Key Publications
For EarlyCDT®—Lung

Risk Assessment of Pulmonary Nodules


Autoantibody Signature Enhances the Positive Predictive Power of Computed Tomography and Nodule-Based Risk Models for Detection of Lung Cancer.


Risk Stratification of High-Risk Patients

Detection in Blood of Autoantibodies to Tumour Antigens as a Case-Finding Method in Lung Cancer Using the EarlyCDT—Lung Test (ECLS): Study Protocol for a Randomized Controlled Trial.

Progress with an RCT of the Detection of Autoantibodies to Tumour Antigens in Lung Cancer Using the EarlyCDT—Lung Test in Scotland (ECLS).

Audit of the Autoantibody Test, EarlyCDT—Lung, in 1600 Patients: An Evaluation of its Performance in Routine Clinical Practice.
Technical & Clinical Validation Studies

Signal Stratification of Autoantibody Levels in Serum Samples and Its Application to the Early Detection of Lung Cancer.


*EarlyCDT—Lung*: an Immuno-biomarker Test as an Aid to Early Detection of Lung Cancer.


Clinical Validation of an Autoantibody Test for Lung Cancer.

Technical Validation of an Autoantibody Test for Lung Cancer.

Autoantibodies for Lung Cancer Detection

Autoantibodies: Opportunities for Early Cancer Detection.

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Tumor-Associated Autoantibodies: Re-Optimization of
*EarlyCDT—Lung* Diagnostic Performance and its Application
to Indeterminate Pulmonary Nodules

**Background**

Low-dose computed tomography (CT) screening reduces lung cancer mortality
but costs are prohibitive for most healthcare budgets due to high false
positive rates. An adjunctive test able to distinguish malignant from benign
pulmonary nodules would be hugely beneficial. *EarlyCDT—Lung* measures
serum autoantibodies to tumor-associated antigens and has found clinical
acceptance to aid early detection of lung cancer for high risk patients. However
performance was optimized for screening. The construction of a receiver-
operating characteristic (ROC) curve would enable optimization of performance
for alternative settings, including nodule malignancy.

**Methods**

A Monte-Carlo search method was used to construct a ROC curve using a case-
control cohort, enabling high and low specificity versions of *EarlyCDT—Lung* to
be determined. These were used for a theoretical evaluation of a nodule cohort,
and positive predictive value (PPV) was calculated under the assumption of
independence of risk source. Patients or their nodules are typically classified
into three risk groups: low (0%–10%), intermediate (10%–65%) and high (>65%)
risk of malignancy. The predicted shift in risk group by application of the high
and low specificity versions, along with the current commercial *EarlyCDT—
Lung*, was then estimated.
Results

The ROC curve, with an area under the curve of 0.743, was constructed. The high specificity (98%), low specificity (49%) and current commercial (91% specificity) versions of EarlyCDT—Lung re-classified 27%, 23% and 26% of intermediate nodules, respectively, to either a higher (10%, 8% and 10%) or lower (17%, 15% and 16%) risk group.

Conclusion

A ROC curve was constructed to allow performance prediction of EarlyCDT—Lung at different specificities in the indeterminate nodule setting. This enabled risk re-classification of intermediate risk nodules, and could therefore facilitate alternative more appropriate intervention. We have shown how a multivariate biomarker test can add to the interpretation of pulmonary nodules and therefore aid patient management.

Autoantibody Signature Enhances the Positive Predictive Power of Computed Tomography and Nodule-Based Risk Models for Detection of Lung Cancer


Introduction

The incidence of pulmonary nodules is increasing with the movement toward screening for lung cancer by low-dose computed tomography. Given the large number of benign nodules detected by computed tomography, an adjunctive test capable of distinguishing malignant from benign nodules would benefit practitioners. The ability of the EarlyCDT—Lung blood test (Oncimmune Ltd., Nottingham, United Kingdom) to make this distinction by measuring autoantibodies to seven tumor-associated antigens was evaluated in a prospective registry.

Methods

Of the members of a cohort of 1987 individuals with Health Insurance Portability and Accountability Act authorization, those with pulmonary nodules detected,
imaging, and pathology reports were reviewed. All patients for whom a nodule was identified within 6 months of testing by *EarlyCDT—Lung* were included. The additivity of the test to nodule size and nodule-based risk models was explored.

**Results**

A total of 451 patients (32%) had at least one nodule, leading to 296 eligible patients after exclusions, with a lung cancer prevalence of 25%. In 4- to 20-mm nodules, a positive test result represented a greater than twofold increased relative risk for development of lung cancer as compared with a negative test result. Also, when the “both-positive rule” for combining binary tests was used, adding *EarlyCDT—Lung* to risk models improved diagnostic performance with high specificity (>92%) and positive predictive value (>70%).

**Conclusions**

A positive autoantibody test result reflects a significant increased risk for malignancy in lung nodules 4 to 20 mm in largest diameter. These data confirm that *EarlyCDT—Lung* may add value to the armamentarium of the practitioner in assessing the risk for malignancy in indeterminate pulmonary nodules.

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