Provider Work Up of Positive Findings in CT Lung Screening

LuCa National Training Network
August 25, 2020
Andrea McKee, MD and Shawn Regis, PHD
Disclosure

✧ Astra Zeneca Educational Materials
Background

- Lung cancer screening (LCS) with low-dose CT improves survival in selected patients
  - National Lung Screening Trial (NLST)\(^1\) – 20% relative risk reduction
  - NELSON trial\(^2\) – 24% risk reduction in men, 48% in women
- Concern over false positive results and iatrogenic harm continue to limit LCS implementation
- Challenge for shared decision making

2. de Koning HJ, et al. NEJM 2020
Positive Findings

- Lung
  - True positive
  - False positive

- Incidental
- Significant Incidental
- Tracking

Andrea McKee, MD
Shawn Regis, PhD
National Lung Screening Trial
What is Positive?

• Treatment Arms:
  – Low Dose Chest CT (1.5 mSv)
  – PA Chest Radiograph (0.02 mSv)

• Screening Intervals:
  – T0: Baseline prevalence screen
  – T1: Year 1 incidence screen
  – T2: Year 2 incidence screen

• Positive Test
  – Non-calcified nodule greater than or equal to 4mm in maximum diameter
  – Other findings suspicious for lung cancer (adenopathy, effusion…)
  – Workup of positives determined by PCPs not NLST
    • NLST reading radiologist recommendation available
National Lung Screening Trial
Results: Rate of Positive Screenings

• CT (24.2%) > 3x more sensitive than CXR (6.9%)
  – T0 & T1 Rate: 27-28%
  – T2 Rate: 16.8%
    • 2 year stability → benign (Fleischner Guidelines)
    • Expected rate for ongoing CT lung screening?

• Significant incidental finding: 7.5%

NLST

Results: False Positive Workup/Adverse Events

• False Positive Rate:
  – 20-25%: Chance you will end up with a false positive
  – ~8-10% for Mammography (“Call back”)

• False Discovery Rate (1-PPV):
  – 96%: Chance if you are positive you do not have cancer
  – Same as mammography

• Intervention without disease:
  – 0.4-2.4%: Chance if screened you will have an unnecessary invasive procedure (LDCT)
  – ~1.5%: Chance if screened you end up having a negative biopsy (mammography)
National Lung Screening Trial

Results: Positive Workup/Adverse Events

• False Positives
  – Most have noninvasive imaging follow-up
    • CXR: 14.4%
    • Chest CT: 49.8%
    • PET/CT: 8.3%
  – Invasive diagnostic procedures: 2.6 %
  – Complication rate: 1.4%
  – Major complication rate: 0.06%

• True Positives
  – Invasive procedure major complication: 11.2%
  – Surgical resection mortality: 1%
What ARE the False Positive Rates for CT Lung Screening?

**The NEW ENGLAND JOURNAL of MEDICINE**

Reduced Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening

The National Lung Screening Trial Research Team

- T0: 26.3%
- T1: 27.2%
- T2: 15.9%
- Overall: 23.3%

**Annals of Internal Medicine**

**ORIGINAL RESEARCH**

Performance of Lung-RADS in the National Lung Screening Trial

A Retrospective Assessment

Paul F. Pinsky, PhD; David S. Gierada, MD; William Black, MD; Reginald Munden, MD; Hrudaya Nath, MD; Denise Aberle, MD; and Elia Kazerooni, MD

- T0: 12.6%
- T1: 5.3%
- T2: 5.1%
- Overall: 7.8%

**JNCCN**

**Original Research**

NCCN Guidelines as a Model of Extended Criteria for Lung Cancer Screening

Brady J. McKee, MD; Shawn Regis, PhD; Andrea K. Borowski-Kitts, MS; MFH; Jeffrey A. Hashim, MD; Robert J. French Jr, MD; Christoph Wald, MD, MBA, PhD; and Andrea B. McKee, MD

- T0: 10.6%
- T1: 5.2%
- T2: 5.0%
- Overall: 7.6%

Rescuing lives from lung cancer today and tomorrow
What ARE the False Positive Rates for CT Lung Screening?

