ORIGINAL ARTICLE

Improvement in Stage of Lung Cancer Diagnosis With Incidental Pulmonary Nodules Followed With a Patient Tracking System and Computerized Registry

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Received 12 November 2021; revised 9 February 2022; accepted 13 February 2022
Available online - 16 February 2022

ABSTRACT

Introduction: Given that an incidental pulmonary nodule (IPN) on chest computed tomography (CT) may represent nascent lung cancer, timely follow-up imaging is critical to assess nodule growth and the need for tissue sampling. We previously reported our institution's systematic process to identify and track patients with an IPN associated with improved CT on follow-up. We hypothesized that this improvement may have led to a higher frequency of early-stage lung cancer. To evaluate this, we performed a study to determine whether cases of early-stage lung cancer were more likely to have had our tracking system applied to suspicious findings.

Methods: An observational study was performed by identifying cases of lung cancer that were detected as IPNs on chest CT scans performed at our institution, from 2006 to 2016. A total of 314 cases were dichotomized into early-stage (stage 1) or late-stage (stages II to IV) disease. A multivariant regression analysis with modeling was used to determine factors associated with a diagnosis of early-stage disease. Factors included the use of the tracking system and nodule registry.

Results: The following factors were independently associated with early-stage lung cancer: index nodule diameter, (OR = 0.971, confidence interval [CI]: 0.948–0.995], p = 0.016), adenocarcinoma histology (OR = 2.930 [CI: 1.695–5.064], p = 0.0001) and use of tracker phrases on CT reports (OR = 1.939 [CI: 1.126–3.339], p = 0.016).

Conclusions: The application of a patient tracking system and computerized lung nodule registry lead to an increased frequency in the diagnosis of stage 1 NSCLC from IPNs. This is a meaningful outcome for patients and should be adapted for IPN management.

Keywords: Incidental pulmonary nodules; Lung cancer screening; Lung nodule follow-up; Lung nodule registry and tracking

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Disclosure: Dr. Carr has been a compensated consultant for AstraZeneca, Eli Lilly, Takeda, EMD Serono, Blueprint Medicines, and Partnership for Health Analytic Research. Dr. Dyer has been a compensated consultant for Imidex and Lung Ambition Alliance. Dr. Kern has been a compensated consultant of AstraZeneca. Dr. Zelarney declares no conflict of interest.

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Cite this article as: Carr LL, Dyer DS, Zelarney PT, Kern EO. Improvement in stage of lung cancer diagnosis with incident pulmonary nodules followed with a patient tracking system and computerized registry. *JTO Clin Res Rep*. 2022;3:100297.

ISSN: 2666-3643
https://doi.org/10.1016/j.jtocrr.2022.100297

Introduction

The most effective way to improve outcomes of NSCLC is to diagnose and treat disease at an early stage. This was most clearly exhibited by improvement in the overall survival seen in the National Lung Screening Trial and other screening trials.[1–4] The National Lung Screening Trial revealed a stage shift from 31% of patients in the control group diagnosed with stage I disease to 50% of those who underwent computed tomography (CT) screening.[1] The diagnosis of NSCLC at an early stage is also of importance in nodules found incidentally on chest imaging performed for another purpose.

As the presence of an incidental pulmonary nodule (IPN) is unexpected, it may be difficult to ensure appropriate follow-up and management.[5,6] Development of systemwide approaches to the management and tracking of these patients has taken increasing importance.[7] The use of tools such as structured radiology reporting with guideline-driven follow-up recommendations, electronic nodule registries, and automated tracking systems have been found to improve timely follow-up.[8–10] When integrated into a comprehensive pulmonary nodule program, these tools have the potential to improve clinical outcomes for patients with lung cancer.[11–13]

Given that an IPN on a chest CT may represent nascent lung cancer, timely follow-up imaging is critical to assess nodule growth and the need for tissue sampling. We previously reported our institution's systematic process to identify and track patients with IPN associated with improved CT follow-up according to Fleischner Society Guidelines.[9] Data from our group revealed this system significantly improved the timeliness of follow-up for IPNs from 46% to 55% and decreased the proportion of patients lacking any imaging follow-up within 2 years from 48% to 31%. We hypothesized that the improved CT follow-up we observed may have led to a higher frequency of early diagnosis of lung cancer among our patients. To evaluate this, we performed a retrospective review to determine if cases of early-stage lung cancer compared with later-stage cancer cases were more likely to have had our tracking system applied to suspicious findings.

