ORIGINAL ARTICLE

Cost-Effectiveness of a Bronchial Genomic Classifier for the Diagnostic Evaluation of Lung Cancer

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ABSTRACT

Introduction: The use of a bronchial genomic classifier has been shown to improve the diagnostic accuracy of bronchoscopy for suspected lung cancer by identifying patients who may be more suitable for radiographic surveillance as opposed to invasive procedures. Our objective was to assess the cost-effectiveness of bronchoscopy plus a genomic classifier versus bronchoscopy alone in the diagnostic work-up of patients at intermediate risk for lung cancer.

Methods: A decision-analytic Markov model was developed to project the costs and effects of two competing strategies by using test performance from the Airway Epithelial Gene Expression in the Diagnosis of Lung Cancer–1 and Airway Epithelial Gene Expression in the Diagnosis of Lung Cancer–2 studies. The diagnostic accuracy of noninvasive and invasive follow-up, as well as associated adverse event rates, were derived from published literature. Procedure costs were based on claims data and 2016 inpatient and outpatient reimbursement amounts. The model projected the number of invasive follow-up procedures, 2-year costs and quality-adjusted life-years (QALYs) by strategy, and resulting incremental cost-effectiveness ratio discounted at 3% per annum.

Results: Use of the genomic classifier reduced invasive procedures by 28% at 1 month and 18% at 2 years, respectively. Total costs and QALY gain were similar with classifier use ($27,221 versus $27,183 and 1.512 versus 1.509, respectively), resulting in an incremental cost-effectiveness ratio of $15,052 per QALY.

Conclusions: Our analysis suggests that the use of a genomic classifier is associated with meaningful reductions in invasive procedures at about equal costs and is therefore a high-value strategy in the diagnostic work-up of patients at intermediate risk of lung cancer.

Keywords: Cost effectiveness; Diagnostic techniques; Lung cancer; Bronchoscopy; Genetic marker

Introduction

Bronchoscopy is a commonly used first diagnostic procedure in the work-up of patients with pulmonary lesions suspected to be lung cancer.[1] Its relatively frequent use is based, in part, on its lower procedure risk profile compared with that of transthoracic needle aspiration (TTNA) or surgical lung biopsy.[2] Prior data suggest that a substantial percentage of patients with benign lesions undergo invasive procedures subsequent to inconclusive findings in the initial bronchoscopy, exposing them to procedural risks and discomfort and creating additional cost burden to the health care system.[3] Recently, findings from Airway Epithelial Gene Expression in the Diagnosis of Lung Cancer (AEGIS)-1 and AEGIS-2, two multicenter prospective substudies

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enrolling current or former smokers undergoing bronchoscopy for suspected lung cancer, have shown that a negative classifier score in patients with an intermediate (10%–60%) pretest probability of lung cancer and a nondiagnostic bronchoscopy result decreases the posttest probability of lung cancer to less than 9%, supporting a more conservative diagnostic approach.[4]

Our primary objective in this study was to evaluate the cost-effectiveness of the use of bronchoscopy plus the classifier versus bronchoscopy alone from a U.S. third-party payer perspective based on the findings of the AEGIS intermediate-risk cohort. Our secondary objective was to estimate the impact of classifier use on the number of invasive procedures performed through 2 years of follow-up.

Methods

Our analysis considered the diagnostic work-up of intermediate-risk patients over a 2-year time horizon, using population and test performance characteristics observed in the AEGIS 1 and 2 studies to assess diagnostic outcomes during the index diagnostic procedure. This information provided the initial input to a state transition (Markov) model used to project, for each strategy, the further diagnostic work-up and invasive and surgical procedures. This model type was chosen because state transition models make it possible to follow subpopulations of patients in different disease states over time and assign different transition probabilities and rewards that can be assessed in uncertainty analyses. A follow-up time horizon of 2 years was chosen on the basis of current clinical guidelines, which recommend ensuring radiographic stability for a period of up to 2 years.

For each of the two strategies, we computed the estimated numbers of invasive procedures including surgery over the 2-year time horizon, the total (technical and professional) costs of noninvasive and invasive follow-up, and gains in health-related quality of life, as measured through projected gains in quality-adjusted life-years (QALYs). A schematic representation of the model structure is shown in Figure 1; further details about the model framework are provided in the Supplementary Data.

The primary outcome measure of the analysis was the incremental cost-effectiveness ratio (ICER), defined as the incremental direct costs of the classifier strategy divided by the incremental health benefits measured as QALYs and taking into account gains in both survival and health-related quality of life.[5] The ICER is the primary metric used in health economic analyses to assess the value of an intervention.[6] Strategies associated with ICER values up to $50,000 per QALY gained are considered "good value" investments for health care systems in the U.S. setting, and ICERs up to $150,000 per QALY are considered to be of value.[7–9]

The secondary outcome measure was the estimated number of invasive procedures performed under each strategy, measured on the basis of model-projected procedure incidence at 1 month and 24 months after the index procedure.

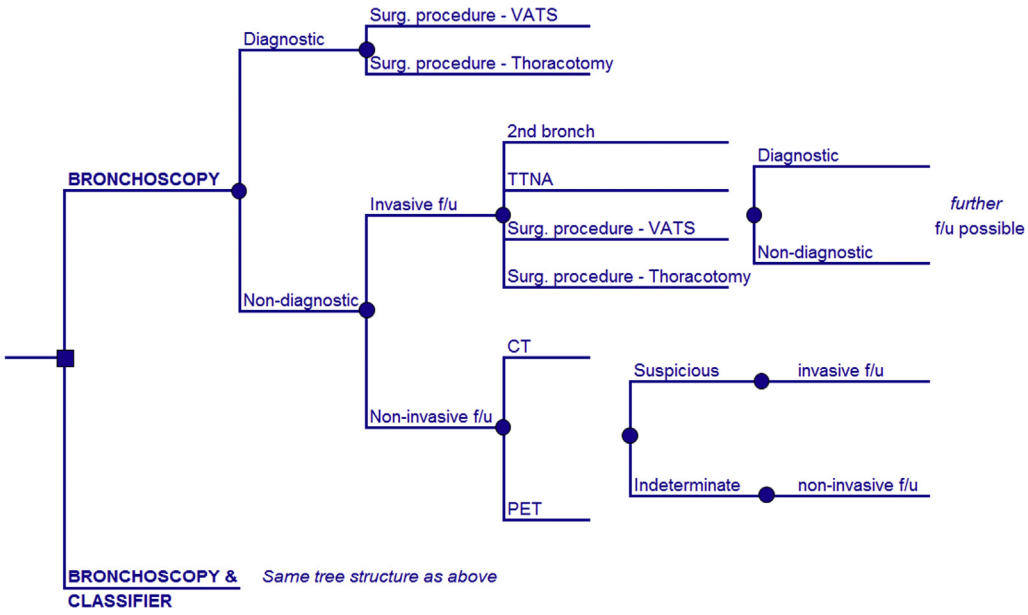

Figure 1. Representation of model structure (simplified). In the classifier strategy, classifier costs were considered only in the case of a nondiagnostic bronchoscopy result. VATS, video-assisted thoracoscopy; f/u: follow-up; TTNA, transthoracic needle aspiration.