Communication About the Probability of Cancer in Indeterminate Pulmonary Nodules

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**IMPORTANCE**  Clinical guidelines recommend that clinicians estimate the probability of malignancy for patients with indeterminate pulmonary nodules (IPNs) larger than 8 mm. Adherence to these guidelines is unknown.

**OBJECTIVES**  To determine whether clinicians document the probability of malignancy in high-risk IPNs and to compare these quantitative or qualitative predictions with the validated Mayo Clinic Model.

**DESIGN, SETTING, AND PARTICIPANTS**  Single-institution, retrospective cohort study of patients from a tertiary care Department of Veterans Affairs hospital from January 1, 2003, through December 31, 2015. Cohort 1 included 291 veterans undergoing surgical resection of known or suspected lung cancer from January 1, 2003, through December 31, 2015. Cohort 2 included a random sample of 239 veterans undergoing inpatient or outpatient pulmonary evaluation of IPNs at the hospital from January 1, 2003, through December 31, 2012.

**EXPOSURES**  Clinician documentation of the quantitative or qualitative probability of malignancy.

**MAIN OUTCOMES AND MEASURES**  Documentation from pulmonary and/or thoracic surgery clinicians as well as information from multidisciplinary tumor board presentations was reviewed. Any documented quantitative or qualitative predictions of malignancy were extracted and summarized using descriptive statistics. Clinicians’ predictions were compared with risk estimates from the Mayo Clinic Model.

**RESULTS**  Of 291 patients in cohort 1, 282 (96.9%) were men; mean (SD) age was 64.6 (9.0) years. Of 239 patients in cohort 2, 233 (97.5%) were men; mean (SD) age was 65.5 (10.8) years. Cancer prevalence was 258 of 291 cases (88.7%) in cohort 1 and 110 of 225 patients with a definitive diagnosis (48.9%) in cohort 2. Only 13 patients (4.5%) in cohort 1 and 3 (1.3%) in cohort 2 had a documented quantitative prediction of malignancy prior to tissue diagnosis. Of the remaining patients, 217 of 278 (78.1%) in cohort 1 and 149 of 236 (63.1%) in cohort 2 had qualitative statements of cancer risk. In cohort 2, 23 of 79 patients (29.1%) without any documented malignancy risk statements had a final diagnosis of cancer. Qualitative risk statements were distributed among 32 broad categories. The most frequently used statements aligned well with Mayo Clinic Model predictions for cohort 1 compared with cohort 2. The median Mayo Clinic Model–predicted probability of cancer was 68.7% (range, 2.4%-100.0%). Qualitative risk statements roughly aligned with Mayo predictions.

**CONCLUSIONS AND RELEVANCE**  Clinicians rarely provide quantitative documentation of cancer probability for high-risk IPNs, even among patients drawn from a broad range of cancer probabilities. Qualitative statements of cancer risk in current practice are imprecise and highly variable. A standard scale that correlates with predicted cancer risk for IPNs should be used to communicate with patients and other clinicians.

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The discovery of indeterminate pulmonary nodules (IPNs) is common in clinical practice. They are found in 17% to 51% of computed tomographic images of the chest, and a conservative extrapolation suggests at least 1.5 million lung nodules are found annually with a 1% to 12% chance of malignancy. Thus, incidentally discovered nodules represent a significant existing diagnostic burden. Because lung cancer is the leading cause of cancer mortality, identifying and resecting limited-stage disease is the key to saving lives. Yet most lung nodules discovered incidentally or on screening computed tomography scans are benign. The appropriate management of IPNs hinges on determining and communicating the probability of cancer.

The American College of Chest Physicians (ACCP) updated practice guidelines in 2007 and included a recommendation to document the pretest probability of a malignant neoplasm for every patient with a solitary pulmonary nodule. Multiple decision tools exist to assist clinicians as they perform these assessments. These tools include diagnostic models, such as the Mayo Clinic Model and the Veterans Affairs pretest probability model, in patients with an identified node being evaluated by pulmonologists or primary care physicians. In addition, the recently developed Thoracic Research Evaluation and Treatment (TREAT) model is used in patients already referred to a thoracic surgeon for consideration of surgical biopsy and/or formal lung resection. Despite the availability and predictive utility of these models, many clinicians rely on clinical judgment when deciding whether to refer patients for additional testing or diagnostic procedures. Adherence to the ACCP guidelines to predict risk of malignancy in a lung nodule is unknown.

