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Frequency and distribution of incidental findings deemed appropriate for S modifier designation on low-dose CT in a lung cancer screening program

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ABSTRACT

Purpose: To describe the frequency, distribution and reporting patterns of incidental findings receiving the Lung-RADS S modifier on low-dose chest computed tomography (CT) among lung cancer screening participants.
Methods: This retrospective investigation included 581 individuals who received baseline low-dose chest CT for lung cancer screening between October 2013 and June 2017 at a single center. Incidental findings resulting in assignment of Lung-RADS S modifier were recorded as were incidental abnormalities detailed within the body of the radiology report only. A subset of 60 randomly selected CTs was reviewed by a second (blinded) radiologist to evaluate inter-rater variability of Lung-RADS reporting.
Results: A total of 261 (45%) participants received the Lung-RADS S modifier on baseline CT with 369 incidental findings indicated as potentially clinically significant. Coronary artery calcification was most commonly reported, accounting for 182 of the 369 (49%) findings. An additional 141 incidentalomas of the same types as these 369 findings were described in reports but were not labelled with the S modifier. Therefore, as high as 69% (402 of 581) of participants could have received the S modifier if reporting was uniform. Inter-radiologist concordance of S modifier reporting in a subset of 60 participants was poor (42% agreement, kappa = 0.2).
Conclusions: Incidental findings are commonly identified on chest CT for lung cancer screening, yet reporting of the S modifier within Lung-RADS is inconsistent. Specific guidelines are necessary to better define potentially clinically significant abnormalities and to improve reporting uniformity.

1. Introduction

An incidental finding is defined as a noted abnormality that is not anticipated and is unrelated to the clinical indication for a given radiologic examination [1]. Such occurrences are well-documented for colon cancer screening with computed tomographic (CT) colonography, as well as for those patients undergoing evaluation of cardiac structures on coronary CT angiography [2–4]. While most incidental findings will be of little or no consequence, identification of clinically significant findings has been reported for both CT colonography and cardiac CT at rates of 2.5% and 2.2%, respectively [2,4].

Lung cancer screening with low-dose chest CT has the potential to reduce lung cancer mortality in high risk patients by 20% based on results from the National Lung Screening Trial (NLST) [5]. However, issues related to qualification and further management of incidental findings have raised concerns about widespread implementation of such screening. The United States Preventive Services Task Force (USPSTF) cited that annual screening with low-dose CT is of moderate net benefit in high risk individuals but concluded that the benefit to harm ratio associated with incidental findings cannot currently be determined [6]. In the NLST, the proportion of 26,722 participants with potentially clinically significant abnormalities on baseline CT was 10% [7]. A systematic review of four smaller lung cancer screening studies (range, 449–1520 screened subjects) utilizing chest CT established that incidental findings occurred in 44%-73% of participants, of which 7%-27% were deemed to be significant [8].

As part of the American College of Radiology's (ACR) Lung Imaging Reporting and Data System (Lung-RADS), clinically significant or potentially significant findings unrelated to the possibility of lung cancer should receive a S modifier as part of the final assessment category [9]. This serves to notify referring providers that further action may be warranted. Currently, however, there are no defined guidelines of what constitutes a clinically significant finding in Lung-RADS. The aim of this investigation was to assess the frequency with which incidental findings noted on low-dose chest CT resulted in S modifier designation in a clinical screening program. The distribution of these incidental findings and the consistency with which the S modifier was employed were also examined.

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2. Methods

2.1. Study participants

This retrospective review included all sequential individuals being screened for lung cancer using low-dose chest CT at our single center academic university hospital between October 2013 and June 2017. During this period of enrollment, the National Comprehensive Cancer Network (NCCN) lung cancer screening guidelines were followed which includes 2 groups: group one comprises individuals aged 55–77 with 30 or more pack year smoking history and current or former smokers within past 15 years; group 2 includes individuals aged 50 years or older with at least a 20-pack year history and one additional risk factor (family history, asbestosis exposure, etc.). Individuals with known malignancy diagnosed in the last 5 years were excluded. The electronic database was used to abstract demographic and radiologic data for this investigation. Patient characteristics included age, gender, smoking status (current or former), number of pack-years, history of lung disease, history of cancer, family history of lung cancer and history of diabetes or hypertension. This study was approved by our institutional review board.