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T0: 10.6%
T1: 5.2%
T2: 5.0%
Overall: 7.6%

Covid-19?
Numbers change as programs mature
Clarification of False-Positive Reporting Language in an Editorial


In the Editorial titled “Failing Grade for Shared Decision Making for Lung Cancer Screening,” published in the October 1, 2018, issue of *JAMA Internal Medicine*, language citing an Original Investigation by Kinsinger et al reporting false-positive findings must be clarified. The phrase in the second paragraph of the Editorial that reads “these harms include a 98% false-positive rate” should more correctly read “the proportion of all positive tests that are falsely positive is 98%.” This Editorial has been corrected online.
Methods & Demographics

- We aimed to evaluate the rates of intervention for benign findings in our large LCS program
  - As of April 2020, 19,158 LCS studies performed in 7521 patients
  - Retrospective review of all Lahey LCS patients from January 2012 – June 2017
    - 4,490 screened patients
    - Follow-up through January 2019
Time to Lung Cancer/Benign Diagnosis from Initial Suspicious (LungRADS 4A/B/X) Exam

Diagnosed Cancers by Initial Suspicious Grade

<table>
<thead>
<tr>
<th></th>
<th>LR4A</th>
<th>LR4B</th>
<th>LR4X</th>
<th>All LR4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>38</td>
<td>60</td>
<td>13</td>
<td>119</td>
</tr>
<tr>
<td>Incidence</td>
<td>19</td>
<td>33</td>
<td>7</td>
<td>59</td>
</tr>
<tr>
<td>Total</td>
<td>57</td>
<td>101</td>
<td>20</td>
<td>178</td>
</tr>
</tbody>
</table>

Predictive Value of a Suspicious Exam (SPV) @ 365 Days

<table>
<thead>
<tr>
<th>SPV</th>
<th>LR4A Patients</th>
<th>SPV</th>
<th>LR4B Patients</th>
<th>SPV</th>
<th>LR4X Patients</th>
<th>SPV</th>
<th>All LR4 Patients</th>
<th>SPV</th>
<th>Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>25.3%</td>
<td>138</td>
<td>54.1%</td>
<td>111</td>
<td>17.7%</td>
<td>62</td>
<td>34.3%</td>
<td>312</td>
<td></td>
</tr>
<tr>
<td>Incidence</td>
<td>27.0%</td>
<td>58</td>
<td>41.8%</td>
<td>55</td>
<td>31.1%</td>
<td>26</td>
<td>51.3%</td>
<td>144</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>26.2%</td>
<td>202</td>
<td>50.0%</td>
<td>166</td>
<td>19.3%</td>
<td>88</td>
<td>33.6%</td>
<td>456</td>
<td></td>
</tr>
</tbody>
</table>
Methods & Demographics

- NCCN guidelines
- Patients with suspicious findings (Lung-RADS 4) were evaluated for interventions and outcomes

<table>
<thead>
<tr>
<th>Characteristics of LungRADS-4 patients</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex – number (%)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>169 (54.3)</td>
</tr>
<tr>
<td>Female</td>
<td>142 (45.7)</td>
</tr>
<tr>
<td>Age at enrollment – yr</td>
<td></td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>65 (60 – 69)</td>
</tr>
<tr>
<td>Range</td>
<td>50 – 77</td>
</tr>
<tr>
<td>NCCN Risk group – number (%)</td>
<td></td>
</tr>
<tr>
<td>Group 1</td>
<td>252 (81.0)</td>
</tr>
<tr>
<td>Group 2</td>
<td>59 (19.0)</td>
</tr>
<tr>
<td>Smoking status – number (%)</td>
<td></td>
</tr>
<tr>
<td>Current</td>
<td>167 (53.7)</td>
</tr>
<tr>
<td>Former</td>
<td>144 (46.3)</td>
</tr>
<tr>
<td>Pack-year of smoking</td>
<td></td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>43 (35 – 60)</td>
</tr>
</tbody>
</table>
Inclusion criteria

