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Community Outreach

Initial Results from Mobile Low-Dose Computerized Tomographic Lung Cancer Screening Unit: Improved Outcomes for Underserved Populations

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Disclosures of potential conflicts of interest may be found at the end of this article.

Key Words. Lung cancer screening • Underserved populations • Mobile low-dose helical computed tomography

Abstract

Introduction. The National Lung Screening Trial (NLST) demonstrated that screening high-risk patients with low-dose computed tomography (CT) of the chest reduces lung cancer mortality compared with screening with chest x-ray. Uninsured and Medicaid patients usually lack access to this hospital-based screening test because of geographic and socioeconomic factors. We hypothesized that a mobile screening unit would improve access and confer the benefits demonstrated by the NLST to this underserved group, which is most at risk of lung cancer deaths.

Patients and Methods. We created a mobile unit by building a Samsung BodyTom portable 32-slice low-dose CT scanner into a 35-foot coach; it delivers high-quality images for both soft tissue and bone and includes a waiting area and high-speed wireless internet connection for fast image transfer. The unit was extensively tested to show robustness and stability of mobile equipment. This project was designed to screen uninsured and underinsured patients, otherwise with eligibility criteria identical to that of the National Lung Screening Trial, with the only difference being exclusion of patients eligible for Medicare (which provides financial coverage for CT-based lung cancer screening).

Results. We screened 550 patients (20% black, 3% Hispanic, 70% rural) with a male-to-female ratio of 1.1:1, median age 61 years (range, 55–64), and found 12 lung cancers at initial screen (2.2%), including 6 at stage I–II (58% of total lung cancers early stage) and 38 Lung-RADS 4 (highly suspicious) lesions that are being followed closely. Incidental findings included nonlung cancers and coronary artery disease.

Discussion. In this initial pilot study, using the first mobile low-dose whole body CT screening unit in the U.S., the initial cancer detection rate is comparable to that reported in the NLST, despite excluding patients over the age of 64 years who have Medicare coverage, but with marked improvement of screening rates specifically in underserved sociodemographic, racial, and ethnic groups and with better outcomes than conventionally found in the underserved and at lower cost per case. ***The Oncologist*** 2020;25:e777–e781

Implications for Practice: This study shows clearly that a mobile low-dose CT scanning unit allows effective lung cancer screening for underserved populations, such as impoverished African Americans, Hispanics, Native Americans, or isolated rural groups, and has a pick-up rate of 1% for early stage disease. If confirmed in a planned randomized trial, this will be policy changing, as these groups usually present with advanced disease; this approach will produce better survival data at lower cost per case.

Introduction

Lung cancer remains the commonest cause of cancer deaths. Screening by plain chest radiography has not improved survival. Using low-dose helical computed tomography (LDCT) screening, the National Lung Screening Trial (NLST) demonstrated a 20% improvement in tumor-specific survival and a statistically significant increase in

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overall survival when compared with plain chest radiography [1]. In the first round of screening, the NLST reported 270 confirmed cases of lung cancer (3.8%). The pilot U.K. Lung Cancer Screening randomized controlled trial, comparing low-dose computed tomography (CT) with "usual care," reported 34 cases of lung cancer among 1,994 scanned participants (1.7%) at first scanning [2]. More recently, the Dutch-Belgian NELSON trial further confirmed the utility of this approach [3], showing that additional screening increased the numbers of lung cancers found [4].

Fewer than 4% of patients in the NLST study were black, compared with the national demographic of 12.2% [5]. Blacks have a higher incidence and higher death rate from lung cancer than do whites. The NLST showed that blacks derived a greater survival benefit from LDCT screening than whites [1], notwithstanding the low rate of accrual.

Although survival benefit from LDCT remains controversial because of some negative screening trials [6], most of these negative studies have been underpowered to identify a statistically significant survival benefit. There is a substantial false-positive rate in LDCT screening programs and a need to improve their cost efficiency and specificity, and we have attempted to achieve this by focusing on traditionally underserved populations with heavy smoking characteristics and poor survival figures for lung cancer.

