The Long Hard Slog: The Journey Since 1990 and Lessons Learned Along the Way
and
How Do We Take It To the NEXT LEVEL

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International Early Lung Cancer Action Program (I-ELCAP), PI

Oncology 2019: 33: 629380 & J Thor Oncology 2018 13:946-57 PMID 29578108

Disclosures

- I am a named inventor on a number of patents and patent applications relating to the evaluation of pulmonary nodules on CT scans of the chest which are owned by Cornell Research Foundation (CRF).
- As of April 2009, I signed away any financial benefit including royalties and any other proceeds related to the patents or patent applications owned by CRF.
- I am the President of the Early Diagnosis and Treatment Research Foundation without compensation
- I am on the Advisory Board of LungLifeAI without compensation

**My views and any VA data that I discuss do not necessarily represent the views and official policies of the Department of Veterans Affairs.

- i3 Health and FLASCO have mitigated all relevant financial relationships

Over the past 45 years (1975-2020), prevention and screening accounted for 4.75 of 5.95 million cancer deaths averted

Recommended **more investment in prevention and screening** strategies for cancers of the breast, cervical, colorectal, lung and prostate as 8 of 10 of these deaths were averted

JAMA Oncology, December 5, 2024; E1-6

I-ELCAP International Early Lung Cancer Action Program

I-ELCAP AIrs Automated Image Reading System

IELCART Initiative for Early Lung Cancer Research on Treatment

The Goal of Screening

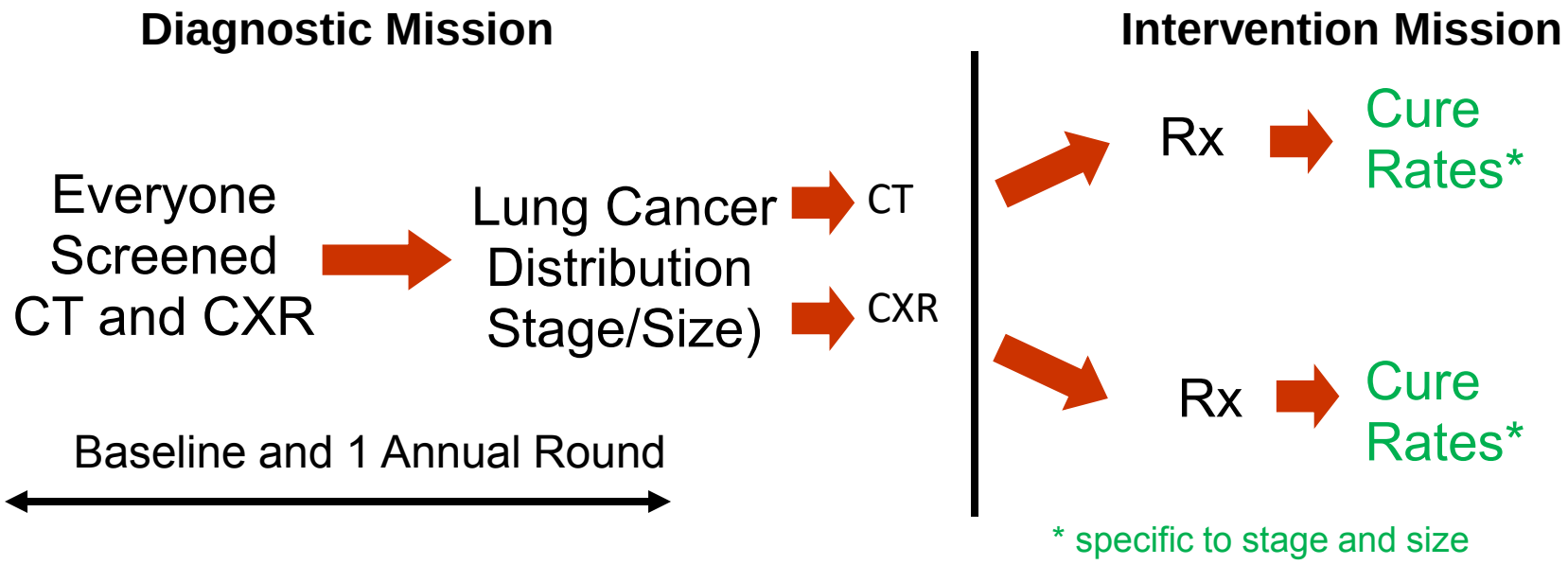
- To reduce deaths from lung cancer by finding lung cancer earlier as early treatment is the best chance for **cure**
- How to start learning about low-dose CT scans in an efficient manner at low budget

Morgan et al. What is the definition of cure in non-small cell lung cancer? Oncol Ther 2021; 9:365-371

The ELCAP Approach:

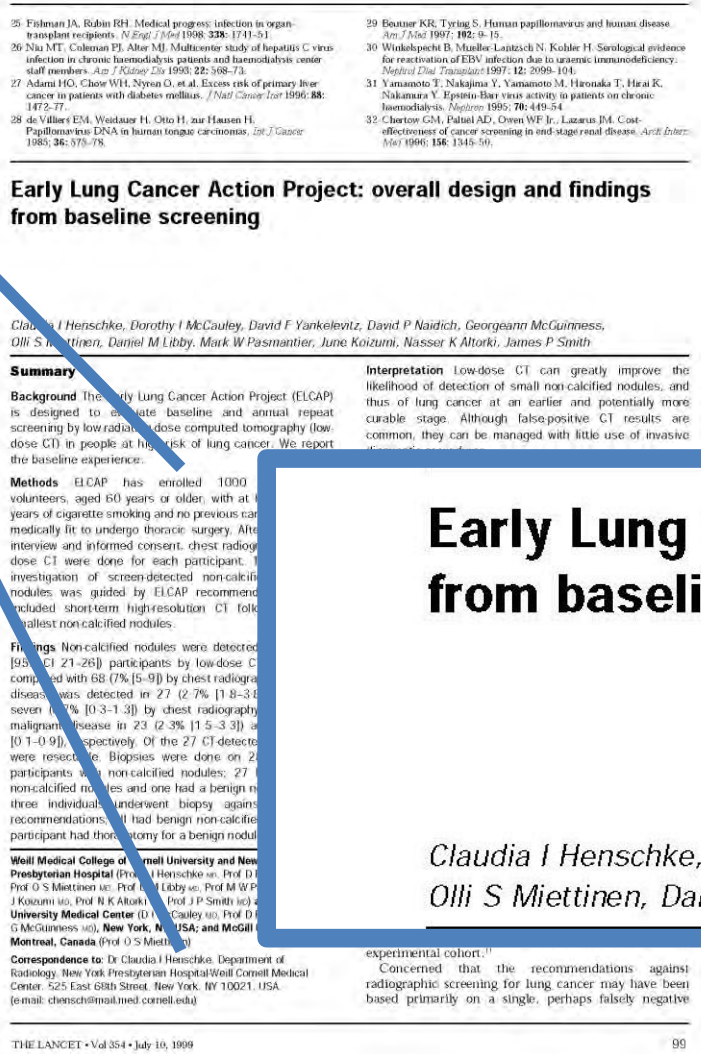
1000 participants, aged 60+ and at least 10 pack-years of smoking