311 Lahey Lung-RADS 4 patients

- 4490 Screening LDCT
- 3280 with Follow-up at Lahey
- 345 LungRADS 4
- 311 LungRADS 4
- 1210 outside Lahey patients
- 2936 LungRADS 1-3 patients
- 34 Incomplete follow-up
  - 20 lost to follow-up after initial LDCT
  - 14 underwent surgery at outside hospital

86 patients underwent one or more invasive diagnostic procedure(s)
- 42 Lung Cancer
- 4 Non-lung malignancy
- 5 Benign
- 35 Non-diagnostic

- 13 SBRT
- 32 SBRT
  - 16 Biopsy-proven cancer
  - 16 presumed lung cancer

51 Lung Resection Surgery
- 83 Total Lung Resection Surgery
  - 75 VATS/Robotic
  - 8 Thoracotomies

- 161 Continued CT Screening
- 16 Biopsy-proven cancer
- 16 presumed lung cancer
- 83 Total Lung Resection Surgery
  - 75 VATS/Robotic
  - 8 Thoracotomies

- 66 Lung cancer
  - 3 Non-lung cancer malignancy
  - 14 Benign disease

- 3280 with Follow-up at Lahey
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32 proceeded to lung surgery
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3280 with Follow-up at Lahey

345 LungRADS 4

311 LungRADS 4
86 patients underwent one or more invasive diagnostic procedure(s)

- 35 Non-diagnostic
  - 4 observation
  - 6 SBRT
  - 15 Surgery
  - 14 observation

- 5 Benign disease
  - 1 Surgery

- 42 Lung cancer
  - 19 chemo +/- rads
  - 6 SBRT
  - 15 Surgery

- 4 Non-lung cancer malignancy
  - 1 Surgery
  - 2 died before treatment

41%
86 patients underwent one or more invasive diagnostic procedure(s)

- 35 Non-diagnostic
  - 4 observation
  - 6 SBRT
  - 15 Surgery

- 5 Benign disease
  - 1 Surgery
  - 14 observation

- 42 Lung cancer
  - 19 chemo +/- rads
  - 6 SBRT
  - 15 Surgery

- 4 Non-lung cancer malignancy
  - 1 Surgery
  - 2 died before treatment
Invasive Diagnostic Procedures

86 patients underwent one or more invasive diagnostic procedure(s)

- 41% Non-diagnostic: 35 patients
  - 4 observation
    - 6 SBRT
    - 15 Surgery
    - 14 observation

- 5.8% Benign disease: 5 patients
  - 1 Surgery
  - 19 chemo +/- rads

- 48.8% Lung cancer: 42 patients
  - 1 Surgery
  - 6 SBRT
  - 15 Surgery
  - 2 died before treatment

- 4 Non-lung cancer malignancy: 4 patients
  - 1 Surgery
## Results – Diagnostic interventions

<table>
<thead>
<tr>
<th>Diagnostic study or procedure</th>
<th>Number of patients (% of Lung-RADS 4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PET scan</td>
<td>192 (61.7)</td>
</tr>
<tr>
<td>CT-guided lung biopsy</td>
<td>31 (10.0)</td>
</tr>
<tr>
<td>Extrathoracic biopsy</td>
<td>6 (1.9)</td>
</tr>
<tr>
<td>Bronchoscopic-guided procedures</td>
<td>55 (17.4)</td>
</tr>
<tr>
<td>Navigational bronchoscopy</td>
<td>16 (5.1)</td>
</tr>
<tr>
<td>EBUS with transbronchial biopsy</td>
<td>47 (15.1)</td>
</tr>
<tr>
<td>Endobronchial biopsy</td>
<td>7 (2.3)</td>
</tr>
<tr>
<td>BAL/brushing</td>
<td>5 (1.6)</td>
</tr>
<tr>
<td>Medical thoracoscopy and pleural biopsy</td>
<td>2 (0.6)</td>
</tr>
<tr>
<td>Mediastinoscopy</td>
<td>26 (8.4)</td>
</tr>
<tr>
<td>Thoracentesis</td>
<td>3 (1.0)</td>
</tr>
<tr>
<td>Pericardiocentesis</td>
<td>1 (0.3)</td>
</tr>
</tbody>
</table>

