Diagnostic accuracy of the CxPREVENTIVE Colon model for early detection of colorectal cancer

First Author & Presenting Author: Sergio J Calleja; Blueberry Diagnostics, Barcelona, Spain

Second Author: Édgar C Patiño; Blueberry Diagnostics, Barcelona, Spain

Sponsor: Juan L. Bayo, MD

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Background

Despite different available methods for colorectal cancer (CRC) screening and their proven benefits, morbidity, and mortality of this malignancy are still high, partly due to technical limitations and low compliance with screening. The aim of the present study was to assess the diagnostic accuracy for early detection of CRC using a modeling algorithm based on multiple blood and urine biomarkers.

Method

In this retrospective cohort study, clinical and blood and urine markers-based algorithms with predefined cutoff values were applied to a generally healthy asymptomatic outpatient cohort of adults aged 50 years or older undergoing colonoscopy and histopathology for routine colorectal cancer screening. We used a modeling algorithm based on two different frameworks (Multiple Biomarkers Disease Activity Algorithm MBDAA [Bioprognos], and Artificial Intelligence Recursive Algorithm AIRA [Mintlot] both in Barcelona, Spain). Both algorithms compute information from a wide number of analytes, tumor markers (AFP, CA 19.9, CA 72.4, CA 125, CEA, Cyr61, NGAL, EGFR and 8-OHdG), and additional clinical data (age, weight, height, and BMI). MBDAA includes Barcelona Criteria (four criteria to correctly interpret the cause of the increase in tumor markers, benign or malignant, defined by the Spanish Society of Clinical Biochemistry and Molecular Pathology, Commission of Biological Markers of Cancer).

To assess the association between the modelling algorithm and downstream diagnosis we used logistic regression to compute receiver operating characteristic curves (ROC). Exact binomial confidence limits were calculated to test accuracy, sensitivity, and specificity.

Results

221 people (median age 63 yr. [IQR 49-77]; 107 [49%] women and 114 [51%] men) who underwent colonoscopy at the Juan Ramón Jiménez Hospital (Huelva, Spain), were included in this analysis. Based on colonoscopy and histopathologic findings, CRC was diagnosed in 45 (20%) patients, colonic polyposis in 56 (25%), inflammatory bowel disease in 37 (17%), and absence of pathological findings (control group) was seen in 83 (38%). The diagnostic intervention for CRC yielded an area under the curve (AUC) of 1 among the entire specimen set, accuracy 1 (95%CI 0.996,1), Se 1 (0.988, 1) and Sp 1 (0.997, 1). Besides, the algorithm also performed very well in the identification of polyps with an accuracy 1 (95% CI, 0.967 to 1), Se of 1 (0.991, 1) and of Sp 1 (0.996, 1), as well in the diagnosis of inflammatory bowel disease with an accuracy of 1 (0.968 to 1), Se of 1 (0.986, 1) and Sp of 1 (0.997, 1).

Conclusions

Using colonoscopy as a gold standard, our data suggest that an innovative newly designed non-invasive blood and urine-based biomarker algorithm CxPREVENTIVE Colon may provide a timely diagnosis of CRC with very high accuracy. Our findings warrant further investigation, and we are planning large-scale (n 10,000), fully powered study to inform clinical practice.