/ethnicity, US geographic region, hospitalization, and comorbidities in the 12 months before LCS. Comorbidities were defined based on the Elixhauser comorbidity score as previously defined.¹²

Next, we assessed individuals who may not meet the LCS criteria based on the following 2 categories: (1) strict inclusion criteria not met in which an individual fell outside the traditional NLST or USPSTF inclusion risk factor(s) (age <55 or >80 years, CT thorax in 11 months before LCS, and a history of nonskin cancer); and (2) liberal exclusion conditions present to investigate less well-

defined comorbid life-limiting condition(s) that may attenuate LCS benefit. Patients with the highest risk of developing lung cancer also reported the highest risk of comorbid cardiovascular and respiratory disease. These comorbidities may be life-limiting and adversely shift the benefit:harm ratio. We defined the comorbid life-limiting condition(s) as patients with any of the following: 3 or more hospitalizations; severe respiratory disease (chronic obstructive disease [COPD]/interstitial lung disease [ILD] and either prescribed long-term oxygen therapy or hospitalized for respiratory failure requiring mechanical ventilation); and severe cardiac disease. Severe cardiac disease was defined as a heart failure diagnosis with either 2 or more hospitalizations for decompensated cardiac disease or patients with a cardiac resynchronization/defibrillation device.

Patient and clinical characteristics were summarized as frequencies and percentages or mean \pm SDs and compared with the χ^2 test or *t* tests as appropriate. All analyses were performed using SAS 9.4. The significance level was set at *P* value of less than .05.

RESULTS

In 2019, 68,129 individuals underwent 69,028 LCS examinations. Of these, 51,551 patients had continuous enrollment in the 12 months before LCS and were analyzed for this study. The Table summarizes the characteristics of the LCS cohort. Overall, mean \pm SD age was 67.5 years, approximately half were women (25,448 [49.4%]), and most patients who underwent LCS recorded no hospitalizations in the preceding year.

Next, we looked at individuals who may have potentially limited benefit of LCS. Of all LCS individuals, 8391 (16.3%) did not meet either strict inclusion risk criteria or possessed liberal exclusion conditions. Of those who did not meet strict inclusion, a small portion were because of age (317 [3.8%]), and over a quarter reported a history of nonskin malignancy (2350 [28%]) and/or underwent a previous CT thorax within the previous 11 months (2211 [26.3%]). A high proportion of individuals with COPD, ILD, and congestive heart failure qualified our definition of potentially limited benefit (67.9%, 71.7%, and 48.7%, respectively).

TABLE. Characteristics of Patients Who Underwent LCS^a

	All LCS N=51,551	Potentially limited benefit n=8391	P
Age (y), mean ± SD	67.5±5.9	68.1±6.5	<.0001
Sex, n (%)			
Female	25,448 (49.4)	4304 (51.3)	<.0004
Male	26,100 (50.6)	4087 (48.7)	
Unknown	3 (<0.01)	0	
Region, n (%)			<.0001
Midwest	13,578 (26.3)	2029 (24.2)	
Northeast	8706 (16.9)	1304 (15.5)	
South	21,581 (41.9)	3923 (46.8)	
West	7508 (14.6)	1109 (13.2)	
Unknown	178 (0.3)	26 (0.3)	
Hospitalizations in previous y, n (%)			<.0001
0	45,948 (89.1)	5758 (68.6)	
1	4042 (7.8)	1566 (18.7)	
2	1001 (1.9)	517 (6.2)	
3+	550 (1.1)	550 (6.6)	
Total Elixhauser score, mean ± SD ^b	2.0±2.1	3.5±2.7	<.0001
Comorbidity components, n (%)			
Chronic obstructive pulmonary disease (yes)	5744 (11.1)	3900 (46.5)	<.0001
Interstitial lung disease (yes)	53 (0.1)	38 (0.45)	<.0001
Coagulopathy (yes)	635 (1.2)	203 (2.4)	<.0001
Congestive heart failure (yes)	2641 (5.1)	1285 (15.3)	<.0001
Pulmonary circulation disorders (yes)	673 (1.3)	334 (4.0)	<.0001
Hypertension without complications (yes)	21,985 (42.6)	4588 (54.7)	<.0001
Hypertension with complications (yes)	2852 (5.5)	1080 (12.9)	<.0001
Chronic pulmonary disease (yes)	16,151 (31.3)	5314 (63.3)	<.0001
Diabetes without complications (yes)	7708 (14.9)	1710 (20.4)	<.0001
Diabetes with complications (yes)	5771 (11.1)	1416 (16.9)	<.0001
Renal failure (yes)	3113 (6.0)	897 (10.7)	<.0001
Liver disease (yes)	1543 (2.9)	363 (4.3)	<.0001