Our study objectives were 2-fold. First, we sought to determine whether clinicians routinely document the pretest probability of malignancy in patients with high-risk IPNs. We hypothesized that clinicians rarely estimate and document the pretest probability of malignancy in an IPN. Second, we sought to compare clinicians’ estimates of the probability of malignancy in an IPN with estimates generated by the Mayo Clinic Model, a validated prediction model. We hypothesized that the prediction model would be more accurate than clinicians’ estimates.

Methods

Study Population

This retrospective, single-institution cohort study included 2 cohorts who received either surgical treatment or pulmonary evaluation. Cohort 1 comprised all patients who underwent surgical resection for known or suspected lung cancer at the Tennessee Valley Healthcare Center in Nashville over a 12-year period from January 1, 2003, through December 31, 2015. Cohort 2 comprised a random sample of veterans who underwent inpatient or outpatient pulmonary evaluation of IPNs at the tertiary hospital from January 1, 2003, through December 31, 2012. Although lesions larger than 3 cm are considered masses and not nodules, both nodules and masses were included in the study under the term IPN.

The Tennessee Valley Healthcare Center institutional review board approved this study and waived the need for patient consent for both cohorts. Inclusion criteria for cohort 1 included a lung resection at the Tennessee Valley Healthcare Center during the dates specified and a preoperative diagnosis or suspicion of cancer. Exclusion criteria included a tissue diagnosis of cancer prior to any clinical encounter with a pulmonologist or surgeon at our facility. For patients who underwent a second lung resection for a separate nodule or for a known or suspected recurrence during the study period, only the first surgical resection was included. Inclusion criteria for cohort 2 included a pulmonary consultation for the evaluation of an IPN. Exclusion criteria included evidence of pulmonary infection or other benign disease and a preconsultation tissue diagnosis of cancer.

Study Procedures and Definitions

We extracted the following information from a medical record review: patient demographics, clinical predictors of lung cancer, final pathologic diagnosis, and any documentation of the preoperative probability of malignancy. When available, we reviewed notes from pulmonary and thoracic surgery clinicians as well as information from multidisciplinary tumor board presentations.

Each clinical encounter note was first reviewed for any documented quantitative prediction of malignancy. Documentation of a quantitative probability of malignancy was defined as the inclusion of a numeric percentage in the form of a point estimate (eg, 80%), a threshold (eg, >50%), or a range (eg, 60%-70%). Information was also collected when a clinician reported using a specific risk model to calculate a quantitative prediction.

In the absence of any quantitative prediction of malignancy, charts were reviewed in detail for qualitative descriptors of the probability of cancer. Documentation of a qualitative probability of malignancy was defined as any phrase that communicated the likelihood that a nodule contained cancer, ranging from general risk statements (eg, suspicious, very concerning) to more specific language (eg, cancer until proven otherwise, high pretest probability). We combined common language found into 14 summary statements labeled as bins. We used bins to categorize similar qualitative terms used to communicate the probability of cancer and to bring some interpretability to highly variable, subjective terminology used for other malignancies.

Findings

In this single-institution cohort study of veterans with indeterminate pulmonary nodules, pulmonary and/or thoracic surgery clinicians documented the quantitative probability of malignancy for fewer than 5% of patients. Seventy-one percent of the remaining patients had some qualitative statement of cancer risk defined in 32 broad categories.

Meaning

Qualitative risk statements of malignancy for indeterminate pulmonary nodules in current practice are imprecise, highly variable, and should be replaced by a standard scale that correlates with predicted risk of cancer.

Key Points

**Question** Do clinicians routinely document the probability of malignancy for patients with high-risk indeterminate pulmonary nodules?

**Findings** In this single-institution cohort study of veterans with indeterminate pulmonary nodules, pulmonary and/or thoracic surgery clinicians documented the quantitative probability of malignancy for fewer than 5% of patients. Seventy-one percent of the remaining patients had some qualitative statement of cancer risk defined in 32 broad categories.

**Meaning** Qualitative risk statements of malignancy for indeterminate pulmonary nodules in current practice are imprecise, highly variable, and should be replaced by a standard scale that correlates with predicted risk of cancer.
among many different clinicians. These statements were categorized based on the language of severity used by the clinicians describing cancer risk.

