

Clinical Evaluation of a New Screening Test for Lung Cancer Based on Galactose Oxidase Schiff's Reactivity in Sputum Samples

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Background: The galactose oxidase Schiff's reaction (GOS) produces a magenta colour in the presence of the sugar moiety D-galactose β [1-3]-N-acetyl-D galactosamine or TF antigen. This colour reaction can be quantified using a portable spectrophotometer producing a numerical result. In a pilot study we showed that the GOS test could differentiate sputum samples from subjects with benign lung disease from those with lung cancer. This study is intended to confirm those initial findings and to extend the study population to include healthy smokers. **Methods:** Spontaneous sputum samples were obtained from 17 cancer patients prior to surgery (7 with stage I disease, 5 with stage II-IV disease, 5 unstaged) and 28 subjects without cancer (17 with benign disease and 11 healthy smokers). The sputum samples were treated with DTT solution and diluted to 1 mg/mL protein before being applied to a glass fiber membrane attached to a slide-shaped holder. After air-drying samples were treated with galactose oxidase and stained with Schiff's reagent. Results were reported as the hue:chroma ratio as measured with a portable spectrophotometer using QA-lite™ software. GOS testing was done blinded to clinical diagnosis. **Results:** Hue:chroma ratios were significantly higher in cancer patients than in subjects without cancer (27.9 vs. 20.3, $p < 0.001$). Using a cutoff of >26.1 (hue:chroma) the GOS test detected 64.7% of the cancers including 57.1% of the stage I cancers and 80% of the later stage disease. Specificity was 93.6% overall (94.1% for benign disease, 90.9% for healthy smokers). **Conclusions:** This simple non-invasive test may have utility in stratifying smokers for lung cancer risk.

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