^aLCS, lung cancer screening

^bElixhauser comorbidity components: chronic pulmonary disease, congestive heart failure, valvular disease, pulmonary circulation disorders, peripheral vascular disorders, hypertension, paralysis, other neurological disorders, diabetes-uncomplicated, diabetes-complicated, hypothyroidism, renal failure, liver disease, peptic ulcer disease excluding bleeding, AIDS, lymphoma, metastatic cancer, solid tumor without metastasis, rheumatoid arthritis/collagen vascular diseases, coagulopathy, obesity, weight loss, fluid and electrolyte disorders, blood loss anemia, deficiency anemia, alcohol abuse, drug abuse, psychoses, and depression.¹¹

When we compared all LCS individuals with those defined as having potentially limited benefit, the demographic characteristics (average age, sex, and geographic locations) were similar. Overall, only a small portion of those with liberal exclusion(s) criteria were related to cardiac comorbidity (≥ 3 hospitalizations [550 {6.6%}]; implantable cardiac support device for end-stage heart disease with ≥ 2 hospitalizations/previous year [719 {8.6%}]). However, nearly half experienced severe respiratory disease (3680 [43.9%]). These included hospitalization for

respiratory diagnosis of COPD, ILD, or respiratory failure (937 [25.5%]), hospitalization for respiratory failure requiring mechanical ventilation (131 [3.6%]), or COPD/ILD requiring outpatient oxygen (3197 [86.9%]).

DISCUSSION

Our study reported a significant number of individuals who may not meet the strict inclusion criteria, and up to 1 in 6 individuals undergoing LCS may have potentially limited benefits owing to comorbidity mostly because of severe cardiopulmonary conditions posing

as competing cause(s) of death. The high prevalence of severe comorbidities observed when compared with NLST warrant specific discussions and incorporation of comorbidities into screening decisions because they affect the general health status and, based on their severity, may affect the balance of risks and benefits of LCS.

Evidence for screening outside the strict inclusion or liberal exclusion criteria is limited. A recent single-center study reported that 19% of the LCS examinations were performed in individuals who did not meet the traditional USPSTF inclusion criteria, and more than 40% experienced 3 or more comorbidities using a decentralized approach.¹³ A veteran's study reported, on average, individuals who underwent LCS had more than 4 comorbidities with 33.2% experiencing COPD and 16.6% heart disease; however, the data were limited because they did not indicate the severity of the comorbidity.¹⁴ The largest published cohort to date examines the American College of Radiology's Lung Cancer Screening registry of over a million screened persons and found that 10% did not meet the strict inclusion criteria and included more older persons who smoke.¹⁵ These previous studies have limited generalizability because they are centers or registries with dedicated interest and resources for LCS. This study used information from a large real-world, representative cross-sectional cohort in the United States.

We based our liberal exclusion category on the existing comorbidity data shown to potentially limit 5- to 10-year of life expectancy, which may preclude individuals from the LCS benefit. Cardiovascular disease affects 98% of the population who received LCS.¹⁶ Heart failure (regardless of the ejection fraction) associated with hospitalization has a 5-year 75% mortality and median survival of 2.1 years.¹⁷ Individuals with advanced heart disease requiring an implantable cardiac device demonstrate a 5-year mortality of approximately 50% and high rate of hospitalizations.^{18,19} This may be the rationale why the NLST excluded individuals with pacemakers.⁶ Among patients with non—small cell lung cancer, comorbid cardiovascular diseases (heart failure, myocardial infarction, and cardiac arrhythmias) are

associated with 1.5-2 times increased mortality, and multiple cardiovascular comorbidities had approximately 2.5 times increased mortality.²⁰

Respiratory disease is also a common comorbidity among the population who received LCS and may also limit the benefits of LCS. Patients with COPD demonstrate double the risk of developing lung cancer,⁵ but individuals with severe COPD (GOLD 3-4) reported no mortality benefit with LCS.²¹ This was because of a higher rate of nonlung cancer deaths mostly related to respiratory and cardiovascular comorbidities, higher rate of complications from the evaluation and treatment of nodules or cancer,²² and reduced lung cancer operability.^{22,23} Finally, the NLST excluded individuals requiring home oxygen supplementation for undisclosed reasons but may be related to poor survival at 5 and 10 years (57% and 24%, respectively) among individuals with COPD.^{6,24}

