

Benefits of Using EarlyCDT®-Lung In Clinical Practice

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PURPOSE

To demonstrate how EarlyCDT®-Lung, a blood test that detects the presence of autoantibodies to lung cancer-associated antigens (1), has benefited our pulmonology practice in detecting lung cancer. Reported here is a review of the clinical outcomes within 6 months of the blood test for our first 70 patients to have been tested by EarlyCDT-Lung.

METHODS

Seventy patients seen in our high risk (for lung cancer) clinic who were tested by EarlyCDT-Lung and consented for their medical records to be shared with Oncimmune® are being reported here. Patients deemed high risk, based on their age, smoking history and/or the presence of a suspicious CT-identified pulmonary lesion, were referred for the blood test. The average 5-year risk of lung cancer (based on age and smoking history alone) for all patients was calculated to be 4.4%. All lung cancers were diagnosed within 6 months of the EarlyCDT-Lung test.

REFERENCES

- Chapman CJ, Healey G, Murray A, et al. EarlyCDT®-Lung test: improved clinical utility through additional autoantibody assays. *Tumor Biology* 2012 Apr 11. Epub ahead of print PMID 22492236.
- Zhong L, et al. Profiling tumor-associated antibodies for early detection of non-small cell lung cancer. *J Thorac Oncol* 2006; 1: 513-519.

RESULTS

Table 2. Lung cancer classification of patients tested by EarlyCDT-Lung who were diagnosed with lung cancer within 6 months of the blood test.

| TRF + | Sample Flag | Stage | Type | Method of Diagnosis |
|------------------|-------------|---------------------------------|---------------------------|---------------------|
| POSITIVES | | | | |
| 1002152 | Positive | IA | Adenocarcinoma G3 | Path |
| 1011844 | Positive | IA or IB (mediastinoscopy path) | Squamous G3 | Path |
| 1015425 | Positive | IB | NSCLC presumed w/o biopsy | CT |
| 1011614 | Positive | IIB | Unknown | CT |
| 1005288 | Positive | IV | NSCLC | Path |
| 1011842 | Positive | IV | Adenocarcinoma G3 | Path |
| NEGATIVES | | | | |
| 1007537 | Negative | IA | Squamous G3 | Path |
| 1015555 | Negative | IA | Squamous G3 | Path |
| 1005090 | Negative | IB | Squamous G3 | Path |
| 1015427 | Negative | IIA | NSCLC | Path |
| 1015550 | Negative | IIB | NSCLC | CT |
| 1007541 | Negative | IIIA | SCLC | Path |
| 1002153 | Negative | IIIA | Adenocarcinoma G3 | Path |
| 1005093 | Negative | IV, bone mets | Adenocarcinoma | Path |
| 1011847 | Negative | IV (pericardial eff.) | Adenocarcinoma | Cyto |

Twelve patients were found to be Positive for at least one lung cancer-associated autoantibody elevated above the clinical cut-off for EarlyCDT-Lung, 57 tested Negative and 1 was Invalid. Six patients who tested Positive and 9 patients who tested Negative were found to have lung cancer within 6 months after EarlyCDT-Lung testing, showing 40% (6/15) sensitivity for lung cancer and specificity of 89% (48/54) (Table 1). Four of the 6 patients (67%) who tested positive and were diagnosed with lung cancer were found at early stage (non small cell lung cancer [NSCLC] stage I or II; small cell lung cancer [SCLC] limited stage) (Table 2). The positive predictive value was 6/12 (1 in 2), revealing that a Positive EarlyCDT-Lung result significantly increases our patients' risk for lung cancer.

Table 1. Clinical performance of EarlyCDT-Lung in our patient population.

| | Lung Cancer Dx | Not Dx Cancer | Overall |
|--------------------|---------------------|---------------|---------|
| Negative | 9 | 48 | 57 |
| Positive | 6 | 6 | 12 |
| Sensitivity | 40.0% | | |
| Specificity | 88.9% | | |
| PPV | 1 in 2 (50%) | | |

Note: These figures take no account of occult lung cancers, which may present over the next few years as cancers have been shown to stimulate an autoimmune response up to 5 years before detection by current imaging methods (2).

CONCLUSIONS

In our clinic, EarlyCDT-Lung has performed as reported in Oncimmune's publications (1). The majority of cancers detected were at early stage. The high positive predictive value makes it a good complement to CT in the cases where a patient is found to have a suspicious pulmonary nodule.

CLINICAL IMPLICATIONS

EarlyCDT-Lung has been, and continues to be, a valuable tool used in our practice for evaluating a patient's risk for lung cancer, for patients with a CT-identified pulmonary nodule as well as those with an extensive smoking history.

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For more information on EarlyCDT(R)-Lung:

* Call 888-583-9030

* Visit www.oncimmune.com