

# Incidental Thyroid Nodules in the National Lung Screening Trial: Estimation of Prevalence, Malignancy Rate, and Strategy for Workup

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**Rationale and Objectives:** There is limited research on the prevalence of incidental thyroid nodules (ITNs) in the United States screening population and on the appropriate evaluation of computed tomography (CT)-detected ITNs. The purpose of this study is to determine the prevalence of ITNs in the National Lung Screening Trial (NLST) and develop a workup strategy for ITNs.

**Materials and Methods:** CT images were obtained for subjects with documented thyroid abnormalities in the CT screening arm of the NLST, subjects diagnosed with thyroid malignancies, and control subjects. Several size thresholds were compared to determine how many nodules would be further evaluated and how many thyroid malignancies would be missed had each threshold been applied at the time of workup.

**Results:** Thyroid nodules were reported in 0.7% (117 of 17,309 subjects). In 663 control subjects without reported thyroid nodules, thyroid nodules were identified in 78 (11.8%). Reported nodules were larger than unreported nodules (21.3 vs 16.9 mm,  $P = .03$ ). Thyroid malignancies were diagnosed in 0.1% (22 of 17,309). If a 20-mm rather than a 10-mm cutoff were used to determine which nodules should be further evaluated, all malignancies would be detected, but 24 rather than 62 patients would require workup, for a workup reduction rate of 48.7% (38 of 78).

**Conclusions:** Less than 1% of subjects in the NLST had reported ITNs. The true prevalence of ITNs was estimated to be 11.8%, which provides a better approximation of the number of patients who could potentially receive workup. A 20-mm rather than a 10-mm cutoff would reduce the workup rate by almost 50% while still capturing all malignancies.

**Key Words:** Thyroid nodule; computed tomography; National Lung Screening Trial; screening.

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## INTRODUCTION

A commonly encountered incidental finding on chest computed tomography (CT) examinations is the incidental thyroid nodule (ITN) (1,2). The majority of imaging-detected ITNs are benign, but the possibility of malignancy can prompt further evaluation with ultrasound and fine needle aspiration biopsy (FNAB) (3,4). If the FNAB results are not conclusive, additional tests and interventions may ensue, including ultrasound surveillance, repeat FNAB, and even surgery for histopathologic diagnosis (5).

There are currently no studies on the prevalence of ITNs in the United States lung screening population. Several

European and Canadian CT lung screening trials, the largest of which had 5200 trial participants, found that ITNs are reported in less than 5% of patients (6–9). Furthermore, there is limited research on the appropriate workup and management of ITNs identified on CT, which has led to variable reporting practices among radiologists (10,11).

This study involves review and analysis of data from the CT screening arm of the National Lung Screening Trial (NLST) (12). The purpose is to determine the prevalence of ITNs on CT in the screening population of the NLST, to determine the incidence of thyroid malignancy, and to compare several size thresholds for CT-detected ITNs.

## MATERIALS AND METHODS

### Study Population

Anonymized data were obtained from the NLST, which was a randomized controlled trial of screening tests for lung cancer (12). From 2002 to 2004, more than 53,000 participants aged 55–74 years, with a history of heavy smoking but no lung cancer, were randomly assigned to two study arms in equal

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proportions (low-dose spiral CT or chest radiography). Of the 26,722 subjects randomized to the CT screening arm of the NLST, the Lung Screening Study randomized 17,309 (64.8%) through 10 screening centers. The other NLST participants (9413, 35.2%) were enrolled at American College of Radiology Imaging Network centers; these participants were not included in this study because detailed information regarding their extrapulmonary findings was not available to the company that stored the NLST data.

### Study Design, Data Collection, and Image Interpretation

Datasets and CT images were obtained for all subjects with documented thyroid abnormalities in the Lung Screening Study, subjects diagnosed with thyroid malignancies during the NLST study period, and control subjects. Per NLST protocol, CT examinations consisted of low-dose, noncontrast images of the chest. NLST readers were asked to document “significant” extrapulmonary abnormalities above and below the diaphragm and to describe the specific findings. For purposes of this study, thyroid nodules identified by NLST readers are considered “reported” thyroid nodules. Control subjects (those without reported thyroid nodules) were frequency matched in a 3:1 ratio to subjects with documented thyroid abnormalities by age, gender, number of lung cancer screening episodes, and lung cancer screening results. Each CT examination was reviewed by two of four neuroradiology fellows for the presence or absence of thyroid nodules. The size of the thyroid nodule (or largest thyroid nodule, if more than one) was measured and recorded.

