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The first report of the association between the Recurrence Score[®] and the risk of recurrence in a Japanese Population (JBCRG-TR 003)

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Goals: The purpose of our study was to evaluate the performance of the Oncotype DX[®] assay to predict distant recurrence in Japanese patients.

Methods: The JBCRG collected 325 tumor tissues from the tamoxifen-treated patients with estrogen receptor (ER)-positive breast cancer who had undergone surgery between 1992 and 1998 in Japan. The tissues were analyzed for 21 genes, and a summary Recurrence Score (RS) to determine a risk group (low (RS<18), intermediate (RS 18-30), or high (RS > 31) with a prescribed algorithm was calculated for each patient.

Results: A total of 280 patients were eligible with adequate RT-PCR profiles for the RS. Of those, 200 and 80 patients had node-negative and node-positive disease, respectively. The proportions of node-negative patients categorized as having a low, intermediate, or high RS were 48%, 20%, and 33%, respectively. In node-negative patients, the Kaplan-Meier (KM) estimates of the distant recurrence rate at 8 years were 2.2% (95% CI, 0.5-8.4%), 0% (95%CI, N/A), and 23.0% (95% CI, 14.3-35.8%) for those in the low, intermediate and high risk groups, respectively. In the primary analysis, the risk of distant recurrence in the low-risk group was significantly lower than that in the high-risk group when the entire KM plots were compared (P<0.001, log-rank test). There was also a significant difference in the KM plots for overall survival between the low- and high-risk groups (P=0.008, log-rank test); the KM estimates for death at 8 years were 5.3% (95% CI, 2.2-12.2%) and 12.5% (95% CI, 6.4-23.4%), respectively. A separate analysis of the eligible patients, adjusting for the number of positive nodes (0, 1-3, 4+), indicated that there was a significant difference between the low- and high-risk groups (p=0.008).

Conclusion: In this population of Japanese women with ER-positive early breast cancer who received adjuvant treatment with tamoxifen, the RS identified a large proportion of patients with very low risks of distant recurrence.