

Management of Pulmonary Nodules by Community Pulmonologists

A Multicenter Observational Study

Nichole T. Tanner, MD, MSCR; Jyoti Aggarwal, MHS; Michael K. Gould, MD; Paul Kearney, PhD;
Gregory Diette, MD, MHS; Anil Vachani, MD; Kenneth C. Fang, MD; and Gerard A. Silvestri, MD



BACKGROUND: Pulmonary nodules (PNs) are a common reason for referral to pulmonologists. The majority of data for the evaluation and management of PNs is derived from studies performed in academic medical centers. Little is known about the prevalence and diagnosis of PNs, the use of diagnostic testing, or the management of PNs by community pulmonologists.

METHODS: This multicenter observational record review evaluated 377 patients aged 40 to 89 years referred to 18 geographically diverse community pulmonary practices for intermediate PNs (8-20 mm). Study measures included the prevalence of malignancy, procedure/test use, and nodule pretest probability of malignancy as calculated by two previously validated models. The relationship between calculated pretest probability and management decisions was evaluated.

RESULTS: The prevalence of malignancy was 25% (n = 94). Nearly one-half of the patients (46%, n = 175) had surveillance alone. Biopsy was performed on 125 patients (33.2%). A total of 77 patients (20.4%) underwent surgery, of whom 35% (n = 27) had benign disease. PET scan was used in 141 patients (37%). The false-positive rate for PET scan was 39% (95% CI, 27.1%-52.1%). Pretest probability of malignancy calculations showed that 9.5% (n = 36) were at a low risk, 79.6% (n = 300) were at a moderate risk, and 10.8% (n = 41) were at a high risk of malignancy. The rate of surgical resection was similar among the three groups (17%, 21%, 17%, respectively; $P = .69$).

CONCLUSIONS: A substantial fraction of intermediate-sized nodules referred to pulmonologists ultimately prove to be lung cancer. Despite advances in imaging and nonsurgical biopsy techniques, invasive sampling of low-risk nodules and surgical resection of benign nodules remain common, suggesting a lack of adherence to guidelines for the management of PNs.

CHEST 2015; 148(6):1405-1414

Manuscript received March 14, 2015; revision accepted May 15, 2015; originally published Online First July 18, 2015.

ABBREVIATIONS: CHEST = American College of Chest Physicians; FN = false negative; FP = false positive; pCA = pretest probability of malignancy; PN = pulmonary nodule; SUV = standard uptake value; TTNA = transthoracic needle aspiration

AFFILIATIONS: From the Department of Medicine (Drs Tanner and Silvestri), Division of Pulmonary and Critical Care Medicine, Medical University of South Carolina, Charleston, SC; the Health Equity and Rural Outreach Innovation Center (Dr Tanner), Ralph H. Johnson Veterans Affairs Hospital, Charleston, SC; Boston Healthcare Associates (Ms Aggarwal), Boston, MA; the Department of Research and Evaluation (Dr Gould), Kaiser Permanente Southern California, Pasadena, CA; Integrated Diagnostics, Inc (Drs Kearney and Fang), Seattle, WA; the Department of Medicine (Dr Diette), Division of Pulmonary and Critical Care Medicine, Johns Hopkins University, Baltimore, MD; and the

Department of Medicine (Dr Vachani), Pulmonary, Allergy, and Critical Care Division, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA.

FUNDING/SUPPORT: This study was supported by Integrated Diagnostic, Inc.

CORRESPONDENCE TO: Nichole T. Tanner, MD, MSCR, 96 Jonathan Lucas St, CSB 810, Charleston, SC 29425; e-mail: tripici@muscc.edu

© 2015 AMERICAN COLLEGE OF CHEST PHYSICIANS. This is an open access article distributed under the terms of the Creative Commons Attribution-Noncommercial License (<http://creativecommons.org/licenses/by-nc/3.0/>), which permits unrestricted use, distribution, and reproduction to noncommercial entities, provided the original work is properly cited. Information for reuse by commercial entities is available online.

DOI: 10.1378/chest.15-0630

Open access under [CC BY-NC-ND license](#).

