

## Abstract PS4-47:

Multi-country clinical validation of can assist breast in Europe indicates robustness of the test

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Cancer Res February 15 2021 (81) (4 Supplement) PS4-47; DOI: 10.1158/1538-7445.SABCS20-PS4-47

## Abstract

**Background:** CanAssist Breast (CAB) is a prognostic test for early stage hormone receptor positive breast cancer patients, that predicts risk of distant recurrence in five years post-diagnosis. Its support vector machine-based algorithm utilizes immunohistochemistry profiles of five biomarkers involved in tumor biology (CD44, ABCC4, ABCC11, N-Cadherin and pan-Cadherin) and three clinical parameters (tumor size, grade, and node status) to categorize patients into low- or high-risk of distant recurrence. CAB was developed on Indian patients, and has been validated in Indian and US patients. The current study presents first ever multi-country, blinded, retrospective validation of CAB. **Methods:** A total of 669 patients' breast tumors from Austria (n=327), Spain (n=292) and Italy (n=50) diagnosed 5-10 years ago along with known clinical parameters were included. CAB was performed on the formalin fixed tumor samples using Roche's automated immunohistochemistry platform at OncoStem's CAP accredited reference laboratory in India. CAB risk predictions were matched with the clinical outcomes by the respective hospitals. Distant Metastasis Free Survival (DMFS), negative predictive value (NPV) and Hazard Ratio (HR) were computed from Kaplan-Meier survival curves using MedCalc software. **Results:** The median age of the cohort was 60 years (range: 28-92 years), with only 28% of patients aged < 50 years. The cohort had equal proportions of stage I and stage II patients and 19% of patients with poorly differentiated tumors (G3). Amongst stage II patients 57% had three nodes positive (N1) disease. Total cohort had of 72% N0 patients and 28% N1 patients. The DMFS of this cohort was 95% in low-risk versus 82% in high-risk category ( $p < 0.0001$ ). The recurrence rate was 5% in low-risk category as against 18% in high-risk category. The risk stratification of patients treated with endocrine therapy alone (68%) was similar to chemo-endocrine therapy (32%) treated patients, both had 95% DMFS in low-risk category. Subtle differences in the NPV was observed across different European patient cohorts: Spain-96%, Italy-100%, Austria-93%. The performance of CAB in European cohort was comparable to the mixed validation cohort of ~1100 patients from India and US, with identical DMFS of 95% in the low-risk category. In a sub-cohort of T1N0 patients (50%), the DMFS in low-risk group was still higher at 97%. In the multivariate Cox proportional hazards model, CanAssist Breast risk score had the highest and significant hazard ratio of 2.9 ( $p=0.0013$ , CI: 1.5-5.5) over clinical parameters (node, grade, tumor size), age and type of therapy (endocrine vs. chemo-endocrine). **Conclusion:** The current study demonstrates the robustness of risk prediction by CAB in an European cohort of diverse nationalities and ethnicities. Similar accuracy of CAB in the Indian and European cohort emphasizes that CAB based risk predictions are driven by tumor biology and are independent of conventional prognostic factors. **Citation Format:** Somashekhar SP, Aparna Gunda, Chandra Prakash V Serkad, Aditya K Sengupta, Patricia Gomez, Cristina Saura, Vicente Peg, Jose Jimenez, Susanne Sprung, Heidelinde Fiegl, Christine Brunner, Daniel Egle, Manjiri M Bakre. Multi-country clinical validation of can assist breast in Europe indicates robustness of the test [abstract]. In: Proceedings of the 2020 San Antonio Breast Cancer Virtual Symposium; 2020 Dec 8-11; San Antonio, TX. Philadelphia (PA): AACR; Cancer Res 2021;81(4 Suppl):Abstract nr PS4-47.

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