Goals: Most women with DCIS will be treated by breast-conserving surgery (BCS) often followed by radiation. However, BCS alone is an option for individuals with low risk of local recurrence (LR). Validated biomarkers are needed to improve risk assessment and treatment of DCIS. The Oncotype DX® DCIS Score (DS) was shown to predict the risk of LR in selected individuals treated by BCS alone in the ECOG E5194 clinical trial. Our objective was to confirm these results in a larger population-based cohort of individuals with DCIS treated by BCS alone.

Methods: We used an established population-based cohort of individuals diagnosed with DCIS from 1994–2003 treated with BCS alone. Treatment and outcomes were validated. Expert breast pathologists centrally reviewed H&E slides. Cases with invasive cancer or positive margins were excluded. The DCIS Score was obtained by quantitative RT-PCR. The DS was evaluated as a continuous score (0–100) and by pre-specified risk groups (low risk DS <39, intermediate risk DS 39–54; high risk DS >55). Cox model was used to determine the relationship between independent covariates, the DS (hazard ratio (HR)/50 units) and LR. Kaplan–Meier method (log rank test) was used to compare differences in 10 year risk of LR by risk group. The primary objective was to determine the relationship between the risk of LR and the DS in patients treated with BCS alone (with ER+ tumors or regardless of ER status) and negative margins (no ink on tumor).

Results: The population cohort includes 1658 cases of pure DCIS treated by BCS alone. Tumor blocks were collected for 828 patients. Final evaluable population includes 571 cases with negative margins. Median follow-up was 9.6 years. 100 cases developed LR (DCIS, N=44; invasive, N=57). The 10 year risk of LR was 19.2%. In the primary pre-specified analysis, the DS was associated with LR (DCIS or invasive) in ER+ patients (HR 2.26; P<0.001) and in all patients regardless of ER status (HR 2.15; P<0.001). DCIS Score was associated with LR after adjusting for age, tumor size, multifocality and subtype (adjusted HR 1.68; P=0.02). The DS was associated with invasive LR (unadjusted HR 1.78; P=0.04) and DCIS LR (unadjusted HR 2.43; P=0.005).