



# READ IT BEFORE YOUR PATIENTS

## Breast

### Validation of a Ductal Carcinoma In Situ Biomarker Profile for Risk of Recurrence after Breast-Conserving Surgery with and without Radiotherapy.

Weinmann S, Leo MC, Francisco M, Jenkins CL, Barry T, Leesman G, Linke SP, Whitworth PW, Patel R, Pellicane J, Wärnberg F, Bremer T.

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#### PURPOSE

A major challenge in ductal carcinoma in situ (DCIS) treatment is selection of the most appropriate therapeutic approach for individual patients. We conducted an external prospective-retrospective clinical validation of a DCIS biological risk signature, DCISionRT, in a population-based observational cohort of women diagnosed with DCIS and treated with breast-conserving surgery (BCS).

#### EXPERIMENTAL DESIGN

Participants were 455 health plan members of Kaiser Permanente Northwest diagnosed with DCIS and treated with BCS with or without radiotherapy from 1990 to 2007. The biological signature combined seven protein tumour markers assessed in formalin-fixed, paraffin-embedded tumour tissue with four clinicopathological factors to provide a DCISionRT test result, termed decision score (DS). Cox regression and Kaplan-Meier analysis were used to measure the association of the DS, continuous (linear) or categorical ( $DS \leq 3$  vs.  $DS > 3$ ), and subsequent total ipsilateral breast events and invasive ipsilateral breast events at least six months after initial surgery.

#### RESULTS

In Cox regression, the continuous and categorical DS variables were positively associated with total and invasive breast event risk after adjustment for radiotherapy. In a subset analysis by treatment group, categorical Kaplan-Meier analyses showed at least two-fold differences in 10-year risk of total breast events between the elevated-risk and low-risk DS categories.

#### CONCLUSION

In this first external validation study of the DCISionRT test, the DS was prognostic for the risk of later breast events for women diagnosed with DCIS, following BCS.