

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