- 86 patients underwent invasive diagnostic procedures
  - No periprocedural deaths or major complications
  - .95% for non-malignant disease
## Therapeutic interventions

<table>
<thead>
<tr>
<th>Therapeutic Intervention</th>
<th>Number of patients (%)</th>
<th>% Lung-RADS 4 patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical pulmonary resection</td>
<td>83</td>
<td>26.7</td>
</tr>
<tr>
<td>Tissue-proven lung cancer prior to surgery</td>
<td>16 (19.3)</td>
<td>5.1</td>
</tr>
<tr>
<td>Presumed lung cancer</td>
<td>67 (80.7)</td>
<td>21.5</td>
</tr>
<tr>
<td>SBRT</td>
<td>25</td>
<td>8.0</td>
</tr>
<tr>
<td>Tissue-proven lung cancer prior to SBRT</td>
<td>6 (24)</td>
<td>1.9</td>
</tr>
<tr>
<td>Presumed lung cancer</td>
<td>19 (76)</td>
<td>6.1</td>
</tr>
<tr>
<td>Chemotherapy</td>
<td>15</td>
<td>4.8</td>
</tr>
<tr>
<td>Adjuvant</td>
<td>9</td>
<td>2.9</td>
</tr>
<tr>
<td>Palliative</td>
<td>6</td>
<td>1.9</td>
</tr>
<tr>
<td>Chemoradiation</td>
<td>16</td>
<td>5.1</td>
</tr>
<tr>
<td>Neoadjuvant</td>
<td>2</td>
<td>0.6</td>
</tr>
<tr>
<td>Definitive</td>
<td>14</td>
<td>4.5</td>
</tr>
<tr>
<td>Palliative thoracic radiation</td>
<td>1</td>
<td>0.3</td>
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83 patients underwent lung resection

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Number of patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Extent of resection</strong></td>
<td></td>
</tr>
<tr>
<td>Wedge</td>
<td>28 (34.1)</td>
</tr>
<tr>
<td>Segmentectomy</td>
<td>12 (14.5)</td>
</tr>
<tr>
<td><strong>Lobectomy</strong></td>
<td>40 (48.2)</td>
</tr>
<tr>
<td>Bilobectomy</td>
<td>3 (3.6)</td>
</tr>
<tr>
<td>Pneumonectomy</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td><strong>Approach</strong></td>
<td></td>
</tr>
<tr>
<td>Thoracoscopy</td>
<td>75 (90.4)</td>
</tr>
<tr>
<td>Coil localization</td>
<td>9 (10.8)</td>
</tr>
<tr>
<td>Robotic assisted</td>
<td>22 (26.5)</td>
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<tr>
<td>Thoracotomy</td>
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</tbody>
</table>
## Surgical results

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Diagnosis</strong></td>
<td></td>
</tr>
<tr>
<td>Lung cancer</td>
<td>66 (79.5)</td>
</tr>
<tr>
<td>Non-lung cancer malignancy</td>
<td>3 (3.6)</td>
</tr>
<tr>
<td>Benign disease</td>
<td>14 (16.9)</td>
</tr>
<tr>
<td><strong>Lung cancer path stage (n = 64)</strong></td>
<td></td>
</tr>
<tr>
<td>Carcinoma in situ</td>
<td>2 (3.0)</td>
</tr>
<tr>
<td>IA</td>
<td>42 (63.6)</td>
</tr>
<tr>
<td>IB</td>
<td>11 (16.7)</td>
</tr>
<tr>
<td>IIA</td>
<td>8 (12.1)</td>
</tr>
<tr>
<td>IIIA</td>
<td>2 (3.0)</td>
</tr>
<tr>
<td>IV</td>
<td>1 (1.5)</td>
</tr>
<tr>
<td><strong>Histology of benign disease</strong></td>
<td></td>
</tr>
<tr>
<td>Granuloma</td>
<td>6</td>
</tr>
<tr>
<td>Hamartoma</td>
<td>4</td>
</tr>
<tr>
<td>Organizing pneumonia</td>
<td>1</td>
</tr>
<tr>
<td>Other</td>
<td>3</td>
</tr>
</tbody>
</table>

