

Ten-year Clinical Outcomes in >1000 Node-negative (NO) Estrogen Receptor (ER)+ Breast Cancer (BC) Patients (Pts) in Whom Treatment Decisions Incorporated the Recurrence Score Results: A Registry Analysis Using TAILORx Categorization

Poster Abstracts

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Goals: To investigate 10-y clinical outcomes in NO ER+ BC pts in whom the 21-gene Oncotype DX Breast Recurrence Score[®] results guided adjuvant treatment decisions in real-life clinical practice.

Methods: This exploratory analysis of the prospectively-designed Clalit Health Services (CHS) registry included all CHS pts with NO ER+ HER2-negative BC who underwent RS testing in Israel between 1/2006 and 12/2009. Ten-year Kaplan-Meier estimates for distant recurrence and BC-specific mortality (BCSM) rates are reported.

Results: The analysis included 1365 pts (median follow-up: 9.0 y); 99.3% females; median age, 60 y; 50.3% grade 2 tumors, 77.1% tumors ≥ 2 cm. The distribution of Recurrence Score[®] (RS) results was as follows: RS 0-10, 17.8%; RS 11-25, 62.5%; and RS 26-100, 19.7%, with corresponding chemotherapy (CT) use of 0%, 9.4%, and 69.9%. Ten-year distant recurrence rates in RS 0-10, 11-25, and 26-100 pts: 2.6% (95% confidence interval [CI], 1.1%, 6.2%), 6.1% (95% CI, 4.4%, 8.6%), and 13.1% (95% CI, 9.4%, 18.3%), respectively ($P < .001$). The corresponding BCSM rates: 0.7% (95% CI, 0.1%, 5.1%), 2.2% (95% CI, 1.3%, 3.7%), and 9.5% (95% CI, 6.0%, 14.9%) ($P < .001$). Subdividing the RS 11-25 group revealed 10-year distant

recurrence rates of 4.0% (95% CI, 2.0%, 7.7%), 5.8% (95% CI, 3.2%, 10.3%), and 8.9% (95% CI, 5.4%, 14.5%) in the RS 11-15, 16-20, and 21-25 subgroups, respectively (corresponding CT use in these 3 subgroups, 1.8%, 7.0%, and 21.6%). When the analysis included pts treated with endocrine therapy alone (95.5%/87.5% of pts with RS 0-10/11-25), 10-y distant recurrence and BCSM rates for RS 0-10 pts were 2.7% (95% CI, 1.1%, 6.5%) and 0.8% (95% CI, 0.1%, 5.3%), respectively, and for pts with RS 11-25, 5.7% (95% CI, 3.9%, 8.3%) and 6.9% (95% CI, 2.6%, 17.8%), respectively. No statistically significant differences were observed in 10-year distant recurrence/BCSM rates in CT-treated vs untreated pts in the RS 11-25 subgroup; however, this should be interpreted cautiously since the number of events was low and pts were not randomized. Notably, of 243 pts with RS 0-10, none received CT. Of the 853 pts with RS 11-25, 9/273, 13/344, and 16/236 distant recurrence events were observed in the RS 11-15, RS 16-20, and RS 21-25 groups, respectively.

Conclusions: In NO ER+ HER2-negative BC pts, in whom the decision to use CT was closely aligned with RS results, those with RS 0-25 (~80% of patients) had excellent outcomes at ten years, despite CT use in <10% of pts.