### Statistical Analysis

Statistical Software, release 12.0 (StataCorp LP) and R Studio software, version 0.99.896 (RStudio, Inc) were used for all statistical analyses. Notes documenting a quantitative or qualitative probability of malignancy were summarized using descriptive statistics. Clinicians’ predictions of malignancy were compared with the objective cancer risk estimates calculated using the Mayo Clinic Model. Complete case analysis was used for missing data. Linear regression was used for the association between the Mayo Clinic Model–predicted probability of cancer and the clinician estimates categorized into bins by order of severity. Two-sided $P$ values less than .05 were considered statistically significant.

### Results

Of 291 patients in cohort 1, 282 (96.9%) were men; mean (SD) age was 64.6 (9.0) years. Of 239 patients in cohort 2, 233 (97.5%) were men; mean (SD) age was 65.5 (10.8) years (Table 1). In cohort 1, of 322 patients with lung resections for known or suspected lung cancer during the study period, 291 (90.4%) had no tissue diagnosis prior to at least 1 clinical encounter at our facility. Patients were predominantly male smokers and were older than 60 years (Table 1). Prevalence of cancer was 88.7% overall, primarily diagnosed as adenocarcinoma and squamous cell carcinoma. Cohort 2 patients were of comparable age and sex distribution, with an overall cancer prevalence of 48.9% (110 of 225 patients with a final definitive diagnosis).

Only 13 patients (4.5%) in cohort 1 and 3 (1.3%) in cohort 2 had a documented quantitative prediction of malignancy prior to the tissue diagnosis. The 13 quantitative predictions for patients in cohort 1 comprised 7 pulmonary clinic notes, 2 multidisciplinary chest conference notes, and 4 thoracic surgery clinic notes. Numeric predictions ranged from 50% to 100%.

Of the 278 patients in cohort 1 without a documented quantitative prediction of malignancy, the proportion of thoracic surgery notes that included either a quantitative or qualitative risk statement increased slightly from 31 of 66 notes (47.0%) to 45 of 74 notes (60.8%) ($P = .14$), whereas the proportion of pulmonology clinic notes documenting the pretest probability of malignancy using risk statements dropped from 83 of 111 notes (74.8%) to 102 of 154 (66.2%) ($P = .17$). The proportion of chest
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ties of cancer with statements categorized in bins aligned well with Mayo Clinic Model predictions, with a significant correlation between ranked progressively higher qualitative statements of risk and higher Mayo Clinic Model–predicted probability of cancer (Figure; correlation, P < .001). However, there was significant spread across a range of Mayo Clinic Model–predicted probabilities of cancer within each bin of similar qualitative risk language.

Table 2. Qualitative Risk Statement Bins and Cancer Prevalence

<table>
<thead>
<tr>
<th>Bin</th>
<th>Qualitative Risk Statement</th>
<th>No. of Patients</th>
<th>Cancer Prevalence, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Benign pattern; not malignant</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>1</td>
<td>Unlikely cancer; very few risk factors</td>
<td>6</td>
<td>67</td>
</tr>
<tr>
<td>2</td>
<td>Doubt malignancy; low concern; probably benign</td>
<td>9</td>
<td>44</td>
</tr>
<tr>
<td>3</td>
<td>Differential diagnosis includes cancer</td>
<td>11</td>
<td>36</td>
</tr>
<tr>
<td>4</td>
<td>Possible cancer; cannot rule out cancer</td>
<td>25</td>
<td>56</td>
</tr>
<tr>
<td>5</td>
<td>Concerning for cancer</td>
<td>72</td>
<td>83</td>
</tr>
<tr>
<td>6</td>
<td>Suspicious for cancer</td>
<td>62</td>
<td>79</td>
</tr>
<tr>
<td>7</td>
<td>Most concerning for cancer; most worrisome for cancer</td>
<td>19</td>
<td>95</td>
</tr>
<tr>
<td>8</td>
<td>Most likely cancer</td>
<td>18</td>
<td>100</td>
</tr>
<tr>
<td>9</td>
<td>Worrisome for cancer; worried about cancer</td>
<td>13</td>
<td>85</td>
</tr>
<tr>
<td>10</td>
<td>Probable cancer; high on differential diagnosis</td>
<td>20</td>
<td>90</td>
</tr>
<tr>
<td>11</td>
<td>High risk; highly suspicious</td>
<td>47</td>
<td>85</td>
</tr>
<tr>
<td>12</td>
<td>Very concerning; very high likelihood</td>
<td>41</td>
<td>93</td>
</tr>
<tr>
<td>13</td>
<td>Assume cancer; consistent with cancer</td>
<td>18</td>
<td>83</td>
</tr>
</tbody>
</table>