A traditional limitation of LDCT has been that the size and weight of whole body CT scanners require installation at hospital- or clinic- based centers, causing reduced access for the group of patients that most often present with advanced lung cancer—heavy smokers, those affected by poverty, poor health education, and geographic isolation. These population groups typically do not participate in hospital-based screening activities and usually first present with advanced cancer [7].

We hypothesized that, analogous to mobile mammography, a mobile LDCT unit would offer improved access for lung cancer screening but discovered that no commercial or research mobile LDCT units were available in the U.S. In collaboration with Samsung Neurologica (Danvers, MA) and Frazer Ltd (Bellaire, TX), we created the first such *mobile* unit in the United States, to our knowledge, and initiated an institutional review board (IRB)–approved program to assess its utility in lung cancer screening, supported by grants from the Bristol-Myers Squibb Charitable Foundation and the Leon Levine Foundation.

Subjects, Materials, and Methods

The BodyTom CT is a portable 32-slice low-dose CT scanner, built into a 35-foot coach, and delivers high-quality images for both soft tissue and bone. It includes a waiting area, high-speed wireless internet connection for fast image transfer, and a portable electronic tablet that delivers smoking cessation and health education programs; there is also a shared decision-making video aid available in English and Spanish. It is easily accessible for handicapped persons. The unit has been repeatedly tested to ensure robustness and stability of the diagnostic equipment after transport and mobile use.

We employ the Lung CT Screening Reporting and Data System (Lung-RADS) approach to lesion classification, providing high specificity and sensitivity in lesion assessment [8], and use electronic image transmission for reporting and central review by an expert panel composed of pulmonologists, diagnostic radiologists, and medical oncologists with a specific interest in lung cancer. This unit has been certified as a lung cancer screening Center of Excellence by the Lung Cancer Alliance. It is noteworthy that the Lung-RADS diagnostic system remains under active clinical investigation, and a recent study from NLST has suggested that Lung-RADS 2 lesions may be more dangerous than previously thought [9]. More recently, Zhang and colleagues (2019) have suggested that a deep convolutional neural network (compared with a clinical panel review) can improve the precision of lung cancer detection via CT scanning [10]. This issue remains under review by our Quality Improvement (QI) team as a continuous QI process with repeated review and follow-up of initial and follow-up scans. For the purposes of the present report, only the first round of LDCT screening has been considered, and the outcomes of subsequent screening episodes and QI reviews will be the subjects of future reports.

The IRB-approved protocol mirrors the entry criteria from NLST [1], including significant current or recent smoking history, age over 55 years, and informed consent. However, there is the important exception that we excluded patients with health insurance (including Medicare), as they have financial coverage for lung cancer screening, but instead focused on those without coverage for this test. Medicaid patients were included because they were not covered for lung cancer screening in North Carolina. The exclusion of patients over the age of 64 years is important, as they represent the population with the highest incidence of lung cancer and thus biased the likely outcome against a detection rate comparable to that of the NLST and NELSON data.

Nurse navigators approached local physicians and underserved community clinics to alert them to our impending visits and to provide updated information on the potential benefits of low-dose CT screening for lung cancer. As Atrium Health is a multisite safety-net organization, consisting of more than 40 hospitals and 60,000 staff, committed to management of the indigent and underserved, we were able to offer complete management of any lesions, irrespective of ability to pay. A nurse navigator and social work support were made available to all participants found to have potentially significant lesions, and smoking cessation programs were offered to active smokers.

Results

We scanned 550 participants (male-to-female ratio of 1.1:1) with a mean age 61 years (range, 55–64) and an average pack-year history of 46.1 (range, 30–220). Age and gender distribution reflect other lung screening trials, but smoking history was heavier in our series [1, 2]. All were uninsured (66%) or Medicaid patients (34%); 70% were rural; 20% were black, 3% were Hispanic, and 0.5% were Native American. These demographics represented major differences from previous published trials [1–5].

