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Key Publications
For *Early*CDT®—Lung

Risk Assessment of Pulmonary Nodules

Tumor-Associated Autoantibodies: Re-Optimization of ***Early*CDT—Lung** Diagnostic Performance and its Application to Indeterminate Pulmonary Nodules.
Healey GF, Macdonald IK, Reynolds C, et al. *J Cancer Ther*. 2017; 8:506–517.

Autoantibody Signature Enhances the Positive Predictive Power of Computed Tomography and Nodule-Based Risk Models for Detection of Lung Cancer.
Massion PP, Healey GF, Peek LJ, et al. *J Thorac Oncol*. 2017; 12(3):578–584.

Cost-effectiveness of an autoantibody test (***Early*CDT—Lung**) as an aid to early diagnosis of lung cancer in patients with incidentally detected pulmonary nodules.
Edelsberg J, Weycker D, Atwood M, et al. *PLoS ONE*. 2018; 13(5): e0197826.

Risk Stratification of High-Risk Patients

Detection in Blood of Autoantibodies to Tumour Antigens as a Case-Finding Method in Lung Cancer Using the ***Early*CDT—Lung** Test (ECLS): Study Protocol for a Randomized Controlled Trial.
Sullivan FM, Farmer E, Mair FS, et al. *BMC Cancer*. 2017; 17:187.

Progress with an RCT of the Detection of Autoantibodies to Tumour Antigens in Lung Cancer Using the ***Early*CDT—Lung** Test in Scotland (ECLS).
Sullivan F & Schembri S. *J Thorac Oncol*. 2015; 10(Suppl 2):S306.

Audit of the Autoantibody Test, ***Early*CDT—Lung**, in 1600 Patients: An Evaluation of its Performance in Routine Clinical Practice.
Jett JR, Peek LJ, Fredericks L, et al. *Lung Cancer*. 2014; 83:51–55.

Technical & Clinical Validation Studies

Signal Stratification of Autoantibody Levels in Serum Samples and Its Application to the Early Detection of Lung Cancer.
Healey GF, Lam S, Boyle P, et al. *J Thorac Dis*. 2013; 5(5):618–625.

***Early*CDT—Lung** Test: Improved Clinical Utility Through Additional Autoantibody Assays.
Chapman CJ, Healey G, Murray A, et al. *Tumor Biology*. 2012; 33(5):1319–1326.

***Early*CDT—Lung**: an Immuno-biomarker Test as an Aid to Early Detection of Lung Cancer.
Lam S, Boyle P, Healey G, et al. *Cancer Prev Res*. 2011; 4(7):1126–34.

Immuno-biomarkers in Small Cell Lung Cancer: Potential Early Clinical Signals.
Chapman CJ, Thorpe AJ, Murray A, et al. *Clin Cancer Res*. 2011; 17(6):1474–1480.

Clinical Validation of an Autoantibody Test for Lung Cancer.
Boyle P, Chapman CJ, Holdenrieder S, et al. *Ann Oncol*. 2011; 22(2):383–9.

Technical Validation of an Autoantibody Test for Lung Cancer.
Murray A, Chapman CJ, Healey G, et al. *Ann Oncol*. 2010; 21(8):1687–93.

Autoantibodies for Lung Cancer Detection

Autoantibodies: Opportunities for Early Cancer Detection.
Macdonald IK, Parsy-Kowalska CB, Chapman CJ. *Trends in Cancer*. 2017; 3(3):198–213.

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Publications Spotlight
For ***Early*CDT—Lung**

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

Healey GF, Macdonald IK, Reynolds C, et al. *J Cancer Ther*. 2017; 8:506–517.

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. ***Early*CDT—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 ***Early*CDT—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 ***Early*CDT—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 ***Early*CDT—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 ***Early*CDT—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

Massion PP, Healey GF, Peek LJ, et al. *J Thorac Oncol*. 2017; 12(3):578–584.

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 ***Early*CDT—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 ***Early*CDT—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 ***Early*CDT—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 ***Early*CDT—Lung** may add value to the armamentarium of the practitioner in assessing the risk for malignancy in indeterminate pulmonary nodules.

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