

Diagnostic accuracy of the CxPREVENTIVE Breast model for early detection of breast cancer

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Background

Despite different available methods for breast cancer (BC) screening (mainly mammographies for ages between 50 and 65 yr.), 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 BC 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 women aged 23 years or older undergoing mammography and histopathology for routine breast cancer screening. We used a modeling algorithm based on two different frameworks (Multiple Biomarkers Disease Activity Algorithm MBDA [Bioprognos], and Artificial Intelligence Recursive Algorithm AIRA [Mintlot] both in Barcelona, Spain). Both algorithms compute information from a wide number of analytes, tumor markers (CA 15.3, CEA, EGFR, NGAL, NSE and 8-OHdG), and additional clinical data (age, weight, height, and BMI). MBDA 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

123 women (median age 48 yr. [IQR 40-63]) who underwent mammography at the Juan Ramón Jiménez Hospital (Huelva, Spain), were included in this analysis. Based on mammography and histopathologic findings, BC was diagnosed in 61 (49.5%) women, and absence of pathological findings (control group) was seen in 62 (51.5%). The diagnostic intervention for BC yielded an area under the curve (AUC) of 1 among the entire specimen set, accuracy 1 (95% CI 0.990,1), Se 1 (0.991, 1) and Sp 1 (0.991, 1).

Conclusions

Using mammography as a gold standard, our data suggest that an innovative newly designed non-invasive blood and urine-based biomarker algorithm CxPREVENTIVE Breast may provide a timely diagnosis of BC with very high accuracy, especially for those women under 50 and over 65yr., where up to 60% of all BC are concentrated. Our findings warrant further investigation, and we are planning large-scale (n 10,000), fully powered study to inform clinical practice.