At first screening, a total of 601 pulmonary nodules was identified; this included 267 participants with Lung-RADS

Table 1. Patients with high-risk lesions and lung cancer

Gender, age	Race, ethnicity	Geography	Pack-years	Insurance	Lung-RADS	Cancer	Histology	Stage
M 64	W, NH	Rural	55	U	4X/4X	No	—	—
M 62	W, NH	Urban	40	U	4X/4X	No	—	—
M 64	W, NH	Rural	90	M	4/4B	Yes	AD	CS IIIA
M 56	W, NH	Rural	40	U	4/4X	Yes	SCLC	CS IIIB
F 63	W, NH	Rural	42	U	4B/4B	No	—	—
F 57	W, NH	Rural	46	U	4B/3	No	—	—
M 56	B	Urban	30	U	4X/4X	Yes	SCC	PS IIA
M 58	W, NH	Rural	35	U	4/4A	No	—	—
M 57	W, NH	Rural	40	U	4B/4B	No	—	—
M 55	W, NH	Rural	60	U	4A/4A	Yes	AD	PS IB
F 60	W, NH	Urban	30	MC	4B/4B	No	—	—
F 59	W, NH	Urban	50	MC	4/4B	No	—	—
M 57	B	Urban	40	U	4A/4A	No	—	—
F 64	W, NH	Rural	36	U	4B/4A	Yes	AD	CS IV
M 64	W, NH	Rural	42	U	4/4B	No	—	—
F 64	B	Rural	30	U	4A/4A	No	—	—
F 62	W, NH	Rural	125	U	4/4A	No	—	—
F 57	B	Rural	40	U	4X/4X	Yes	AD	PS IIIB
M 62	W, NH	Rural	45	U	4A/4A	No	—	—
F 61	W, NH	Urban	40	MC	4A/4A	Yes	SCC	CS IA
M 56	W, NH	Urban	60	MC	4A/4A	No	—	—
M 63	W, NH	Urban	67	U	4A/4A	No	—	—
M 62	W, NH	Rural	30	MC	4B/4B	No	—	—
M 58	W, NH	Rural	40	MC	4A/4A	No	—	—
M 59	W, NH	Rural	30	MC	4A/4A	No	—	—
M 52	W, NH	Rural	34	MC	4A/2	No	—	—
F 64	W, NH	Rural	48	U	4A/4A	No	—	—
M 64	W, NH	Rural	30	U	4A/4A	No	—	—
F 59	W, NH	Rural	46	U	4A/4A	No	—	—
M 57	W, NH	Urban	60	MC	4A/4A	No	—	—
M 54	B	Urban	30	U	4	Yes	AD	CS IIIC
M 59	W, NH	Rural	30	U	4A/4A	Yes	AD	CS IV
M 61	W, NH	Rural	45	MC	4A/4A	No	—	—
M 59	W, NH	Rural	47	MC	4B/4B	No	—	—
F 63	W, NH	Rural	45	U	4A/4A	No	—	—
F 59	W, NH	Rural	43	MC	4B/4B	Yes	SCC	PS IB
M 58	W, NH	Rural	88	U	4X/4X	Yes	AD	PS IB
F 56	W, NH	Rural	80	MC	4B	Yes	SCC	PS IIA

Note: Lung-RADS column shows initial diagnosis and diagnosis via review panel.
Abbreviations: AD, adenocarcinoma; B, black; CS, clinical stage; F, female; Lung-RADS, Lung CT Screening Reporting and Data System; M, male; MC, Medicaid; NH, non-Hispanic; PS, pathologic stage; SCC, squamous cell cancer; SCLC, small cell lung cancer; U, uninsured; W, white.

1, 183 participants with Lung-RADS 2, 62 participants with Lung-RADS 3 (11%), and 38 participants with Lung-RADS 4 lesions (6.9%). As we are following the NLST protocol design, two extra CT scans are performed in participants without identified lesions, and follow-up protocols have been defined for those with purportedly benign lesions. Patients with high-risk (Lung-RADS 4) lesions are summarized in Table 1. We have identified 12 participants with lung cancer, including 6 with primary non-small cell lung cancers (NSCLCs), 5 with metastatic NSCLC, and 1 with metastatic small cell undifferentiated lung cancer; we treated 5 primary NSCLCs and 1 primary renal cancer by surgical resection with curative intent; 1 primary lung cancer and 1 incidental head and neck squamous cell carcinoma were treated by radiotherapy; in one case, a clinical stage II NSCLC was shown to be pathologic stage IIIA at surgical

resection. Where appropriate, the patients with metastatic lung cancer were treated with systemic agents. We also detected one case of metastatic pancreatic cancer. All of the detected lung cancers were initially Lung-RADS 4. As shown in Table 1, the initial Lung-RADS diagnostic category was usually but not always confirmed by our multidisciplinary review panel.