Materials and Methods

Patients

This was a retrospective, observational study with approval from the institutional review board. As the study was a minimal risk, informed consent was waived. A 100% sample of 22,527 adults (>18 y of age) with a Colorado residence ZIP code and at least one chest CT performed at our institution from 2008 to 2016 was compiled from the Allscripts electronic health record. Identifiers were submitted to the Colorado Central Cancer Registry, which returned 937 cases of primary lung cancer among 887 individuals.

Patients had a primary lung cancer diagnosis per International Classification of Diseases 9 and 10 codes; cases of in situ disease or lymphoma were excluded. We included only lung cancer cases in which at least one chest CT at our institution was performed before the lung cancer diagnosis date. We excluded cases in which the chest CT was performed for lung cancer screening, in preparation for a lung biopsy (CT-guided or navigational bronchoscopy), or for a clinical trial. We also excluded cases in which the most recent chest imaging occurred more than 2.5 years before the lung cancer diagnosis date. In addition, we excluded cases in which the first and only chest CT led to an immediate lung cancer diagnosis, without intervening imaging. The remaining 314 lung cancer cases were included in the analysis, as illustrated in Figure 1.

Suspicious Nodules Preceding Cancer Diagnosis

Chest CT reports preceding the diagnosis date of the lung cancer were reviewed for the presence of an IPN matching the laterality and lobe of the diagnosed lung cancer. If reports lacked descriptions of nodule size or density, CT images were also reviewed (LC and DD). The date of the first chest CT identifying an IPN in the matching lobe was considered the index date, and the nodule was considered the index nodule for subsequent cancer.

Lung Cancer Comparison Groups

Cancer histology, location, and TNM classification, (sixth and seventh edition, American Joint Committee on Cancer) were ascertained from the Colorado Central Cancer Registry data. A stage group was assigned to each case on the basis of pathologic staging when available; otherwise, the clinical staging was used. Patients whose cancer was stage group I were assigned to the early-stage group. Patients with stage group II to IV were assigned to the late-stage group. Cases with incomplete staging information available that were clearly more advanced than stage I were included in the late-stage group

From the electronic health record data, we ascertained the age of patients on the date of the index CT scan along with sex, pack-years of cigarette smoking, presence of a diagnosis of interstitial lung disease (ILD), and ordering physician for the CT as potential predictive characteristics between the two groups.

Tracker Phrase in Chest CT Reports

We determined whether or not the index CT for each cancer case contained a tailored recommendation for

