Category: Early Detection

The LuCED Test for Detection of Early Lung Cancer: A Criterion to Complete the Test with High Sensitivity

Background

The Cell-CT imaging platform produces 3D volumetric cell images based upon computed tomography as shown in the figure. The Cell-CT's cell-by-cell morphological analysis in 3D overcomes obscuration issues and biases associated with perspective and focal plane selection inherent to slide imaging and 2D analysis. Thus, regression of 3D cell features to expertly identified cell type produces a classifier that almost perfectly distinguishes cancer from normal cells. This Cell-CT classifier forms the basis of VisionGate's LuCED test to triage the population at high risk for lung cancer to X-Ray CT for tumor localization and treatment. Since LuCED evaluates mostly normal cases, a criterion is needed to determine when to discontinue analysis of additional cells while preserving high sensitivity for cases with diagnostic (dysplasia and cancer) cells. This criterion can be found by assessing the prevalence of diagnostic cells and other normal epithelial cells in sputum. These results are presented here.

Methods

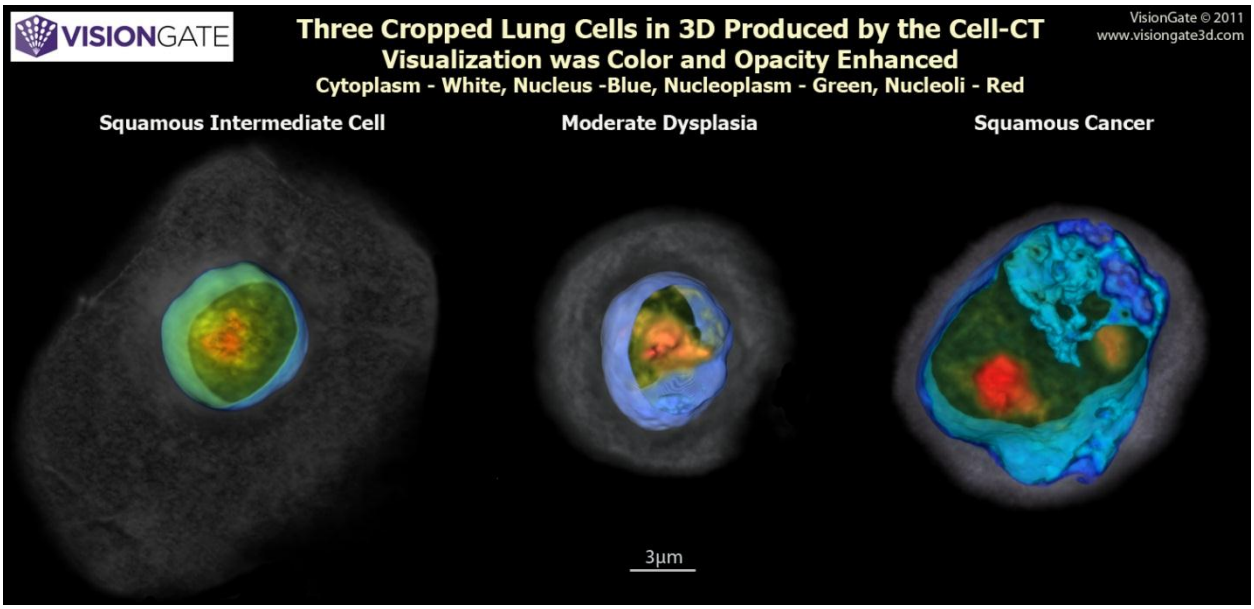
Specimens were obtained from an FDA phase III trial to assess a sputum expectorant. Patients were enrolled based on high likelihood of lung cancer and contributed spontaneous and/or induced sputum. Cancer presence and type was established through biopsy 120 days after the trial completion. A portion of each sputum was stained and deposited on a slide. These slides were scanned by a cytotechnologist to produce counts of various cell types. Results were analyzed to determine the proportion of diagnostic cells to normal epithelial cells. 147 patients comprised our study group that produced 180 specimens with diagnostic cells. Sputum from 44 patients with adenocarcinoma, 68 with squamous cancer, and 68 with other types of lung cancer were analyzed.

Results

Statistical characteristics of diagnostic cells and normal epithelial cells were assessed across many sputa to determine a criterion to terminate the LuCED test. Results show that 90% of the sputum specimens have at least one diagnostic cell per 100 epithelial cells irrespective of tumor type.

Conclusions

Our results show that analysis of sputum by the LuCED test should proceed until 100 epithelial cells have been examined. Doing so establishes an efficient way to discontinue LuCED sputum processing for normal cases, and ensures that the patient is forwarded for additional testing if the sputum contains diagnostic cells.



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