A pulmonary nodule (PN) is defined as a radiographic opacity ≤ 3 cm in diameter surrounded by lung parenchyma.¹ The prevalence of PNs is unknown, with estimates ranging from 150,000 to 1 million per year in the United States.² The identification of PNs may increase over the next decade for several reasons. First, chest CT scans are ordered frequently for a myriad of clinical indications, including dyspnea or chest pain. Smith-Bindman et al³ estimate the rate of chest CT scanning as 23 per 1,000, which, extrapolated to the US population, equates to approximately 7 million chest CT scans performed annually. Second, the National Lung Screening Trial found three fewer deaths from lung cancer per 1,000 in those screened annually for 3 years with low-dose chest CT scans, leading to the B recommendation by the US Preventive Services Task Force⁴ to screen high-risk individuals with yearly low-dose CT scans. However, the National Lung Screening Trial also found a 25% rate of screen-detected nodules, 96% of which were benign. Currently, 8.6 million Americans meet the criteria for screening.⁵ Depending on the penetration of screening, the incidence of detected PNs could increase dramatically.⁶

The American College of Chest Physicians (CHEST) and the Fleischner Society have published guidelines for management based on pretest probability of malignancy (pCA).^{7,8} Management decisions fall into three general categories based on the physician's pCA. For those in whom the pCA is low, serial imaging is recommended. When

the pCA is intermediate, functional imaging (PET scan), biopsy, or both is warranted. When the pCA is high, surgery is recommended.⁸ Although these recommendations appear straightforward, other factors such as patient

FOR EDITORIAL COMMENT SEE PAGE 1365

SEE RELATED ARTICLES PAGES 1415 AND 1422

comorbidities and preferences often influence the choice of management strategy.⁸ Clinical prediction models have been developed and validated to assess the pCA in PNs, which can be used to help guide decisions about selection and interpretation of additional diagnostic testing.⁹⁻¹²

Outside clinical practice guidelines, there remain significant challenges in interpretation of the literature. First, the prevalence of malignancy in a PN varies by the context within which it is studied, from a low of 2% in lung cancer screening trials to a high of 83% in surgical series.¹³⁻¹⁵ Unfortunately, most of these studies are from single-center academic institutions focused on a single aspect of nodule management (eg, PET scan use) and do not always combine modalities to give a cohesive picture of how nodules are managed from presentation to final outcome. We undertook this study to better understand the management patterns of physicians faced with the evaluation of intermediate-sized nodules, which most often present a diagnostic dilemma,¹⁶ in community settings across the United States.

Materials and Methods

This was a multicenter, community-based, retrospective observational study of patients with PNs, ranging from 8 to 20 mm in diameter, presenting to 18 geographically representative outpatient pulmonary clinics across the United States. The study was approved at 15 sites by a central institutional review board and at three sites by local institutional review board approval.

Site Selection

Four hundred forty sites were identified based on investigator databases and claims data from a large insurance carrier whose coverage population was representative of the overall US population. Of these, 77 sites expressed interest in participating, and 48 sites went on to sign confidentiality agreements. Of these, 17 did not request additional information, leaving 31 sites undergoing qualification review. Eighteen outpatient pulmonary clinics were chosen to participate based on the following criteria: (1) management of patients with PNs, (2) availability of medical records, and (3) ability to perform data abstraction. In addition, investigators targeted enrollment of geographically diverse patients to limit the potential bias associated with differences in practice patterns and to account for variation in disease prevalence (eg, endemic mycoses) that could alter management decisions.

Patient Selection

Patients were identified by querying databases (eg, billing and scheduling systems) using five *International Classification of Diseases, Ninth Revision, Clinical Modification* codes for PN (793.1, 786.6, 518.89, 519.8,

519.9) to ensure homogeneity in patient identification and inclusion.¹⁷ Manual chart abstraction was then used to identify those who met the criteria. To minimize selection bias, the sites were not permitted to use additional codes during database query to identify patients. To ensure a systematic sample, patient eligibility was determined by examining consecutively referred patients to the site.

Inclusion criteria included age ≥ 40 years and ≤ 89 years at the time of nodule finding, presentation to a pulmonologist, nodule size 8 to 20 mm, and definitive diagnosis ascertained by tissue diagnosis or radiographic follow-up for 2 years. Exclusion criteria included chest CT scan performed > 60 days prior to the initial visit, prior diagnosis of any cancer within 2 years of nodule detection, or incomplete chart data.

Patients were categorized into three groups by the most invasive procedure performed during management, as follows: surveillance (serial imaging), biopsy (CT scan-guided transthoracic needle aspiration [TTNA] or bronchoscopy), or surgery (including mediastinoscopy, video-assisted thorascopic surgery, and/or thoracotomy).

Data Collection

Clinical data were abstracted retrospectively by designated study staff into an electronic data capture system from initial consultation through establishment of a definitive diagnosis (ie, pathology results) or a minimum 2-year follow-up. Data included patient demographic and clinical characteristics, PN characteristics, imaging tests, invasive testing, and surgery. PET scan reports were reviewed and abstracted where available for a subset of patients. To adjudicate a PET scan

Download English Version:

<https://daneshyari.com/en/article/5953545>

Download Persian Version:

<https://daneshyari.com/article/5953545>

[Daneshyari.com](https://daneshyari.com)