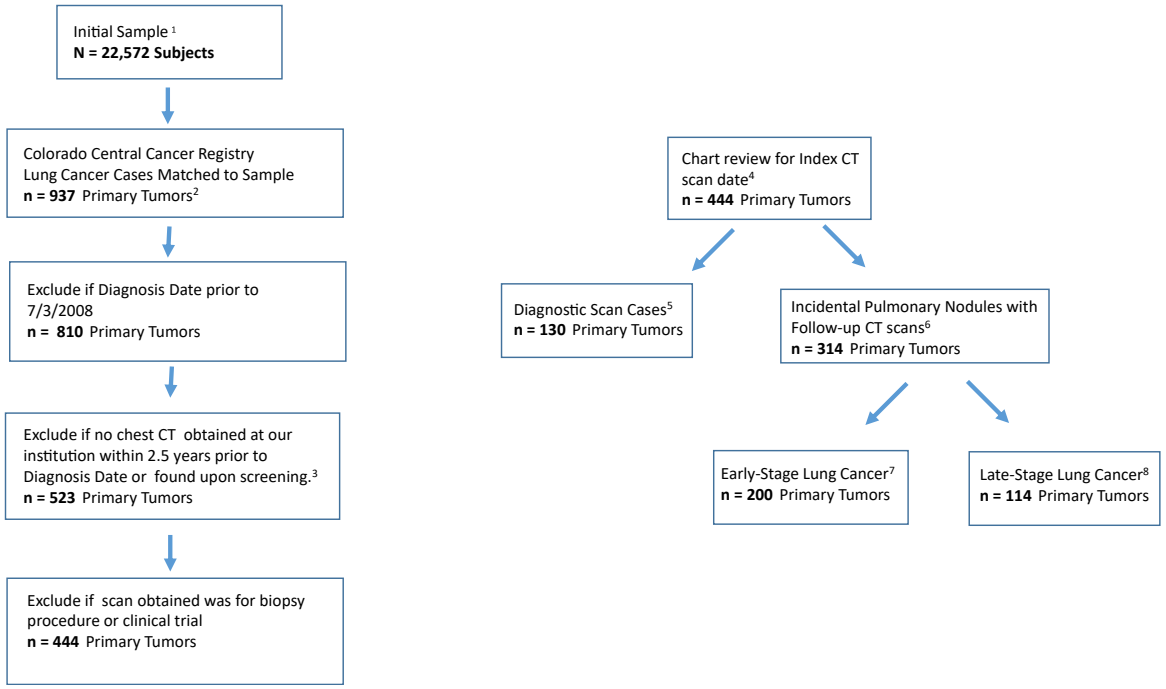

Figure 1. Selection of lung cancer cases previously identified as IPN. [1]The initial sample included all patients from our institution who had a chest CT between July 3, 2008 and December 31, 2016, were more than 18 years of age at the time of the chest CT and had Colorado listed as the primary residence. [2]Identifiers from the initial sample were matched to primary lung cancer cases from the Central Colorado Cancer Registry. [3]Cases of lymphoma and carcinoma in situ were excluded. [4]Index CT scans were defined as the chest CT scan in which an IPN was first identified in the same laterality and lobe of the lung as the subsequent primary tumor. [5]Diagnostic cases were defined as those in which the only CT scan with an abnormality led directly to a diagnosis of lung cancer, without follow-up imaging of an IPN. [6]IPN cases were defined as those in which additional CT scans were obtained to follow a suspicious IPN. [7]Early-stage lung cancer group—stage I per sixth and seventh edition AJCC TNM staging. [8]Late-stage lung cancer group—stage II to IV (and staging information not available) per sixth and seventh ed AJCC TNM staging. AJCC, American Joint Committee on Cancer; CT, computed tomography; IPN, incidental pulmonary nodule.

IPN management in accordance with the IPN tracking system developed and implemented by our facility in 2011. The characteristics of the system are described in our previous publication.[9] Briefly, the system is initiated by radiologists and, on the basis of nodule characteristics, matched to Fleischner Society Guidelines. Radiologists selected one of 14 tracker phrase macros within the PowerScribe dictation system to add an explicit recommendation for nodule management to the report. The inclusion of the unique tracker phrase within the paragraph containing the recommendation enables accurate identification of the IPN by a computerized word-finding algorithm. Patient and provider identifiers and the date of the CT are automatically linked to the IPN finding. A facility-built electronic registry (lung nodule registry), retrieves tracker phrases within the CT reports monthly and calculates the expected date for the follow-up scan, then alerts providers and patients when expected follow-up scans are greater than 30 days overdue.

Tracker system report macros were piloted by a subset of radiologists in March 2011, followed by a full rollout in August 2011. In the current study, index and subsequent CT reports were evaluated for the presence or absence of a tracker phrase. Lung nodules identified with a tracker phrase in the index or follow-up CT scan reports spanned the period from April 2009 to October 2016. Those lacking the tracker phrase spanned the period from May 2006 to August 2016. The presence of a tracker phrase in a CT report implied that the patient was tracked within the lung nodule registry system, whereas the lack of a tracker phrase implied that the patient was not tracked within the system. Cases in which an IPN was initially missed, but identified on a subsequent CT scan with an accompanying tracker phrase, were assigned to the tracked category because the patient was entered into the tracking system before diagnosis.

Statistical Analyses

Cases of lung cancer were dichotomized as early-stage, (stage I) versus late-stage, (stage II–IV or unstaged). Cases were retrospectively evaluated for previous identification of an IPN, and the radiologist's insertion of the tracker phrase with attendant Fleischner