Table 3. Proposed Risk Scale to Communicate Probability of Malignancy

<table>
<thead>
<tr>
<th>Risk Level</th>
<th>Probability of Malignancy, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low risk</td>
<td>0-5</td>
</tr>
<tr>
<td>Moderate risk</td>
<td>6-50</td>
</tr>
<tr>
<td>High risk</td>
<td>51-80</td>
</tr>
<tr>
<td>Most likely cancer</td>
<td>81-100</td>
</tr>
</tbody>
</table>

The Mayo Clinic Model–predicted probability of cancer median was 68.7% (range, 2.4%-100.0%).

Discussion

Our primary finding indicates that fewer than 5% of clinicians are documenting quantitative estimates of the probability of malignancy in IPNs prior to a tissue diagnosis of cancer. The majority of patients in both cohorts (72.0%) had at least some risk statements or qualitative language used that attempted to communicate the likelihood that the IPN could be a malignant neoplasm. The qualitative risk statements were vague, wide-ranging, and not systematic but reflected an attempt by each clinician to document a high-risk IPN that required biopsy for diagnosis.

To our knowledge, this is the first report on documentation habits of clinicians regarding the probability of malignancy in IPNs. It is known that their beliefs and practices about lung cancer screening do not align perfectly with well-disseminated guidelines. This pattern was true even before the US Preventive Services Task Force recommendation in favor of low-dose computed tomographic scans for high-risk patients.

The proportion of lung resections for benign disease varies by institution and has risen in recent years with the pervasive use of video-assisted thoracoscopic surgery. Clinician-to-clinician and clinician-to-patient communications about the probability of cancer in an IPN play a critical role in deciding to undergo a diagnostic thoracic surgery. Research suggests that a shared decision-making model is most appropriate for decision making among veterans with IPNs. Quantitative communication about the risk of lung cancer facilitates joint decision making. Effective clinician-to-patient communication about lung cancer has been shown to increase the probability of receiving appropriate cancer-directed therapies, including chemotherapy.

Determining and communicating the pretest probability of cancer informs patients, family members, and other clinicians and facilitates the most timely and cost-effective strategy for diagnosis and management of an IPN. Further research is needed to determine whether clinician evaluations are comparable to validated models at predicting diagnosis and prognosis of cancer. Initial research suggests that a multidisciplinary team discussion improves the prognostic accuracy of individual clinicians.

We propose a simple standardized scale (Table 3) for clinicians to communicate the probability of cancer in lieu of documenting a quantitative prediction. The cutoff points are based on cost-effectiveness studies and clinical guidelines for the management of IPNs.
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Limitations and Strengths
This study was limited to a single Department of Veterans Affairs facility, and the findings may not be widely generalizable to other medical contexts. Additional limitations included lack of data regarding the primary surgical procedure performed and complete clinical staging. Clinical stage and/or lung wedge resection rather than a lobectomy may have correlated with clinicians’ estimates of the probability of malignancy for the IPN. We included 2 cohorts to better investigate how clinicians document cancer probability across a range of clinical settings and cancer prevalence for high-risk IPNs. We were also concerned that lack of documentation in the cohort I group could show bias since the IPNs were mostly “high risk” lesions by the nature of being referred to the surgical clinic. The final prevalence of cancer was high in cohort 1, particularly because the benign disease rate at our facility has dropped in recent years.15 The ACCP guidelines regarding documentation of the probability of malignancy are arguably more relevant to the clinical care of the population of patients with pulmonary lung nodules in cohort 2, with a lower cancer prevalence of 48.9%. We believe that replicating results found in cohort 1 (variability of language and lack of quantitative documentation of cancer risk) to the cohort 2 group strengthens the robustness of our findings.

Conclusions
Neither pulmonologists nor surgeons provide routine quantitative documentation of the probability of cancer in high-risk IPNs. Qualitative statements of risk in current practice are highly variable but correlate well with Mayo Clinic Model predictions. We propose a standard risk scale to better communicate with patients and other clinicians about the risk of malignancy in an IPN.

REFERENCES