A study of the Recurrence Score by the 21-gene signature assay as a predictor of clinical response to neoadjuvant exemestane for 24 weeks in estrogen-receptor-positive breast cancer.

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Abstract Disclosures

Abstract:

Background: Exemestane (EXE) is a steroidal aromatase inhibitor, one of the key drugs for postmenopausal ER-positive breast cancer patients (pts). We have reported that 24 wks neoadjuvant treatment of EXE has shown attractive response with sufficient safety and tolerability from multicenter phase II trial (JFMC34-0601; Toi M, et al. Cancer Science, 2011). The additional translational investigations were performed to find biomarkers that might be recommended for individualizing treatment in the neoadjuvant setting. This exploratory study was conducted to investigate the clinical usefulness of the 21-gene signature (Oncotype DX) for prediction of response to neo-EXE therapy.
Methods: We tested whether the Recurrence Score (RS) by the 21-gene signature determined on core biopsy specimen at baseline would correlate with clinical objective response rate (ORR) in pts who were enrolled in the JFMC34-0601 trial. Postmenopausal pts over 55-yrs-old were eligible with confirmed Stage II or IIIA invasive breast cancer and ER-positive status. Results: Of 116 pts registered between 2006 and 2008, RS was obtained for 64 pts with adequate sufficient tissue. The median age and tumor size were 64 yrs (range, 56-77) and 27 mm (15-58). There were 47/15/2 pts for stage IIA/IIB/III and 2/50/12 pts for HER2-positive/negative/equivocal. The numbers of pts in the low, intermediate, or high RS groups were 32 (50%), 17 (27%), and 15 (23%), respectively. ORR to neo-EXE therapy was 59% (95%CI, 40–76%), 59% (33–82%), and 20% (4–48%) for pts in the low, intermediate, and high RS groups, respectively. There was a significant difference for ORR between the low and the high RS groups (P=0.015, Fisher exact test). In a multivariate logistic regression model, the continuous RS provided significant predictive power that was independent of age and tumor size (P=0.019, likelihood ratio test).

Conclusions: This is the first report that the 21-gene signature has value in predicting a response to neo-EXE therapy in postmenopausal pts with ER-positive breast cancer, and provides preliminary evidence for the clinical usefulness of the neoadjuvant treatment selection.