

[P5-08-02] Real-life analysis evaluating 1594 N0/Nmic breast cancer patients for whom treatment decisions incorporated the 21-gene recurrence score result: 5-year KM estimate for breast cancer specific survival with recurrence score results ≤ 30 is $>98\%$

Stemmer SM, Steiner M, Rizel S, Soussan-Gutman L, Geffen DB, Nisenbaum B, Ben-Baruch N, Isaacs K, Fried G, Rosengarten O, Uziely B, Svedman C, Rothney M, Klang SH, Ryvo L, Kaufman B, Evron E, Zidan J, Shak S, Liebermann N. Davidoff Center, Rabin Medical Center, Petah Tikva, Israel; Lin Medical Center, Haifa, Israel; Teva Pharmaceutical Industries Ltd, Shoam, Israel; Soroka University Medical Center, Beer Sheva, Israel; Meir Medical Center, Kfar Saba, Israel; Kaplan Medical Center, Rehovot, Israel; Ha'emek Medical Center, Afula, Israel; Rambam Health Care Campus, Haifa, Israel; Shaare Zedek Medical Center, Jerusalem, Israel; Hadassah Hebrew University Medical Center, Jerusalem, Israel; Genomic Health Inc., Redwood City, CA; Clalit Health Services, Tel Aviv, Israel; Tel-Aviv Sourasky Medical Center, Tel Aviv, Israel; Sheba Medical Center, Ramat Gan, Israel; Assaf Harofeh Medical Center, Zerifin, Israel; Ziv Medical Center, Safed, Israel

Background: The 21-Gene Recurrence Score® Assay (Oncotype DX®) has been validated as a prognostic and predictive tool in estrogen receptor (ER)+ breast cancer in multiple studies using archival specimens of clinical trials with long term follow up. Prospective outcome data from patients where treatment decisions incorporated the Recurrence Score results have not been reported. We evaluated treatments and clinical outcomes in patients undergoing Recurrence Score testing in 9 medical centers within Clalit Health Services (CHS), the largest HMO in Israel. Methods: Medical records of patients with N0/Nmic ER+ HER2-negative disease undergoing testing from 12/2004 to 12/2010 in 9 medical centers (Rabin, Lin, Soroka, Meir, Kaplan, Hadassah, Ha'emek, Rambam, and Shaare Zedek) within CHS were individually reviewed to verify treatments given, recurrence, and survival status. 5-year Kaplan-Meier (KM) and standard error estimates for distant recurrence and breast cancer specific survival were determined. Results: 1594 patients were evaluated with 5.9 years median follow-up. Median age, 61 (25-85) years; N0/Nmic (90%/10%); Grade I (16%), II (48%), III (16%), N/A (19%); histology, IDC (80%), lobular (13%), other (7%). Distribution of Recurrence Score risk groups (Recurrence Score results of <18 , $18-30$, ≥ 31): low (51%), intermediate (38%), and high (11%), with chemotherapy (CT) use of 1%, 26%, and 89%, respectively. Distant recurrence was reported in 17/813, 33/612, and 24/169 patients in the low, intermediate, and high Recurrence Score groups, respectively. In the high Recurrence Score group, distant recurrence was reported in 20/150 (13.3%) of CT-treated patients and in 4/19 (21.1%) of untreated patients. In the intermediate Recurrence Score group, the respective values were 9/162 (5.6%) and 24/450 (5.3%). The 5-year KM estimate for distant recurrence rate was 1.4% (95% CI: 0.9-2.3%) for the entire cohort, and 0.5% (95% CI: 0.2-1.6%), 1.2% (95% CI: 0.6-2.8%), and 6.9% (95% CI: 3.7-12.9), for the low, intermediate, and high Recurrence Score groups, respectively. The 5-year KM estimate for breast cancer specific survival was 98.4% (95% CI: 97.6-98.9%) for the entire cohort, and 99.9% (95% CI: 99.0-99.98%), 98.5% (95% CI: 97.1-99.2%) and 90.6% (95% CI: 84.5-94.4%), for the low, intermediate, and high Recurrence Score groups, respectively.

Conclusions: These are the first prospective long term clinical outcome data from approximately 1600 patients for whom the 21-gene Recurrence Score assay has been incorporated in real-life clinical decision making. The documented use of CT was appropriately based on the Recurrence Score result, and the outcomes for recurrence and survival are consistent with previously reported prospective-retrospective studies of the 21-gene assay. The 5 year KM estimates for distant recurrence rate in patients with low and intermediate Recurrence Score results who were treated based upon their Recurrence Score results were very low (0.5% and 1.2%, respectively).

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Poster Session 5: Prognostic and Predictive Factors: Prognostic and Predictive Factors -- Other (5:00 PM-7:00 PM)

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