2.2. CT imaging

All CT examinations were performed on a General Electric Medical Systems (Milwaukee, WI) Lightspeed 64 row detector CT scanner. Scan parameters were as follows: 64 × 0.625 detector configuration, 120 kVp, 40–80 mA, and pitch of 1. No intravenous contrast material was administered. CT scans were obtained from the lung apex through the upper abdomen to ensure complete inclusion of the posterior recess. Images were displayed on a 3 megapixel flat-panel monitor (Barco medical system, Duluth, GA) at 1.25 mm slice thickness in a lung algorithm (window width of 1500 Hounsfield units (HU) and level of 600 HU) and 5 mm slice thickness in a soft tissue algorithm (window width of 250 HU and level of 50 HU). Additionally, osseous structures are best viewed with a window width of 1800 HU and level of 400 HU. Each CT scan was interpreted by one of six Board Certified radiologists with various subspecialty experience in thoracic radiology (2–12 years).

2.3. Incidental findings with S category designation

The reports of baseline (first visit) low-dose screening chest CTs for all participants were manually reviewed by one of the authors. Final assessment included Lung-RADS categorizations for every individual, as per radiologic reporting protocol at our institution. In addition to identifying incidental findings which resulted in S modifier designation, CT reports were also investigated for mention of incidental findings described in the body text but for which an S modifier was not assigned by the reviewing radiologist.

2.4. Radiologist inter-observer variability

To assess inter-rater variability, a subset of 60 participants from the study cohort screened after October 2014 were randomly selected and reviewed by a second radiologist with 10 years of experience in thoracic imaging. This radiologist was blinded to the results of the initial interpretation but not to the purpose of the study. The subsample intentionally included participants with baseline CTs performed at least one year after the establishment of the lung cancer screening program to minimize any biases resulting from protocols that were still being developed and may not have been fully standardized at the time of the program's inception. The subsample also only included CTs for individuals that the second radiologist did not initially interpret. The second radiologist recorded any incidental findings and a final Lung-RADS assessment category, to include presence or absence of the S modifier.

2.5. Statistical analysis

Demographic and other patient characteristics were stratified by those with and without an S classification modifier. Differences between groups were assessed using chi-square tests for categorical variables and *t*-tests for continuous factors. P-values ≤ 0.05 were taken to indicate statistical significance. Descriptive statistics including frequencies and percents are provided to indicate distributions in Lung-RADS scores, as well as S classification categories and noted severity of coronary artery calcifications. Kappa statistics and percent agreement were used to assess inter-rater concordance with respect to S modifier usage. SPSS version 24 was used to conduct these analyses.

3. Results

This investigation included 581 individuals (404 qualified for NCCN group 1 and 177 qualified for NCCN group 2) who underwent baseline low-dose CT for lung cancer screening between October 2013 and June 2017. Of those, 261 (45%) were designated with Lung-RADS S modifier, indicating the presence of a potentially clinically significant incidental finding.

Table 1 presents the demographic and medical history characteristics of study participants stratified by S modifier status. Participants who were found to have an incidental finding on CT were older (mean age: 61.6 vs 59.9 years, $p < 0.010$) and more likely to be male (75% vs 59%, $p < 0.010$). In addition, a significantly higher percentage of participants classified with a Lung-RADS S modifier reported a history of hypertension compared to those who did not receive an S denotation (45% vs 30%, $p < 0.010$). Individuals with and without an assigned S categorization were similar with regard to smoking status, history of lung disease and cancer, and history of diabetes.

The distribution of final Lung-RADS assessment categories is presented in Table 2. A total of 28% of participants screened received a Lung-RADS score of 1, approximately half were classified with a score of 2 and the remaining 15% and 6% of participants were classified as

Table 1
Participant characteristics.

Variable	S modifier negative N = 320	S modifier positive N = 261	P-value
Age (years), mean ± SD	59.9 ± 6.2	61.6 ± 6.4	< 0.010
Male gender (%)	192 (60)	196 (75)	< 0.010
Current smoker (%)	138 (43)	115 (44)	0.821
History of other lung disease (%)	87 (27)	68 (26)	0.842
History of other cancer (%)	65 (21)	44 (17)	0.252
Family history of lung cancer (%)	90 (28)	60 (23)	0.144
Number of pack years smoked, mean ± SD	45.7 ± 24.4	46.8 ± 22.8	0.591
History of diabetes (%)	32 (10)	36 (14)	0.203
History of hypertension (%)	96 (30)	118 (45)	< 0.010