Table 1. Subject Characteristics, Overall and by Lung Cancer Stage Group

Characteristic	All Patients	Early-Stage (Stage I) n (%) or Mean (SD)	Late-Stage (Stage II-IV, or Not Staged[a]) n (%) or Mean (SD)	*p* Value Early-Stage vs. Late-Stage
Number of patients	314	200 (64)	114 (36)	
Age (y)	67.3 (9.6)	66.7 (9.6)	68.3 (9.4)	0.1715
Pack-years of cigarette smoking	30.9 (28.7)	28.5 (28.0)	35.1 (29.4)	0.0514
Sex				
Female	175(56)	123 (62)	52 (46)	0.0064
Male	139 (44)	77 (38)	62 (54)	
Interstitial lung disease				
Yes	38 (12)	16 (8)	22 (19)	0.0040
No	176 (88)	84 (92)	92 (81)	
Nodule diameter on index CT (mm)[b]	15.4 (11.6)	14.2 (8.7)	18.2 (15.9)	0.0316
Laterality				
Left	145 (46)	96 (48)	49 (43)	0.5597
Right	164 (53)	104 52)	61 (54)	
NOS	4(1)	0	4 (3.5)	
Histology				
Adenocarcinoma	183 (58)	136 (68)	47 (41)	
Adenosquamous	2 (1)	2 (1)	0 (0)	
Carcinoid	12 (4)	9 (5)	3 (3)	
Large cell carcinoma	2 (1)	0 (0)	2 (2)	
Large cell neuroendocrine	4 (1)	1 (1)	3 (2)	
Non-small cell carcinoma, NOS	52 (17)	22 (11)	30 (26)	
Sarcomatoid carcinoma	3 (1)	3 (2)	0 (0)	
Small cell carcinoma	17 (5)	4 (2)	13 (11)	
Squamous cell carcinoma	39 (12)	23 (12)	16 (14)	
Adenocarcinoma	183 (58)	136 (68)	47 (41)	<0.0001
Nonadenocarcinoma	131 (42)	62 (32)	67 (59)	
Tracker phrase in CT report				
No tracker	155 (49)	86 (43)	69 (61)	
Tracker	159 (51)	114 (57)	45 (39)	0.0033

[a]Seven patients had no staging.
[b]A total of 43 patients missing data on nodule diameter: n equals 15 for stage I, n equals 28 for stage II to IV or not staged.
CT, computed tomography; NOS, not otherwise specified.

Society Guidelines within the index and subsequent CT reports.

Additional variables evaluated were age at the time of the index CT scan, sex, smoking exposure in pack-years, diagnosis of ILD, the diameter of the nodule on the index CT, and cancer histology dichotomized as adenocarcinoma or nonadenocarcinoma.

Student's *t* test, chi-square, and multivariable logistic regression were used to test associations of the tracker phrase in CT reports with an early-stage lung cancer diagnosis. The *p* values less than 0.05, two-tailed, were considered statistically significant. Statistical software was Statistical Analysis System version 9.4, (Cary, NC).

Results

A total of 314 patients with an IPN followed by chest CT at our institution with a subsequent diagnosis of lung cancer were identified. Data regarding the ordering physician was available for 300 index chest CT scans. At least 73 individual physicians, 90% of whom were pulmonologists, ordered the chest imaging.

The characteristics of patients in the early-stage (n = 200) and late-stage (n = 114) groups are presented in Table 1. The seven patients who had no final staging determination were included in the late-stage group. There was no significant difference between the groups regarding age (mean of 66.7 versus 68.3 y, $p = 0.171$), cigarette smoking (mean of 28.5 versus 35.1 pack-years, $p = 0.051$), or laterality of cancer ($p = 0.560$). Compared with late-stage, those with early-stage lung cancer were more likely to be women (62% versus 46%, $p = 0.006$), have adenocarcinoma histology (68% versus 41%, $p \leq 0.0001$), and have a smaller index nodule (mean of 14.2 versus 18.2 mm, $p = 0.0316$). The late-stage group was more likely to have an ILD diagnosis (19% versus 8%, $p = 0.004$).

A total of 43 cases (15 cases among the early-stage group and 28 cases among the late-stage group) were

