Lack of concordance between Ki67 labeling index and 21-gene Breast Recurrence Score® test results in patients with ER+, HER2-, clinically node-negative breast cancer: A secondary analysis of TransNEOS neoadjuvant study

Poster Abstracts

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Goals: Incorporation of the nuclear proliferation marker Ki67 labeling index (LI) to guide decisions on adjuvant or neoadjuvant therapy varies across clinical guidelines. Ki67 LI in combination with other clinicopathologic factors is used in some regions to guide adjuvant or neoadjuvant therapy, although validation of this approach is pending. The Recurrence Score® (RS) result is validated for prognosis and prediction of chemotherapy benefit in the adjuvant setting, and for prognosis in the neoadjuvant setting. In TransNEOS, the Recurrence Score result predicted clinical response to neoadjuvant letrozole and was significantly associated with achievement of breast conserving surgery (Iwata Breast Cancer Res Treat 2018). Here, we present an analysis of the relationship between Ki67 LI and Recurrence Score results using pre- treatment core biopsies from TransNEOS patients.

Methods: TransNEOS patients were diagnosed with ER+, HER2−, clinically node-negative breast cancer, had tumors ≥2 cm, and had archived core biopsies taken before neoadjuvant letrozole that were later sent for 21-gene testing. Ki67 LI was evaluated by immunohistochemistry [IHC]) on core biopsy specimens using MIB1 as the primary antibody. The counting was performed in at least 100 tumor cells after identifying the hot spots of the specimens by two of the authors (YS and HS). Spearman correlation (95% confidence interval [CI]) between Ki67 LI and Recurrence Score result was examined. Recurrence Score groups were RS 0-25 and RS 26-100, as defined by TAILORx (Sparano N Engl J Med 2018).

Results: Of 295 patients (median age 63 y; median tumor size 2.5 cm; 66% grade 1), 76% had RS 0-25, and 24% had RS 26-100 (median RS 17; range RS 0-68). Of those with Ki67< 10%, 88% had RS 0-25. Of those with Ki67≥40%, 74% had RS 26-100. A weak correlation was found between Ki67 LI and Recurrence Score results (Spearman correlation 0.37; 95% CI 0.26 to 0.47).

Conclusions: Our findings demonstrated that Ki67 LI was rather weakly correlated with Recurrence Score results but did confirm that the two factors were independent in nature. Therefore, Ki67 LI and Recurrence Score results can by no means substitute for each other and both must be performed in the appropriate fashion in the management of patients.