Although this study was focused on early detection of lung cancer, 16% of screened patients had moderate or severe coronary artery disease, based on multifocal cardiac vessel calcification, and 27% showed vascular atherosclerosis. These patients were referred back to their primary care physician practices or to cardiologists for further care, and the outcomes of this group will be the subject of a future report.

Although our study was not set up to assess patient satisfaction, we have noted that 66% of patients due to return for their second annual scan have accepted the invitation and completed the process; this is unusual compliance for this population group, suggesting a good level of patient satisfaction with the program.

We have compared, at a preliminary level, the potential initial costs of (indigent) care for resection of the identified primary cancers (approximately $300,000 to $400,000 with curative intent) versus the anticipated costs of providing palliative or life-extending systemic therapy for this series of patients with lung cancer, renal cell carcinoma, and nasopharyngeal cancer, who would normally have presented late, with advanced disease, and generated costs well in excess of $2,000,000, based on current pricing for systemic targeted or cytotoxic drugs and immunotherapies. As we have not yet had access to full follow-up data for the cardiac patients, we have not yet attempted to estimate the cost savings from early referral for cardiac care of early stage disease.

Discussion

Because of their participation in this program and the identification of early stage lung cancers (and cardiac disease) in this complex population of heavy smokers, mobile LDCT scanning may provide a better approach for lung cancer screening. This applies specifically for those at highest risk of presenting with unresectable lung cancer (i.e., the underserved, geographically isolated, and undereducated populations). Although annual LDCT lung cancer screening is now covered by private insurance and Medicare, significant disparity exists for Medicaid patients in many states and for isolated or uninsured populations. In addition, black patients from lower socioeconomic groups, in addition to experiencing financial barriers, may have intrinsic concerns about experimentation and novel approaches to health care and to hospital-based care [7]. Our series has included significant numbers of black, Hispanic, and rural isolated participants and even a small number of Native Americans. The black and rural populations exceed our regional demographic, and the Hispanic and Native American participants reflect the population distribution. The heavy smoking history reflects that we work in the "smoking belt" of North Carolina and South Carolina.

Conclusion

The rate of detection and treatment of six stage I–II NSCLCs (1.1%) in this study is consistent with initial screening figures from NLST and the U.K. trial but is likely to increase based on the follow-up scan data. Of importance, the exclusion of patients aged more than 64 years (covered by Medicare insurance) has selected in favor of a lower detection rate (as the highest incidence of lung cancer is in the older-aged population).

Earlier identification could also have a profound economic impact—the initial management of these six stage I–II lung cancer cases would cost less than $400,000 [11, 12], with potential for cure, versus more than $2,000,000 for modest life prolongation and palliation if these patients had initially presented with metastatic disease. This difference would be increased by the other incidental findings described above. We have designed a larger, randomized multicenter trial that will compare hospital-based versus mobile LDCT to validate these data and to compare respective utility in screening for lung cancer in underserved populations. In view of our preliminary data, with significant demonstration of both early and advanced lung cancer in patients under the age of 64 years, we have also initiated a pilot study of LDCT in heavy smokers aged 45–55 years of age, who currently fall outside the U.S. guidelines for reimbursement for LDCT screening for lung cancer.

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Disclosures

Kathryn F. Mileham: Takeda (H), AstraZeneca (C/A), Celgene (RF), Merck (other—speakers' bureau); **Daniel Carrizosa:** Aeglea BioTheraeutics, AstraZeneca, Celgene, GlaxoSmithKline, Loxo, Merck (RF). The other authors indicated no financial relationships.

(C/A) Consulting/advisory relationship; (RF) Research funding; (E) Employment; (ET) Expert testimony; (H) Honoraria received; (OI) Ownership interests; (IP) Intellectual property rights/inventor/patent holder; (SAB) Scientific advisory board

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Editor's Note:
See the related commentary, "Exploring Ways to Improve Access to and Minimize Risk from Lung Cancer Screening," by Humberto Choi and Nathan A. Pennell on p. 364 of this issue.