Stage and Size distribution can be answered in 2 years
by a single baseline round and one annual repeat round
Cure rate requires long-term follow-up of annual screenings



July 10, 1999

Lancet Article



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28 de Villiers EM, Weidauer H, Otto H, zur Hausen H. Papillomavirus DNA in human tongue carcinomas. *Int J Cancer* 1983; **36**: 873–78.
29 Beutner KR, Tyring S. Human papillomavirus and human disease. *Am J Med* 1997; **102**: 9–15.
30 Winkelspecht B, Mueller-Lantzsch N, Kohler H. Serological evidence for reactivation of EBV infection due to uraemic immunodeficiency. *Nephrol Dial Transplant* 1997; **12**: 2099–104.
31 Yamamoto T, Nakajima Y, Yamamoto M, Hironaka T, Hirai K, Nakamura Y. Epstein-Barr virus activity in patients on chronic haemodialysis. *Nephron* 1995; **70**: 449–54.
32 Chertow GM, Paltiel AD, Owen WF Jr., Lazarus JM. Cost-effectiveness of cancer screening in end-stage renal disease. *Arch Intern Med* 1996; **156**: 1345–50.

Early Lung Cancer Action Project: overall design and findings from baseline screening

Claudia I Henschke, Dorothy I McCauley, David F Yankelevitz, David P Naidich, Georgeann McGuinness, Olli S Miettinen, Daniel M Libby, Mark W Pasmantier, June Koizumi, Nasser K Altorki, James P Smith

Summary

Background The Early Lung Cancer Action Project (ELCAP) is designed to evaluate baseline and annual repeat screening by low radiation dose computed tomography (low-dose CT) in people at high risk of lung cancer. We report the baseline experience.

Methods ELCAP has enrolled 1000 volunteers, aged 60 years or older, with at least 10 years of cigarette smoking and no previous cancer, medically fit to undergo thoracic surgery. After interview and informed consent, chest radiography and low-dose CT were done for each participant. The investigation of screen-detected non-calcified nodules was guided by ELCAP recommendations, which included short-term high-resolution CT follow-up of small non-calcified nodules.

Findings Non-calcified nodules were detected in 233 (95% CI 21–26]) participants by low-dose CT, compared with 68 (7% [5–9]) by chest radiography. Lung cancer was detected in 27 (2·7% [1·8–3·9]) participants by low-dose CT, seven (0·7% [0·3–1·3]) by chest radiography, and 23 (2·3% [1·5–3·3]) at baseline, [0·1–0·9]), respectively. Of the 27 CT-detected cancers, were resectable. Biopsies were done on 2 participants with non-calcified nodules; 27 non-calcified nodules and one had a benign nodule. three individuals underwent biopsy against recommendations, all had benign non-calcified participant had thoracotomy for a benign nodule.

Weill Medical College of Cornell University and New York Presbyterian Hospital (Prof C I Henschke MD, Prof D I McCauley MD, Prof O S Miettinen MD, Prof D M Libby MD, Prof M W Pasmantier MD, Prof J Koizumi MD, Prof N K Altorki MD, Prof J P Smith MD) and **Mount Sinai School of Medicine, New York University Medical Center** (Prof D F Yankelevitz MD, Prof D P Naidich MD, Prof G McGuinness MD), **New York, NY, USA; and McGill University, Montreal, Canada** (Prof O S Miettinen MD)

Correspondence to: Dr Claudia I Henschke, Department of Radiology, New York Presbyterian Hospital-Weill Cornell Medical Center, 525 East 68th Street, New York, NY 10021, USA (e-mail: chensch@mail.med.cornell.edu)

Interpretation Low-dose CT can greatly improve the likelihood of detection of small non-calcified nodules, and thus of lung cancer at an earlier and potentially more curable stage. Although false-positive CT results are common, they can be managed with little use of invasive

experimental cohort.[11]

Concerned that the recommendations against radiographic screening for lung cancer may have been based primarily on a single, perhaps falsely negative

Early Lung Cancer Action Project: overall design and findings from baseline screening

Claudia I Henschke, Dorothy I McCauley, David F Yankelevitz, David P Naidich, Georgeann McGuinness, Olli S Miettinen, Daniel M Libby, Mark W Pasmantier, June Koizumi, Nasser K Altorki, James P Smith

The Lancet 1999: 18:16-20

I-ELCAP International Early Lung Cancer Action Program

IELCART Initiative for Early Lung Cancer Research on Treatment

CT IMAGING IN 1990

12 tiny images on 1 x-ray film
24-30 images on 2-3 x-ray films

15 images on 1 X-RAY

Low dose acquisition just introduced

Celebrating NYC Chest conferences

Conferences 2000 to 2001

- **3rd International Conference on Screening for Lung Cancer** on October 27-29, 2000
  - Call to develop an international consortium
  - Create working groups
  - Call to develop an international protocol
  - Develop strong ties to all interested organizations
- **4th International Conference on Screening for Lung Cancer** on February 23-25, 2001
  - Recommended combining screening and smoking cessation
  - Recognized part-solid and nonsolid nodules and the need to study these
  - Dr. Fagerstrom (NCI) presented plans for NLST of 150,000 participants and 10 years of follow-up (revised at later meetings)

