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Title: Risk stratification in early stage luminal breast cancer patients treated with and without RT

Background: The goal was to develop and validate a biologic signature for 10-year ipsilateral invasive breast event (IBE) risk in luminal Stage 1 breast cancer (BC) patients treated surgically and either with or without radiation therapy (RT).

Methods: This cohort was from Uppsala University and Västerås Hospitals diagnosed with Stage 1 BC and treated surgically between 1987 and 2004. Treatment was neither randomized nor strictly rules based, including adjuvant RT, Hormone Therapy (HT), and Chemotherapy (CT). Biomarkers (HER2, PR, Ki67, COX2, p16/INK4A, FOXA1 and SIAH2) were assessed on tissue microarrays in PreludeDx's CLIA lab by board-certified pathologists. Risk groups were calculated using biomarkers and clinical factors age and size. A multivariate Cox proportional hazards analysis was used to determine hazard ratio for biologic signature. 10-year IBE risk was assessed using Kaplan-Meier survival analysis.

Results: There were 423 luminal cases with biomarker data having 54 IBEs, and a median follow-up of 11.8 years. There were 372 patients treated with BCS and 51 with Mastectomy, and 325 received RT, 169 received HT, and 47 received CT. In a multivariate analysis, the biologic signature (HR = 1.6, p = 0.019) and RT (HR = 0.51, p = 0.027) were associated with IBE risk adjusting for other treatments (HT and CT) and Luminal A status (p = 0.37). For patients over 50 yrs of age with luminal A disease and treated without CT (n = 205), an elevated biologic signature identified a subset of patients with a 15% (+/- 14%) 10-year IBE risk without RT (n = 38) compared to a 4% (+/-6%) IBE risk with RT (n = 72), while patients with a low biologic signature had a 10-year IBE risk of 4% (+/- 4%) without RT (n = 26) and 3% (+/-5%) IBE risk with RT (n = 69).

Conclusions: With further prospective validation, the biologic signature identified herein may provide a tool enabling improved management for women diagnosed with early luminal BC.

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