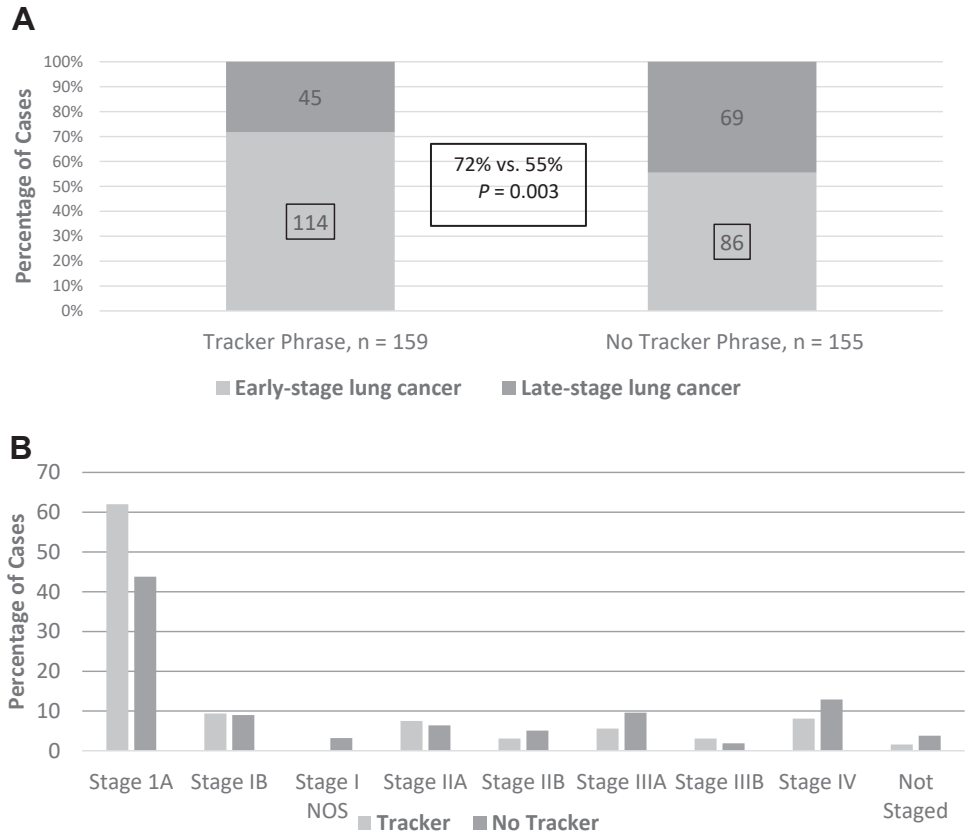

Figure 2. Percentage of lung cancer cases by stage among nodules followed by tracker versus no tracker. (*A*) A higher percentage of lung cancer cases among those with nodules followed with tracker phrases were early stage, (stage I) than those without tracker phrases, (57% versus 39%, $p = 0.003$). (*B*) Stage group of lung cancer cases in nodules followed by tracker phrases and those without tracker phrases. NOS, not otherwise specified.

missing data on index nodule diameter. Missing data was because of the index CT scan being performed at an outside institution, with the IPN referenced, but incompletely described in the follow-up scan at our facility, or the nodule was endobronchial or within a fibrotic area of the lung and not amenable to measurement on review of images.

Compared with the late-stage group, a greater percent of early-stage cases had a tracker phrase applied to the index chest CT report: 57% (114 of 200) for early-stage versus 39% (45 of 114) for late-stage ($p = 0.003$) (Table 1). A total of 72% (114 of 159) of cases with a tracker phrase provided for the IPNs resulted in an early-stage diagnosis, compared with 55% (86 of 155) resulting in an early-stage diagnosis when tracker phrases were not applied ($p = 0.003$) (Fig. 2*A*). Figure 2*B* illustrates the frequencies for each stage group by tracker category.

Full Model of Factors Associated With Early-stage Lung Cancer

A multivariable regression analysis of factors potentially associated with early-stage lung cancer versus late-stage lung cancer is detailed in Table 2. In this model, all cases were included, whether or not nodule diameter data was missing. As in the univariate analysis, the presence of a tracker phrase in the index chest CT report (OR = 1.996 [CI: 1.142–3.49], $p = 0.015$) and adenocarcinoma histology (OR = 2.652 [CI: 1.512–4.652], $p = 0.0007$) were positively associated with early-stage cancer, whereas larger nodule diameter on index CT (OR = 0.972 [CI: 0.948–0.996], $p = 0.0249$), and a diagnosis of ILD (OR = 0.411 [CI: 0.171–0.989], $p = 0.0471$) were negatively associated. Age, sex, and pack-years of smoking had no statistically significant association with an early-stage diagnosis.