1st – 5th

at Weill Cornell Medical College starting in October 1999

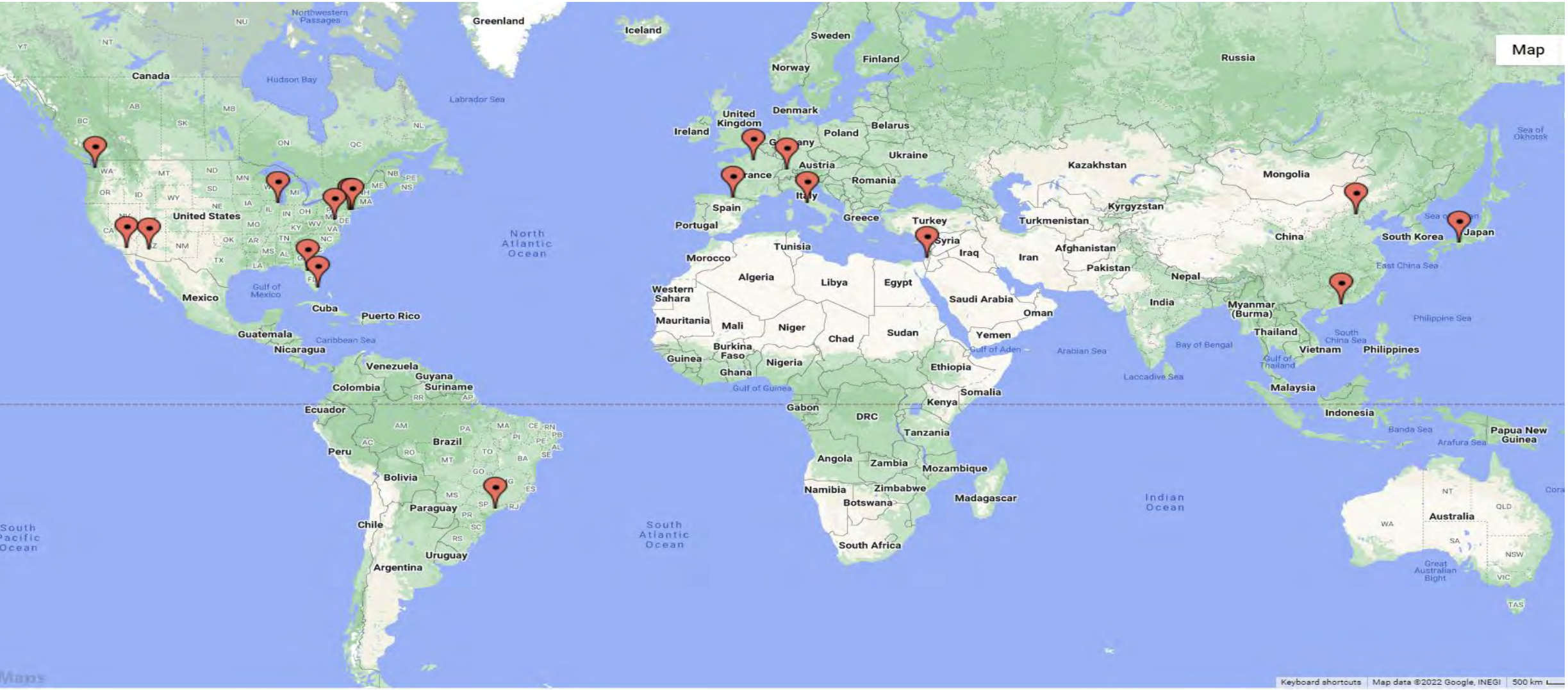
I-ELCAP International Early Lung Cancer Action Program

21 held in New York City, 25 at other sites

IELCAP.org

IELCART Initiative for Early Lung Cancer Research on Treatment

I-ELCAP Held International Conferences on Screening for Lung Cancer Every 6 Months



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Paris, France
Rome, Italy
Nara, Japan
Jerusalem, Israel
Zhuhai, China
Beijing, China
Zurich, Switzerland
Verona, Italy
Madrid, Spain
São Paulo, Brazil

New York City, New York
Miami, Florida
Washington, DC
Palm Springs, California
Newark, Delaware
Seattle, Washington
Scottsdale, Arizona
Chicago, Illinois
Poughkeepsie, New York

Multiple Pathology Panels 2001-2006

William Travis MD, Elizabeth Brambilla MD, Darryl Carter MD, Adi Gazdar MD, Masayuki Noguchi MD together with June Kozumi, Madeleine Vazquez and Doug Flieder from Weill Cornell Pathology

- reviewed all the early stage cases from screening

Flieder DB, Vazquez M, Carter D, Brambilla E, Gazdar A, Noguchi M, Travis WD, Kramer A, Yankelevitz DF, Henschke CI. Pathologic findings of lung tumors diagnosed on baseline CT screening. American Journal of Surgical Pathology 2006; 30:606-13

Carter D, Vazquez M, Flieder DB, Brambilla E, Gazdar A, Noguchi M, Travis WD, Kramer A, Yip R, Yankelevitz DF, Henschke CI, ELCAP and NY-ELCAP Investigators. Comparison of pathologic findings of baseline and annual repeat cancers diagnosed on CT screening. Lung Cancer 2007; 56:193-9 PMID:17239983

Vazquez M, Carter D, Brambilla E, Gazdar A, Noguchi M, Travis W, Huang Y, Zhang L, Yip R, Yankelevitz DF, Henschke CI. Solitary and Multiple Resected Adenocarcinomas after CT Screening for Lung Cancer: histopathologic features and their prognostic implications. Lung Cancer 2009; 64:148-54 PMID:18951650 PMCID: PMC2849638

Multiple Pathology Panels 2001-2006

American Cancer Society grant for pathology review led to

- Changes pathology descriptors
  - Atypical adenomatous hyperplasia (AAH)
  - Adenocarcinoma-in-situ (AIS)
  - Minimally invasive adenocarcinoma (MIA)
  - Invasive adenocarcinoma according to **predominant findings**
- These insights and definitions change
  - the workup paradigm
  - the treatment paradigm

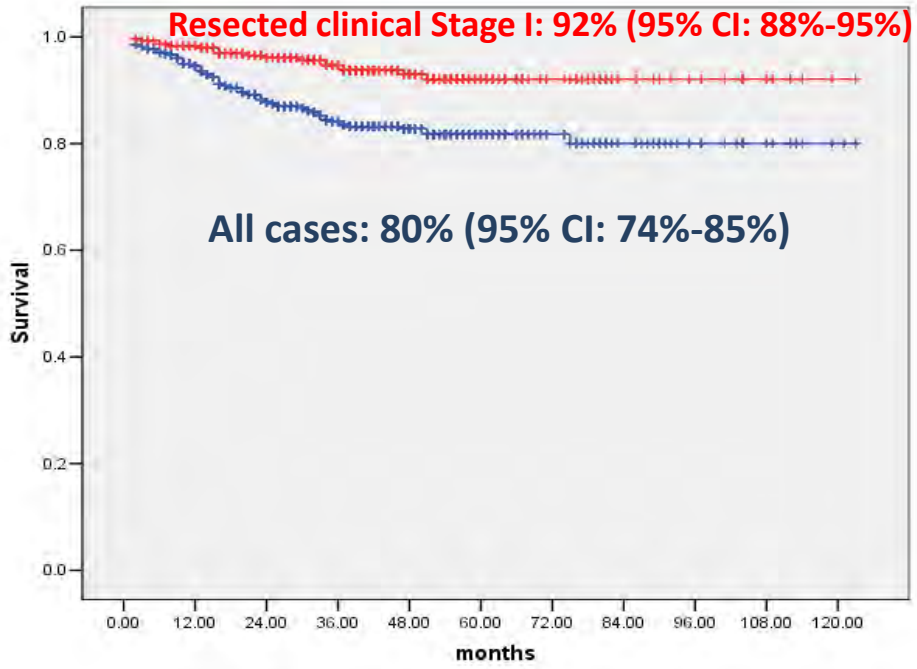
I-ELCAP Investigators. CT Screening for Lung Cancer: Comparison of three baseline protocols. European Radiology. 2019; 29: 5217-26

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 OCTOBER 26, 2006 VOL. 355 NO. 17