The American Thoracic Society acknowledges choosing whom to screen for LCS is a complex interplay of risk of developing LC, treatment-related harms, and competing the risk of death.⁷ Proposed strategies that may identify individuals with the best risk:benefit ratio have been exclusion of those with life expectancy less than 5 years^{9,25} or 10 years.²⁶⁻²⁸ The National Cancer Institute defines those with high benefit of LCS as if an individual stood to gain 16.2 life days or more and recorded a life expectancy of at least 5 years.²⁹ This same threshold was further supported in microsimulation analyses conducted during development of the most recent CHEST LCS guidelines.³⁰ The NLST excluded those with a medical condition that posed a significant risk of mortality during the 8-year trial period without guidance on how to identify this population.³ Critiques of this strategy are numerous. Providers often overestimate, underestimate, or avoid discussing life expectancy with the patients.³¹ Patients may not value life expectancy in their decision making. Another strategy uses life-gained calculations,³² such as the Life Years gained from Screening-computed tomography model²⁹ that calculates the difference in life expectancy with and without LCS, including factors, such as comorbidity and performance status. Determining a specific life-gained threshold is difficult owing to the complexity of maximizing

cost, screening efficiency, patient-centered outcomes, and mortality benefits of LCS. Discussion of these results may be important in the shared decision-making process.

Appropriate timing and intervals for LCS are another consideration. The NLST excluded those with previous imaging within 18 months, likely to reduce over imaging. We chose previous 11 months to look for any CT thorax in our study as a conservative interval compared with the more liberal previous 18 months for any CT thorax imaging defined by the NLST. There was a moderate number of LCS in patients who reported another type of CT thorax imaging performed within the previous 11 months. Previous diagnostic CT thorax examinations may be appropriate to review in lieu of repeating LCS examinations more frequently than annually. This can limit the number of imaging examinations and radiation exposure. Less than half of individuals who underwent LCS and CT thorax within the previous 11 months had their examinations performed at the same facility, which may also highlight a need for universal electronic health information exchange.

There were limitations to this study. The biggest limitation is that we did not possess the outcomes of mortality for these patients to determine whether the population defined as potentially limited benefit reported a higher mortality than those without these defined factors. However, we particularly chose risk factors with evidence of increased mortality and did not suspect that the lung cancer screened population with these defined comorbidities were healthier or unlikely to experience different mortality than the populations that were studied. We cannot assess whether ordering providers considered the exclusion criteria. We presume patients had shared decision making with their provider before a decision for the LCS. This should include potential exclusionary criteria, but we cannot assess the quality of this process. Previous studies have shown that shared decision making rarely occurs, and the quality is shown poor at best.³³⁻³⁵ In addition, we presume individuals with LCS met the eligibility regarding the smoking history. We cannot verify these data. However, smoking history documentation was shown to be extremely unreliable, and given the high rate of not

meeting other eligibility criteria, this presumption might underestimate the number of ineligible patients.³⁶ By contrast, the use of risk calculators might have been used for individuals who did not meet the traditional eligibility criteria, which could not be assessed. The use of the Elixhauser comorbidity index correlate with clinical outcomes in retrospective studies of screening for other malignancy but not LCS; in addition, it does not capture the severity of the disease. Finally, results from Optum may not be generalizable to non-Optum health plans. In addition, we cannot exclude the possibility of coding error—whether the CT scans were ordered for a clinical reason other than LCS.

To our knowledge, this is the first large real-world study to observe carefully and to define and characterize individuals who may have potentially limited benefit of LCS. Further research is needed to help guide clinical decision making in patients with comorbidities in whom LCS may not benefit. The Personalised Lung Cancer Screening study is an ongoing study using simulation models to estimate the effect of comorbidity, functional limitations, and impaired pulmonary function in LCS individuals.³⁷

CONCLUSIONS

In this large nationally representative sample, we identified 1 of 6 low-dose computed tomography may have limited benefit from LCS owing to competing comorbidities. LCS should include those with both a high risk for cancer and a life expectancy long enough to benefit from screening, evaluation, and treatment. Future studies are needed to discern the association between comorbidities and LCS outcomes and implement standardized measures for incorporating comorbidities in screening decisions.

POTENTIAL COMPETING INTERESTS



The authors report no competing interests.

Abbreviations and Acronyms: COPD, chronic obstructive pulmonary disease; **ILD**, interstitial lung disease; **LCS**, lung cancer screening; **NLST**, National Lung Screening Trial; **USPSTF**, United States Preventive Task Force

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