### Statistical Analysis

The prevalence of “reported” thyroid nodules was determined by dividing the number of thyroid nodules identified by NLST readers by the total number of subjects in the Lung Screening Study. The “true” prevalence of thyroid nodules was estimated by dividing the number of thyroid nodules identified by the neuroradiology fellows (considered “unreported”) by the total number of control subjects. The size of reported and unreported thyroid nodules was compared using the unpaired *t* test. *P* values less than 0.05 were considered statistically significant.

The incidence of thyroid malignancy was determined by dividing the number of diagnosed malignancies during the NLST study period by the total number of subjects in the Lung Screening Study. CT images were reviewed to determine how many of these subjects had thyroid nodules. Assuming that imaging-detected thyroid nodules led to the diagnosis of thyroid malignancy during the study period, several size thresholds (10 mm, 15 mm, 20 mm, and 25 mm) were compared to determine how many nodules would be further evaluated and how many malignancies would be missed if each threshold had been applied at the time of workup. The institutional review board exempted this Health Insurance

Portability and Accountability Act-compliant retrospective study from the requirement for informed consent.

## RESULTS

There were 17,309 subjects (mean age 61.3 years, standard deviation [SD] 5.0 years) who underwent CT in the Lung Screening Study. Of these subjects, 10,568 (61.1%) were male, and 6741 (38.9%) were female. Thyroid abnormalities were reported by NLST readers in 221 subjects (thyroid nodules in 117, thyroid gland enlargement or goiter in 101, thyroidectomy in 2, and thyroid atrophy in 1). Thus, thyroid nodules were reported by NLST readers in only 0.7% (117 of 17,309 subjects). The reported thyroid nodules were identified by at least one neuroradiology fellow reader in 99 of 117 subjects (84.6%). The mean maximal size of reported thyroid nodules was 21.3 mm (SD 11.6 mm).

In the 663 matched control subjects, thyroid nodules were identified in 78 (11.8%) by at least one of the neuroradiology fellow readers. Eight of the 78 subjects had more than one nodule, for a total of 88 nodules. These thyroid nodules were not reported by NLST readers. The unreported thyroid nodules in 78 subjects were identified by two neuroradiology fellow readers in 43 subjects (55.1%) and by one neuroradiology fellow reader in 35 subjects (44.9%). The mean maximal size of these unreported thyroid nodules was 16.9 mm (SD 9.1 mm). There was a statistically significant difference in size between the reported and unreported thyroid nodules (21.3 mm vs 16.9 mm, *P* = .03).

Thyroid malignancies were diagnosed in 0.1% (22 of 17,309 subjects) with a mean age of 60.5 years (SD 4.4 years). Thirteen (59.1%) were male, and nine were female (40.9%). The mean number of days between randomization and thyroid cancer diagnosis was 759 days (range 61–2068 days). Of the 22 subjects with thyroid malignancies, 16 (72.7%) had reported (8) or unreported (8) thyroid nodules. The mean maximal size of these nodules was 30.9 mm (SD 7.4 mm, range 22–53 mm).

If a size threshold of 20 mm were used to determine whether a thyroid nodule requires further workup, less than one-third of nodules (24 of 78, 30.8%) would have been further evaluated, and all malignancies (16 of 16, 100%) would have been detected (Table 1). If a smaller size threshold were used (10 mm or 15 mm), all thyroid malignancies would have been detected, but more benign thyroid nodules would have been

**TABLE 1. Comparison of Nodule Sizes to Direct Further Workup of Incidental Thyroid Nodules**

Size of Thyroid Nodule	Nodules Requiring Workup (%)	Detected Malignancies (%)
≥10 mm	62/78 (79.5%)	16/16 (100%)
≥15 mm	42/78 (53.8%)	16/16 (100%)
≥20 mm	24/78 (30.8%)	16/16 (100%)
≥25 mm	17/78 (21.8%)	13/16 (81.3%)

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