Survival of Patients with Stage I Lung Cancer Detected on CT Screening

The International Early Lung Cancer Action Program Investigators*



31,567 participants

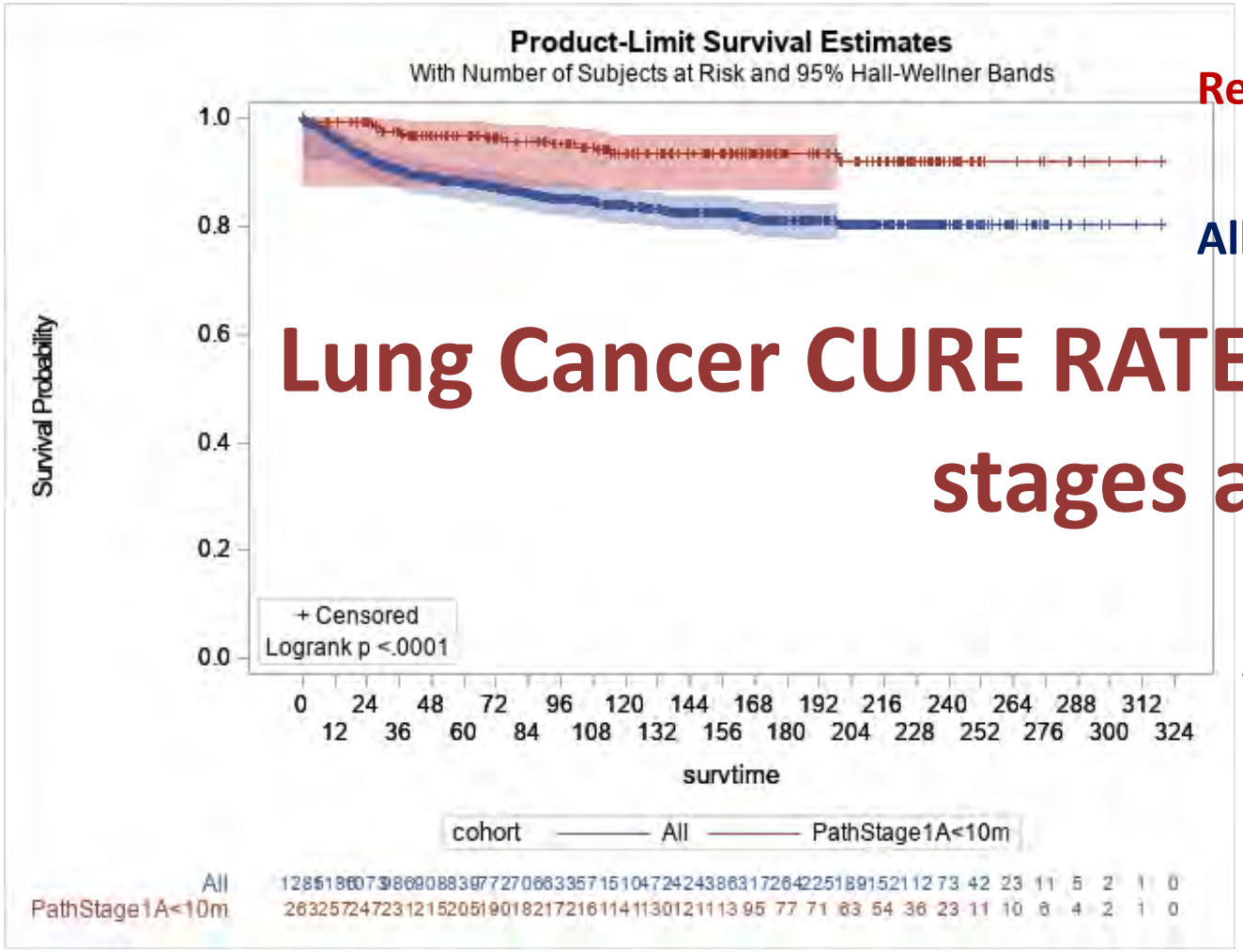
484 participants diagnosed with lung cancer

85% (412/484) were clinical Stage I

Median follow-up time=49 months

Lung cancer deaths =88/484 (18.2%)

I-ELCAP reported on the 20-Year Lung Cancer Survival Rate in 1285 Participants



Resected Path T1a N0M0<10mm **95%**

All cases **80.5%**

Lung Cancer CURE RATE: 80%, inclusive of all stages and treatments

Awarded the Alexander R. Margulis Award for best scientific paper

Radiology

REVIEWS AND COMMENTARY • EDITORIAL

Cure Rate of Lung Cancer Diagnosed at Annual CT Screening

Philippe A. Grenier, MD

Dr Philippe A. Grenier is a former professor of radiology and chaiman at Sorbonne University in Paris, France. He currently works at Foch Hospital in Suresnes, France, in affiliation with Versailles-Saint Quentin University. His main interests are lung cancer imaging and diffuse lung disease. Dr Grenier is past president of the Fleischner Society and European Society of Thoracic Imaging. He has received the European Congress and Association of Radiology Gold Medal.

participants enrolled in the prospective I-ELCAP from 1992 through 2022. Eligible participants were aged at least 40 years and were current or former cigarette smokers or had never smoked but had been exposed to secondhand tobacco smoke. Among 89 404 participants, 1257 (1.4%) were diagnosed with a first primary lung cancer at baseline and annual screenings. The median age at diagnosis was 66 years, with a median smoking history of 43 pack-years. Of the 1257 cases of lung cancer, 1008 (80.2%) were solid and 249 (19.8%) were subsolid. The median tumor diameter was 14 mm, and 81% of all cancers (1017 of 1257)

"This study is the first to report on 20-year lung-cancer–specific survival for low-dose CT screening programs."

"The primary outcome reported in this study was that for all these categories of lung cancers, the lung cancer–specific survival reached a plateau after 10 years of followup. **Hence, Henschke and Yip et al confirm the results of their previously published study (3), where they estimated the 10-year cure rate of patients diagnosed with lung cancer during annual screening to be 80%.** They also confirm with real data the estimates provided by empirical demonstrations published in the literature, **that is, 8–10 years of follow-up after diagnosis is sufficient to estimate cure rates for lung cancer (5–7)."**

Radiological Society of North America (RSNA) Alexander R. Margulis Award 2024

The 20-year Follow-up of the International Early Lung Cancer Action Program (I-ELCAP)

I-ELCAP International Early Lung Cancer Action Program

I-ELCAP AIRS Automated Image Reading System

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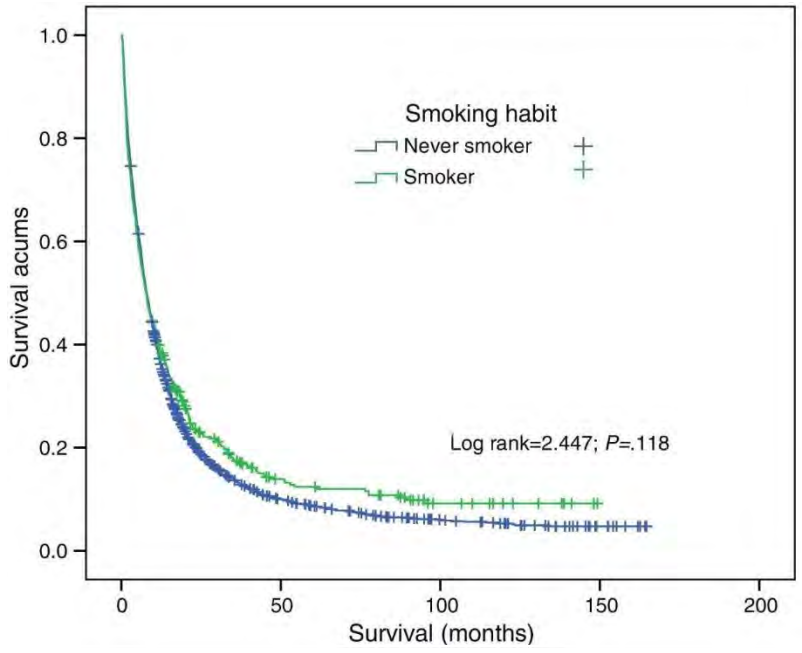
THE JOURNAL OF
THORACIC AND
CARDIOVASCULAR SURGERY