- 0.43% of all Lahey LCS patients surgery for benign disease
### Surgical results - complications

<table>
<thead>
<tr>
<th>Complication Grade</th>
<th>Number of patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clavien-Dindo Grade</strong></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>12 (14.5)</td>
</tr>
<tr>
<td>II</td>
<td>23 (27.7)</td>
</tr>
<tr>
<td>III</td>
<td>10 (12.0)</td>
</tr>
<tr>
<td>IV</td>
<td>2 (2.4)</td>
</tr>
<tr>
<td>V (death)</td>
<td>0</td>
</tr>
<tr>
<td><strong>NLST Grade</strong></td>
<td></td>
</tr>
<tr>
<td>Major</td>
<td>5 (6.0)</td>
</tr>
<tr>
<td>Intermediate</td>
<td>42 (50.6)</td>
</tr>
</tbody>
</table>

- There were no deaths within 60 days of surgery
- 6.0% had “major” complications according to NLST criteria
- Compared to 11.9% in NLST trial
## SBRT in LCS

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Number of patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tissue-proven lung cancer prior to SBRT</td>
<td>6 (24.0)</td>
</tr>
<tr>
<td>Presumed lung cancer</td>
<td>19 (76.0)</td>
</tr>
<tr>
<td>Thoracic surgeon SBRT shared decision making</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>24 (96.0)</td>
</tr>
<tr>
<td>No</td>
<td>1 (4.0)</td>
</tr>
<tr>
<td>Recurrence following SBRT</td>
<td>8 (32.0)</td>
</tr>
<tr>
<td>Patients initially with tissue-proven lung cancer</td>
<td>4</td>
</tr>
<tr>
<td>Patients initially presumed to have lung cancer</td>
<td>4</td>
</tr>
<tr>
<td>Median follow-up time from January 1, 2019 (months)</td>
<td>31.5</td>
</tr>
</tbody>
</table>
NLST
Results: False Positive Workup/Adverse Events

• False Positive Rate:
  – 20-25%: Chance you will end up with a false positive (7.8%)
  – ~8-10% for Mammography (“Call back”)

• False Discovery Rate (1-PPV):
  – 96%: Chance if you are positive you do not have cancer (85%)
  – Same as mammography

• Intervention without disease:
  – 0.4-2.4%: Chance if screened you will have an unnecessary invasive procedure (LDCT) (0.4%-0.95%)
  – ~1.5%: Chance if screened you end up having a negative biopsy (mammography)
National Lung Screening Trial

Results: Positive Workup/Adverse Events

• True Positives
  – Invasive procedure major complication: 11.2% (6%)
  – Surgical resection mortality: 1% 0
Challenges Shared Decision Making

False positive rate in modern clinical practice CTLS?

98%, 60%, 50%, 23%, 12%, 7%, 5%, 2%

Overdiagnosis

70%, 50%, 18%, 10%, 3%

Likelihood of surgery 0.4% or intervention 0.95% for benign disease

Significant Incidental Findings

70%, 40%, 10%, 6%, 4%, 2%
Shared Decision Making Conversation

• You are at high risk for lung cancer (2% baseline)
• New screening guidelines annual CTLS
• Finds early stage lung cancer 85% of the time
• Screen detected stage I lung cancer is 90% curable with surgery
• Less than 10% chance nodule is found that is not cancer – managed mainly with imaging follow up
• Surgery for benign disease .43%
• Invasive diagnostic intervention is rare .95%
Shared Decision Making Conversation

• If imaging follow up is recommended, and cancer ultimately found, it would be early stage
• No co-pay for annual screening exam
• Radiation exposure of a mammogram
• Smoking cessation for current smokers
• Small possibility we find something other than lung cancer requiring care escalation