

Bronchial Genomic Classifier in Patients with Suspected Lung Cancer

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In 2014, an estimated 224,000 new diagnoses and 160,000 deaths of patients with lung cancer occurred in the United States and lung cancer remains the leading cause of cancer mortality in this country. In the United States, estimated 500,000 bronchoscopies are performed per year, and approximately half are for the diagnosis of lung cancer. Bronchoscopy is considered to be safer than other invasive sampling techniques, such as transthoracic needle biopsy or other surgical methods, but is frequently non-diagnostic in patients with suspected lung cancer. This frequently results in additional invasive testing, although many lung lesions are benign. Nevertheless, the diagnostic yields of bronchoscopy are ranging from 34% (for < 2 cm. peripheral nodules) to 88% (for larger, centrally located lesions). However, the overall clinical sensitivity of bronchoscopy for lung cancer has not improved substantially. Invasive procedures following the inconclusive bronchoscopy occur frequently and the majority is performed in patients diagnosed with benign disease. When bronchoscopy is non-diagnostic, clinicians are frequently left with the ambiguity of whether to perform further invasive diagnostic procedures, with associated complications or select diagnostic imaging surveillance. Approximately, one third of patients are determined to have benign disease when these invasive procedures are performed, indicating that these procedures are avoidable. Diagnostic techniques that reduce this ambiguity by substantially improving the diagnostic yield of bronchoscopy could improve patient care.

Alteration of the gene expression profile of cytologically-normal bronchial airway epithelial cells in patients with suspected lung cancer has been previously identified. The bronchial airway transcriptome from reversible and irreversible impact of cigarette smoke has been characterized and a set of gene-expression alterations in the bronchial epithelium has been identified in present and former cigarette smokers with lung cancer. A new test for detection of lung cancer called "bronchial genomic classifier" has been developed to help people avoiding costly and invasively lung biopsies. This test takes cell samples from the windpipe of a cigarette smoker during a bronchoscopy procedure. This new test completely negates the need to perform a separate biopsy. The device will test 23 genes for exposure to toxins identified in cigarette. The 23-gene molecular classifier's performance is proven in clinical validation studies enrolling more than 1,000 patients. The classifier uses genomic technology to detect molecular changes that occur in the epithelial cells lining the respiratory tract in present or former cigarette smokers with lung cancer. These changes can be detected in cells obtained from standard cytology brushing taken during bronchoscopy from the main bronchus and indicate the presence of malignancy or disease process from distant sites in the lung. Therefore, the test is designed to determine a lung nodule's or lesion's likelihood of cancer in patients at low risk of cancer following an inconclusive bronchoscopy result, to enable these patients to be safely monitored with computerized tomographic scans, without the need to sample the nodule or lesion directly. The gene-expression classifier improves the diagnostic performance of bronchoscopy for the detection of lung cancer. The test appeared to have approximately 91% of the negative predictive value which indicates that the test can reclassify patients who are at low risk. Due to high negative predictive value of classifier, it could potentially make clinical decisions regarding the need of further invasive testing in patients whose bronchoscopic examination is non-diagnostic. A negative classifier score in intermediate-risk patients with a non-diagnostic bronchoscopic examination provides confidently support for a more conservative diagnostic approach. The high sensitivity of this classifier, measured in a specimen readily accessible during bronchoscopic examination result in a very low probability of lung cancer when the test result is negative, and indicates that clinicians could confidently pursue active surveillance and reduce risky invasive procedures in patients without lung cancer.

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