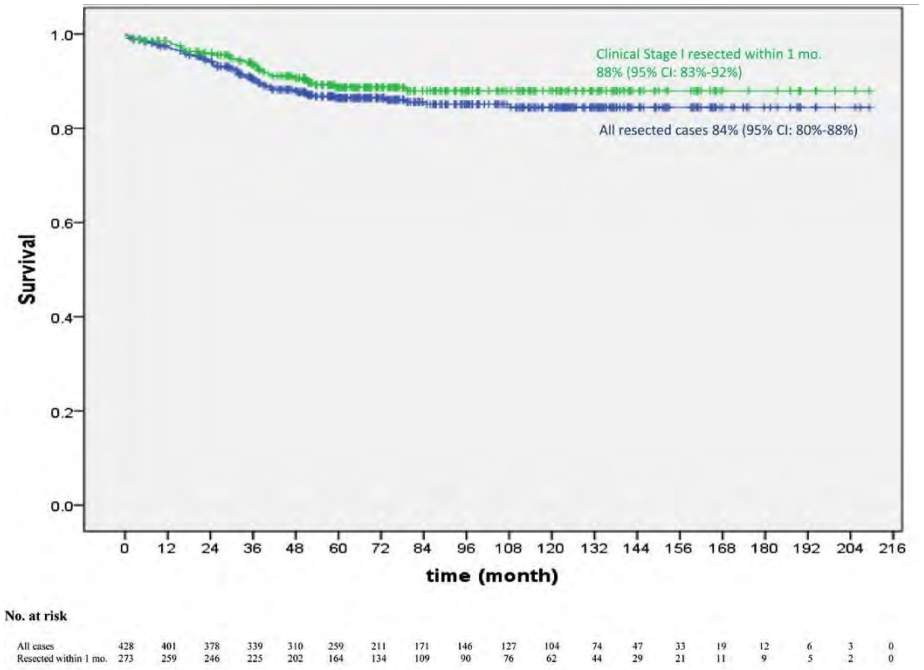
Lung Cancer Survival

Current Lung Cancer Survival



Lamelas, IP, et al. Arch Bronconeumol.2014;50:62-6

I-ELCAP



J Thorac Cardiovasc Surg 2014; 147:1619-1626.

1st Conference on Integrating Early Detection of Heart and Lung Disease through Low-Dose CT

"Scientific Think-Tank Event Exploring New Frontiers in Averting Preventable Premature Deaths through AI-enabled Early Detection"

Together with

46th International Conference on Screening for Lung Cancer

14th Conference on Early Lung Cancer Research on Treatment

Integrating Cardiac and Lung Screening

September 19-21, 2024

New York Academy of Medicine in New York City

European Heart Journal (2014) **35**, 2792–2796
doi:10.1093/eurheartj/ehu296

CURRENT OPINION

Combined detection of coronary artery disease and lung cancer

Harvey S. Hecht*, Claudia Henschke, David Yankelevitz, Valentin Fuster, and Jagat Narula

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Received 3 March 2014; revised 12 June 2014; accepted 8 July 2014; online publish-ahead-of-print 11 August 2014

Introduction

Coronary artery disease (CAD) and lung cancer have several important features in common. First, their dramatic increases are in large part attributable to societal ills, including worsening dietary patterns, obesity, and tobacco use. Secondly, as these behaviours permeate the world, the diseases are disproportionately increasing in the poorer societies with limited resources for healthcare. Consequently, it is necessary to develop cost-effective strategies. Both disease states may be amenable to early detection by a single low radiation dose CT scan.

In an attempt to simplify cholesterol treatment, the 2013 ACC/AHA Guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults[6] restricted the use of CAC to the patients who did not fall into four designated conventional risk factor-based categories. Coronary artery calcium was downgraded to a Class IIb status (recommendation's usefulness/efficacy less well established),[7] ignoring the robust CAC literature that initially engendered the Class IIa recommendation, and the more recent data from three prospective, population-based outcome trials that the CAC Net Reclassification Index of the FRS is extremely high, particularly for the intermediate-risk group (52–66%) (*Table 1*).[8–10] The guide-

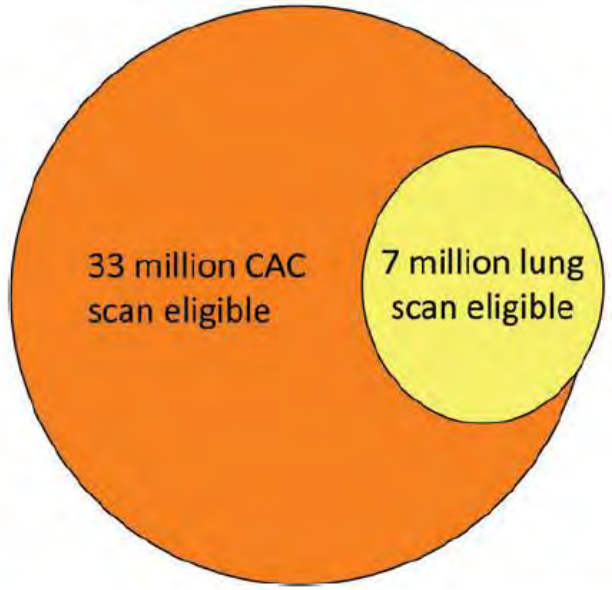


Figure 1 USA estimates, and overlap, of coronary artery calcium and lung scan eligible patients. The number of eligible patients in the USA is estimated at 33 million for coronary artery calcium scanning (orange)[28] and 7 million for lung scanning (yellow).[27] Excluding lung scan eligible patients who have established coronary disease (5.3%, unpublished data from the I-ELCAP database) yields an overlap of 6.6 million lung scan patients who would be expected to benefit from coronary artery calcium scanning.