Adjusted Models of Factors Associated With Early-stage Lung Cancer

Factors independently associated with early-stage lung cancer in adjusted multiple logistic regression models are detailed in Table 3. In model 1, only the 271 cases with known nodule diameter on the index scan were included. In this model, the use of the tracker phrase on CT reports independently predicted early-

Table 2. Full Multivariable Regression Model of Factors Associated With Early-Stage Versus Late-Stage Lung Cancer at Diagnosis

Factor	OR	95% Confidence Interval	*p* Value
Age in y	1.007	0.976-1.038	0.6687
Male sex	0.781	0.439-1.390	0.4006
Pack-years of cigarette smoking	0.992	0.982-1.002	0.0986
Interstitial lung disease	0.411	0.171-0.989	0.0471
Nodule diameter on index CT (mm)	0.972	0.948-0.0996	0.0249
Adenocarcinoma	2.652	1.512-4.652	0.0007
Tracker phrase used in CT report	1.996	1.142-3.490	0.0153

CT, computed tomography.

stage lung cancer (OR = 1.939 [CI: 1.126–3.339], $p = 0.016$), as did adenocarcinoma histology (OR = 2.930 [CI: 1.695–5.064], $p = 0.0001$). Larger index nodule diameter was negatively associated with early-stage cancer (OR = 0.971 [CI: 0.948–0.995], $p = 0.016$). However, in this model, which excluded 43 cases in which nodule diameter data were missing, ILD diagnosis and sex were not statistically associated with an early-stage diagnosis.

Model 2 excluded nodule diameter as a variable so that all 314 cancer cases could be evaluated. Again, the use of tracker phrases (OR = 1.930 [CI: 1.176–3.166], $p = 0.009$) and adenocarcinoma histology (OR = 2.703 [CI: 1.651–4.426], $p \leq 0.001$) remained positively associated with early-stage diagnosis. In contrast to model 1, however, male sex (OR = 0.574 [CI: 0.350–0.942], $p = 0.028$) and ILD diagnosis (OR = 0.433 [CI: 0.209–0.987], $p = 0.024$) were negatively associated with early-stage diagnosis.

To understand the different associations of ILD and sex with early-stage cancer in the two models, we evaluated relationships among nodule diameter, sex, and ILD. We found that index nodule diameter (mm) was greater among men than women (mean of 17.4 versus 14.0 mm, $p = 0.026$). Nodule diameter did not differ between those with or without ILD (mean of 15.5 versus 15.4 mm, $p = 0.993$). However, of the 32 cases of ILD, only 26 included information on the index nodule diameter.

Association of Tracker System Use With Follow-Up Imaging

The use of the tracker system in the index CT was associated with a greater number of follow-up scans, (mean of 2.7 scans versus 2.1 scans, $p = 0.001$). Although the time interval between index CT scan date and diagnosis date was shorter among those with tracker phrases on CT reports (mean of 441 d [SD = 501] versus 524 d [SD = 571], $p = 0.174$), it did not reach statistical significance.

Discussion

In this single-center study, the radiologists' use of the tracker system in the chest CT report on recognition of an IPN almost doubled the likelihood that the patient would have stage I versus later-stage lung cancer at diagnosis. This association was consistent and independent of adenocarcinoma versus nonadenocarcinoma histology, nodule diameter when the IPN was first recognized, age, sex, or smoking exposure. Among our patient population, we observed that the percentage of stage I cases increased to 72% when the tracker system was used compared with 55% when the tracker phrase system was not used.

Our finding of the increased use of CT follow-up among cases in which the tracker system was used is expected, because the tracker system intended to promote a greater intensity of appropriate follow-up imaging in accordance with established Fleischner Society Guidelines.[14–16]

The recognition of an IPN is, by definition, an unexpected finding on a CT scan. Because it falls to the ordering provider (who may or may not have expertise in pulmonary nodule management) to arrange for follow-up, the addition of explicit tailored recommendations for follow-up within the CT report may reduce delays in care. As such, the tracker system might improve the early diagnosis of lung cancer by providing medical decision support for nonpulmonary specialists. In our study, we found improvement in early diagnosis with the use of the tracker system, even among ordering providers who were predominantly pulmonologists, and presumably experienced in IPN management. Prospective studies would be needed to identify how provider behavior is influenced by a tracking system for IPNs.

The early-stage group was characterized by more women, smaller nodules, and adenocarcinoma histology, consistent with other studies.[17–19] The positive association of male sex with larger nodule size may explain the loss of association of sex with early-stage diagnosis in model 1, which included only cases with known nodule diameter.

