[P2-08-01] Prospective trial of endocrine therapy alone in patients with estrogen receptor positive, HER2-negative, node-negative breast cancer: Results of the TAILORx low risk registry

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Background: The Trial Assigning Individualized Options for Treatment (TAILORx) is a prospective trial evaluating the role of endocrine therapy or chemoendocrine therapy in patients 18-75 years of age with estrogen receptor (ER)-positive, HER2-negative breast cancer, a primary tumor between 0.6-5.0 cm, and negative axillary nodes, a population for whom chemotherapy is typically recommended or least considered based on National Comprehensive Cancer Center Network (NCCN) guidelines.
Methods: The trial was designed to demonstrate non-inferiority of endocrine therapy compared with chemoendocrine therapy in the randomized group with an Oncotype DX Recurrence Score (RS) of 11-25. Patients with a low RS < 11 were assigned to endocrine therapy alone and with a high RS > 25 assigned to chemoendocrine therapy, and both groups were followed in a prospective registry. The definition of an intermediate RS differed in this trial (RS 11-25) from the original reports (RS 18-30) in order to reduce the risk of chemotherapy undertreatment in patients with a mid-range or low RS (Sparano & Paik. J Clin Oncol 2008; 26:721-728).
Results: The trial enrolled 10,273 patients between April 2006 and October 2010, of whom 6907 patients (67.2%) had a mid-range RS of 11-25, 1737 (16.9%) had a high RS > 25, and 1639 (15.9%) had a low RS of < 11. At the fourth planned interim analysis, the ECOG-ACRIN data monitoring committee recommended that the study continue as planned for the randomized group with a RS 11-25, and that the results be released to the investigators for the low risk group with a RS <11. The characteristics of the low risk registry population are as follows: age 50 or less (27%), 51-60 (35%), > 60 (39%); tumor size < 1 cm (8%), 1-2 cm (61%), > 2 cm (31%); histologic grade low (34%), intermediate (59%), high (7%); breast conservation (68%) or mastectomy (32%). Initial endocrine therapy included tamoxifen in 35%, aromatase inhibitors in 59%, ovarian function suppression in 3%, and unspecified therapy in 3%; 5 patients received adjuvant chemotherapy (1 of whom relapsed). Five-year rates (and 95% confidence intervals [CI]) for low RS group were 99.2% (98.5, 99.6%) for distant relapse free interval, 98.5% (97.7, 99.1%) for relapse-free interval, 93.7% (92.2, 94.9%) for invasive disease free survival, and 98.2% (97.3, 98.7%) for overall survival. Information regarding ER, PR, and HER2 RNA expression will be presented.
Conclusions: Despite meeting guidelines for recommending or at least considering adjuvant chemotherapy based on classical clinicopathologic features, the risk of recurrence was very low at 5 years in patients with ER-positive, HER2-negative, axillary node-negative breast cancer and a low RS of < 11 treated with endocrine therapy alone without chemotherapy.

Thursday, December 10, 2015 7:30 AM

Poster Session 2: Prognostic and Predictive Factors: Prognostic Factors -- Clinical Testing and Validation (7:30 AM-9:00 AM)