Ordinal Coronary Artery Calcification Score

Frequency of CAC on LDCT Screenings

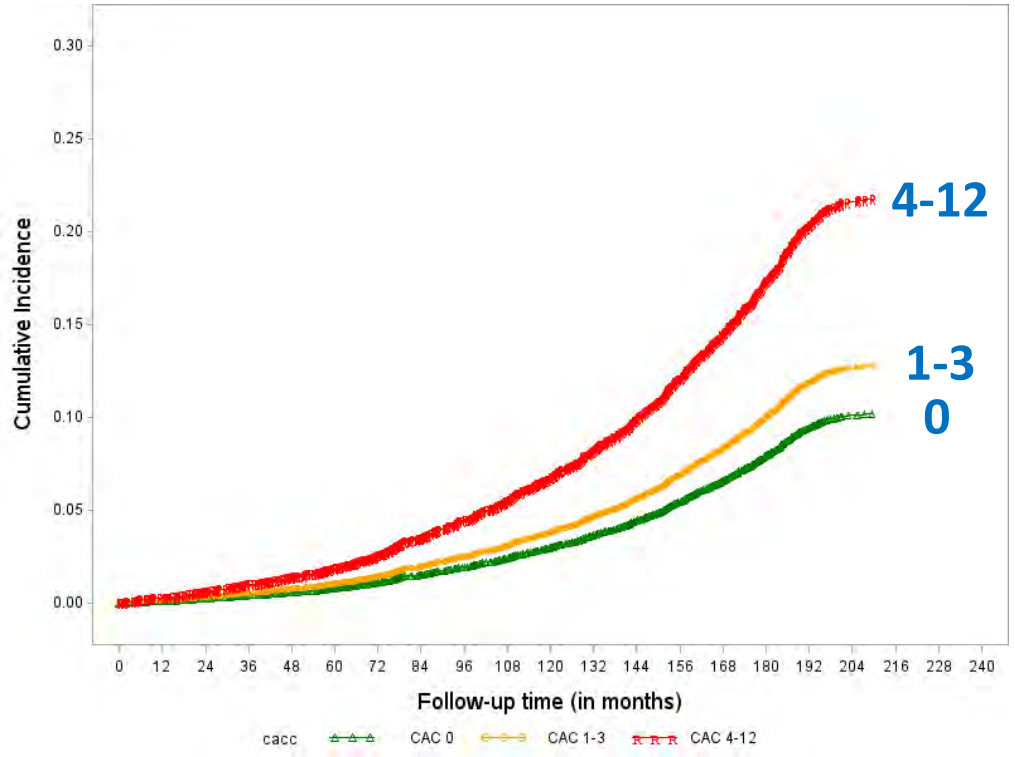
- In 2006, scored visualized CACs in the four coronary artery (main, left anterior descending, circumflex, and right) were scored separately as 0 (absent), 1 (mild), 2 (moderate), or 3 (severe)
  - **Yielded a total possible score of 0-12 for each person.**
- In 2010, we demonstrated the clinical relevance of this visual Ordinal CAC score as a strong predictor of death from CVD up to 8-years of follow-up in a screening cohort of 8792 New York State participants.
- We also showed that three Ordinal CAC score categories of 0, 1-3 and 4-12 were highly correlated with
  - **Agatston score categories of 0 (low risk), 1-400 (intermediate risk) and 400+ (high risk)**

Shemesh J, Henschke CI, Farooqi A, Yip R, Yankelevitz DF, Shaham D, Miettinen OS, *Clinical Imaging 2006:30:181-185*

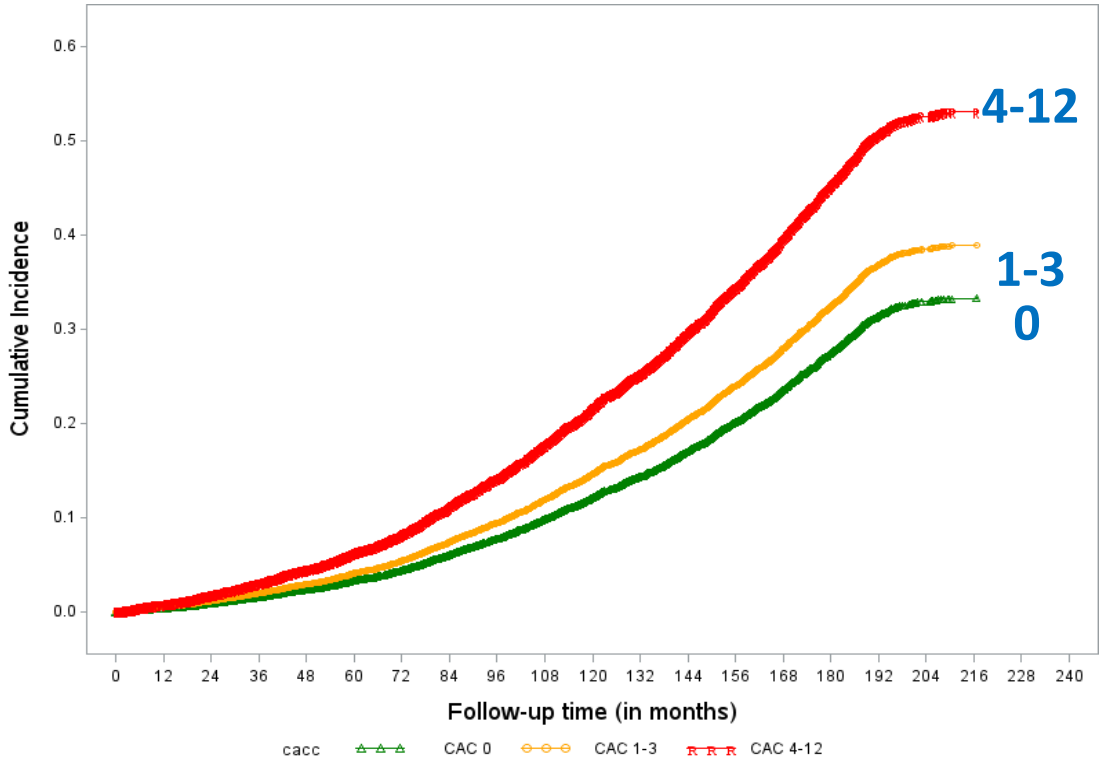
Shemesh J, Henschke CI, Shaham D, et al. *Radiology 2010; 257;541-8*

A Single Ordinal Coronary Artery Calcification Score Predicts 25-Year CVS and All-Causes of Death

Cardiovascular Deaths



All causes of death



I-ELCAP International Early Lung Cancer Action Program

Shemesh J, Yip R, Cham M, Shaham, D, Yankelevitz DF, Henschke CI.

A single CAC ccore strongly predicts 25-year cardiovascular and all-cause mortality

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AI-CARDIAC CHAMBER ASSESSMENT ON CT

A Strong Predictor of Atrial Fibrillation and Heart Failure

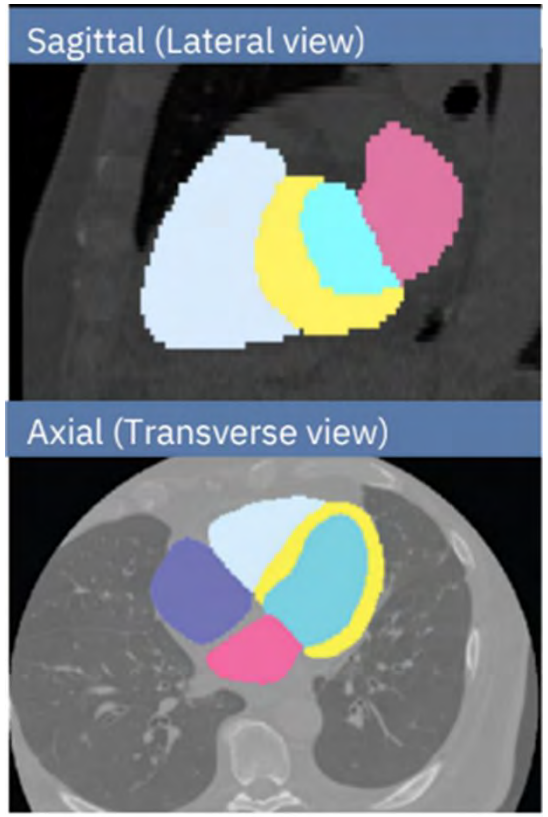
1. Naghavi M, Yankelevitz DF, Reeves AP, Budoff MJ,et al. AI-enabled left atrial volumetry in coronary artery calcium scans (AI-CACTM) predicts atrial fibrillation as early as one year, improves CHARGE-AF and outperformed NT-proBNP: The multi-ethnic study of atherosclerosis. J of Cardiovasc Comput Tomogr. 2024; 18:383-391. PMID: 38653606 PMCID: PMC11216863