Table 3. Final Multivariable Regression Model of Factors Associated With Early-Stage Versus Late-Stage Lung Cancer at Diagnosis

	Early-Stage Lung Cancer			
	Model 1 (n = 271)[a]		Model 2 (n = 314)	
Factors	OR (95% CI)	*p* Value	OR (95% CI)	*p* Value
Nodule diameter on index CT (mm)	0.971 (0.948-0.995)	0.0166		
Male sex			0.574 (0.350-0.942)	0.0281
Interstitial lung disease			0.433 (0.209-0.987)	0.0242
Adenocarcinoma	2.930 (1.695-5.064)	0.0001	2.703 (1.651-4.425)	<0.0001
Tracker phrase present	1.939 (1.126-3.339)	0.0169	1.930 (1.176-3.166)	0.0093

[a]Model 1 excludes 43 cases that are missing index nodule diameter.
CI, confidence interval.

Interestingly, ILD diagnosis was not associated with nodule size. However, because only 26 cases with ILD diagnosis remained in model 1 when cases lacking nodule diameter were excluded, loss of power may explain why the negative association of ILD diagnosis with early-stage diagnosis disappeared in model 1. It is not surprising that the presence of ILD predicted late-stage lung cancer in the univariate analysis and full multivariable models because lung fibrosis is a known risk factor for lung cancer and extensive parenchymal lung abnormality in ILD makes the detection of small nodules more difficult.[20,21]

Our study is confined to lung cancer cases diagnosed after the identification of an IPN on chest CT at our facility. Only IPNs were discovered within 2.5 years before the diagnosis of cancer, and within the same lobe as the cancer was included, which strengthens the likelihood that the IPN was the first radiologic manifestation of cancer. Our study is limited by the lack of data on the diameter of the IPN among 43 patients, disproportionately distributed between the early-stage and late-stage groups. However, the beneficial effect of the tracker system on early-stage diagnosis remained consistent, whether or not cases lacking nodule diameter were in the model. Our study is also limited by confinement to a single-center where most cases of IPNs are managed by pulmonologists and all chest CTs are read by subspecialty trained thoracic radiologists.

We previously analyzed the frequency of missed nodules within the tracker system.[9] After the first year of implementation, (2012–2016) we found an average of 6% of CT reports in which the tracker phrase is not applied to an IPN. In the current study, we assigned cases in which the nodule was initially missed but later identified with a tracker phrase before cancer diagnosis to the tracked category because this situation reflects the real-world application of our program. Despite the error, the implementation of the tracker system improved clinical outcomes.

A review of the literature suggests this is the first report of an automated tracking system for IPNs to exhibit a stage shift in the diagnosis of lung cancer. A report by LeMense et al.[11] described a stage shift with electronic and manual chart review. The use of a radiologist-initiated front-end process to identify nodules needing follow-up avoids the use of manual chart review.

By using a word-finding algorithm on the basis of the specific tracker phrase detected within the text of the CT report, we can upload not only patient and CT-specific information into our facility-built database, but also calculate a due date for the next CT for each patient with an IPN. This enables monthly, automated reports of patients who have failed to have their recommended CT scan follow-up within our facility.

Although the tracker system is unique to our facility, key features could be adapted to commercially available software systems to enhance nodule case-finding. Because the tracker phrases eliminate ambiguity on the time interval to follow-up imaging, it may be possible to adapt the tracker phrase menu to commercial database systems designed for tracking of IPNs through natural language processing. Radiologists reading diagnostic chest CTs could apply the appropriate tracker phrase when an IPN is identified, similar to the use of the Lung imaging reporting and data system categories when nodules are detected in lung cancer screening.[22]

In conclusion, we observed an increase in the percentage of stage I lung cancers diagnosed among patients whose cancer was preceded by recognition of an IPN when an automated tracking process on the basis of the characteristics of the IPN was implemented. This is a clinically meaningful outcome for patients and should be adopted for IPN management.

CRediT Authorship Contribution Statement

Laurie L. Carr: Conceptualization, Methodology, Investigation, Data curation, Writing - original draft,

Writing - review & editing, Visualization, Supervision, Project administration.

Debra S. Dyer: Conceptualization, Methodology, Investigation, Writing - original, Writing - review & editing, Visualization.

Pearlanne T. Zelarney: Data curation, Writing - review & editing.

Elizabeth O. Kern: Conceptualization, Methodology, Investigation, Writing - original, Writing - review & editing, Visualization.

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