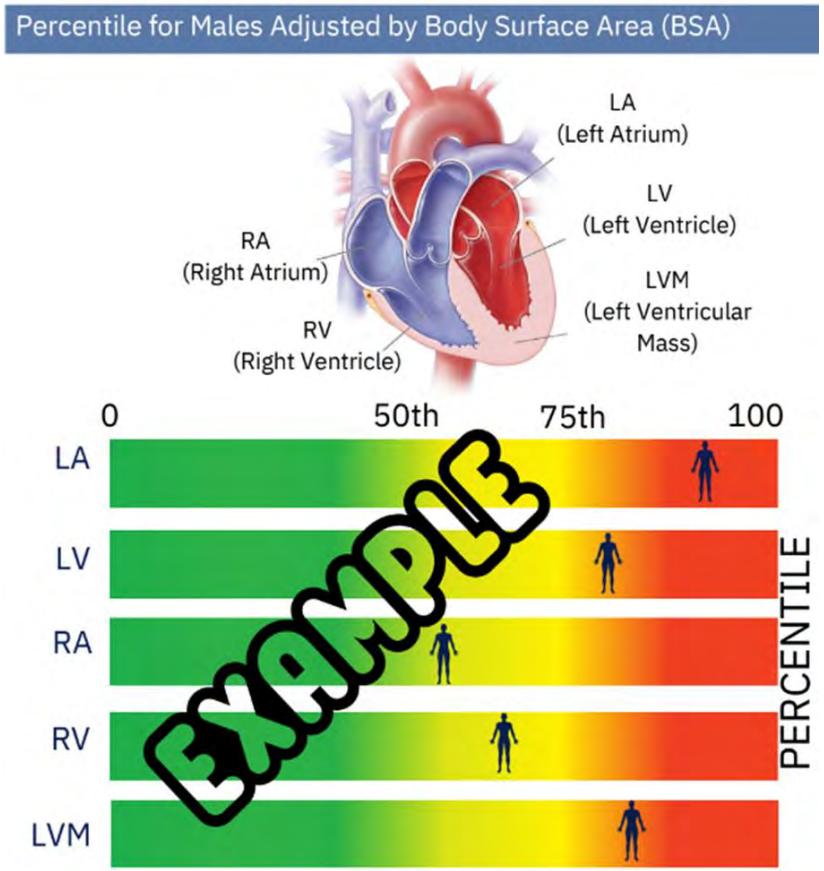
2. Naghavi M, Budoff M, Greenland P, et al. AI-enabled auto mated cardiac chambers volumetry in coronary calcium scans outperforms NT-proBNP for prediction of health failure: the multi-Ethnic Study of Atherosclerosis. J Cardiovasc Comput Tomogr 2024; 18:392-400. PMID: 38664073 PMCID: PMC11216890

3. Naghavi M, Reeves, Atlas K, Zhang C, Atlas T, Henschke C, Yankelevitz D, Budoff M, et al. AI-enabled cardiac chambers volumetry and calcified plaque characterization in coronary artery calcium (CAC) scans (AI-CAC) significantly improves on Agatston CAC score for predicting all cardiovascular events: The multi-ethnic study of atherosclerosis. Res Sq 2024; 20;rs-4433105. PMID: 38947043 PMCID: PMC11213177

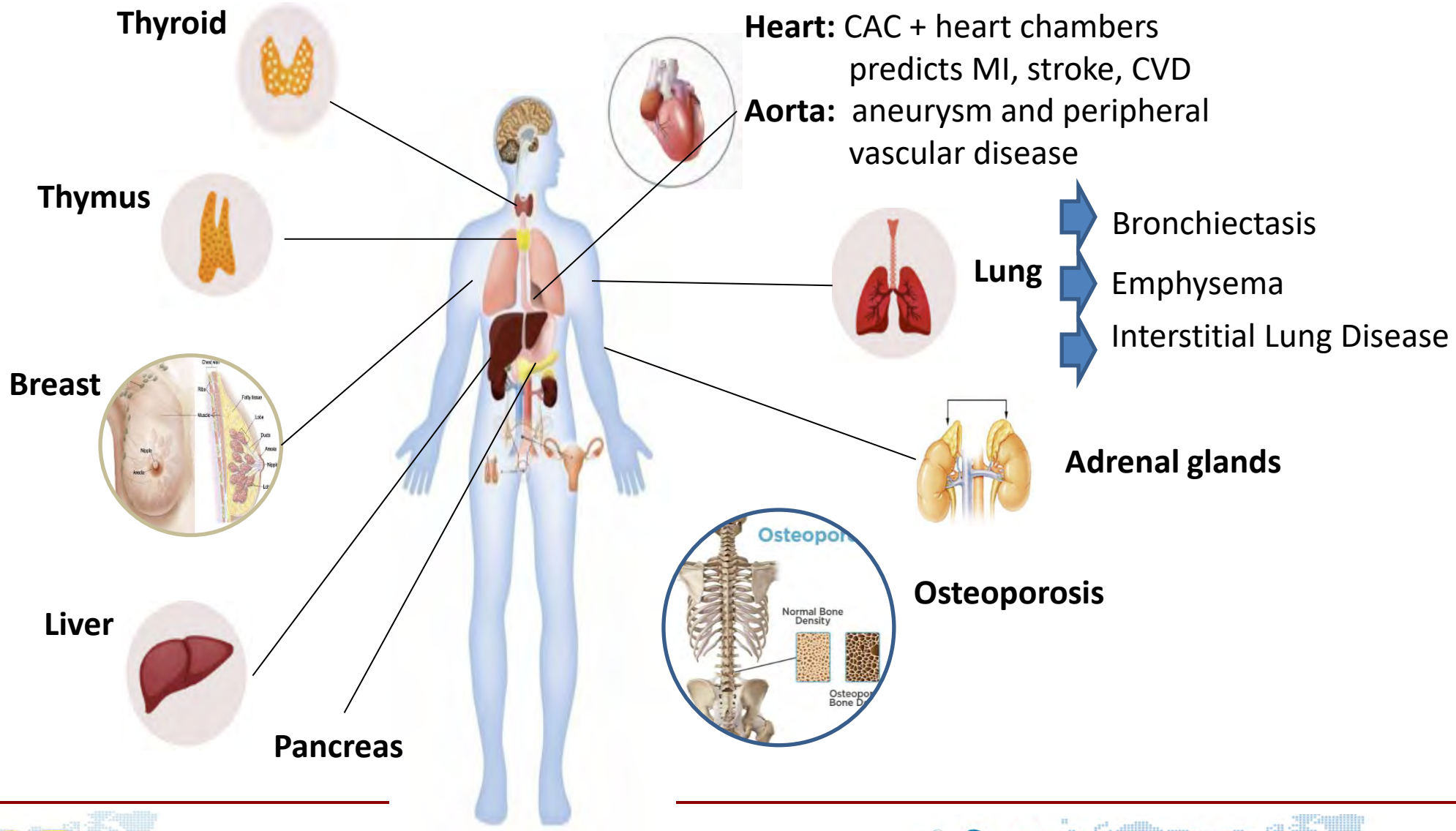
4. Naghavi M, Reeves AP Atlas K, Li D, Zhang C, Atlas T, Roy SK, Budoff MJ, Henschke CI, Yankelevitz DF, Wong ND. AI-powered coronary artery calcium scans (AI-CAC) cardiac volumetry predicts heart failure comparable to cardiac JACC In press 2024.

CARDIAC CHAMBER ANALYSIS





LDCT is Comprehensive Health Screening



I-ELCAP Awards Banner Time

- Ochsner Award from the Ochsner Clinic in New Orleans 2023
- Joseph W. Cullen Prevention/Early Detection Award from the International Association for the Study of Lung Cancer. September 7, 2024
- Honorary Member of the Chinese Society of Radiology for promoting lung cancer screening (Shanghai, China November 14, 2024)
- Radiological Society of North America: Alexander R. Margulis Award for best scientific paper in 2024

The Long Hard Slog not finished

- I-ELCAP Protocol since 2002
  - People who have smoked or never smoked
  - Age 40 and older with at least 5 years of life expectancy
  - Annual LDCT and follow-up as per protocol
  - Published more than 300 scientific papers
- But there are around 40,000 deaths each year in never smokers, 2/3 of them women –they need screening
- Now expanding the I-ELCAP Protocol to countries with limited resources but increasing frequency of smoking and lung cancer

Global Lung Cancer Statistics in 2020

- 2.2 million people were diagnosed with lung cancer
- One fifth (1/5) of all deaths from cancer were due to lung cancer
  - Almost twice as many deaths as 2nd most (colorectal cancer) or 3rd most (liver cancer) cancer
- Lung cancer has a higher economic burden than any other cancer
- Without LDCT screening, the cure rate for lung cancer is low

To Maximize the Benefit of Screening

We need to keep rethinking and optimizing all components of the diagnostic-treatment paradigm

An **Open Source automated image reading system (AIRS)** that determines **no clinical change has occurred** – **no new nodules** and **no nodule size change**

How to Improve Lung Cancer Outcomes

- Find the lung cancer when it is smaller using the latest generation of CT scanners
- Development of optimal protocol for accurate growth assessment
  - Enhanced automated accurate methods for determining growth rates of pulmonary nodules and their probability of malignancy
  - Integrate AI in the screening protocol and in the future blood biomarkers when available
- Integrate management systems to continuously reevaluate and update the workup protocol
- Develop Heart and Lung protocols
  - Integrate new software tools for comprehensive health checks of cardiac illness, lung illness and personalized measures of health
- Expand outreach to the at risk population
  - Improve with natural language processes making reports more specific and easier to understand
  - Translation to other languages

I-ELCAP International Early Lung Cancer Action Program

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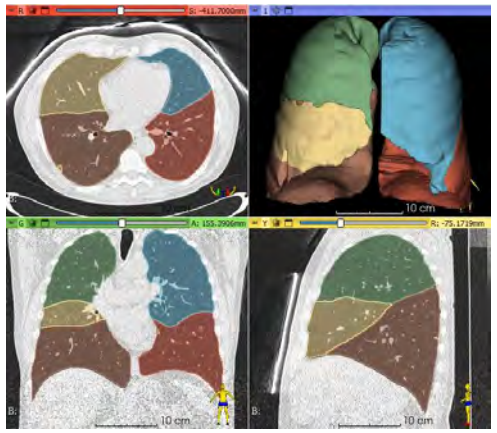
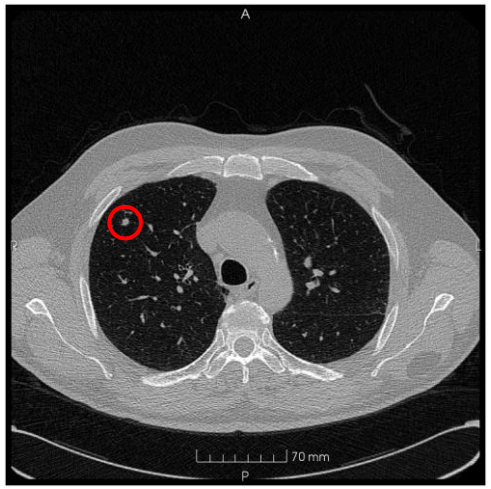
Imagine What Could be Accomplished

If sites around the world had access to this tool it would:



- Dramatically reduce the burden on radiologists, especially in low and moderate income countries
- Allow for automation of the entire screening process by connecting to a management system, such as the open source VAPALS-ELCAP / ScreeningPLUS system
- Standardize quality of scan interpretations



I-ELCAP International Early Lung Cancer Action Program

IELCART Initiative for Early Lung Cancer Research on Treatment

SAVE THE DATES

April 3rd – 5th , 2025 in BANGKOK, THAILAND

2nd AGILE DxRx Conference

47th International Conference on Screening for Lung Cancer & **15th Conference on Research for Early Lung Cancer Treatment**

Princess Srisavangavadhana College of Medicine

Host: Natthaya Triphuridet, MD, PhD

AGILE DxRx

CHULABHORN ROYAL ACADEMY
Princess Srisavangavadhana College of Medicine

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Recommended **more investment in prevention and screening** strategies for cancers of the breast, cervical, colorectal, lung and prostate as 8 of 10 of these deaths were averted

JAMA Oncology, December 5, 2024; E1-6

I-ELCAP International Early Lung Cancer Action Program

I-ELCAP AIrs Automated Image Reading System

IELCART Initiative for Early Lung Cancer Research on Treatment

"Never doubt that a small group of thoughtful, citizens can change the world; indeed, it's the only thing that ever has."

Margaret Mead, Anthropologist

Never underestimate what a dedicated group of physicians, epidemiologists, statisticians, and engineers can accomplish by self-funded collaboration using a common protocol and screening management system

THANK YOU on behalf of the I-ELCAP Investigators

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Thanks and Acknowledgements

- **The efforts of all the I-ELCAP Investigators and their teams**

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- **Our very, very special thanks to the thousands of screening participants** who have allowed us to follow their progress over the years so that others could benefit from the information gleaned from their experiences. We greatly appreciate their generosity of spirit.

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EARLY DIAGNOSIS AND EARLY TREATMENT

A new era in Preventive Health