

P246 Risk assessment by St.Gallen 2013 recommendation and Oncotype DX[®]: results from the WSG PlanB trial

Poster Abstracts II

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Goals: In HR+, HER2⁻ early breast cancer (BC), the 2013 St. Gallen Consensus recommends adjuvant chemotherapy (CT) for patients with pN >2, recurrence score (RS) >25, G3, or high Ki-67/low PR. Here, we present early outcome data from PlanB for prospective evaluation of these different risk assessment tools.

Methods: The WSG-PlanB trial compares 6⁺TC vs. 4⁺EC plus Doc in pN+ or high risk N0 HER2⁻ BC defined by St. Gallen 2007 (pT >2, G2–3, age <35 years old, high uPA/PAI). After an early amendment (August, 2009), HR+ patients with pN0–1 and RS \geq 11 were selected to forgo CT, receiving only endocrine therapy. Luminal B (semiquantitative Ki-67 >20% or PR <20% or G3) subtype was centrally assessed by an independent trial pathologist. Aim of present analysis is to compare the adjuvant CT indication based on St. Gallen 2013 or RS.

Results: From April 2009 to December 2011, 3,198 patients were recruited; of these, 2,449 were randomized for the CT question. Median age was 56 years; 84.1% were HR+ (local pathology), 60.8% pN0. The central tumor bank population reported here included 3,071 cases. RS was available in n=2,568 (RS 0–11: 18%, 11–25: 60.4%, >25: 11.6%). In 348 patients (14.6% of pN0–1 patients after amendment), CT was omitted based on RS \geq 11. 37.1% of HR+ pN0–1 patients had luminal-A tumors. 96.4% of them had RS <25. Within the luminal-B (62.9%) subgroup, 70.1% had RS <25. After 35 months median follow-up, 3-year EFS in the no-CT group was 98.3%. In the central HR+ population, EFS was substantially shorter in patients with RS >25 than in others (3^y EFS: 92% vs. 98% in both RS 12–25 and RS 0–11; p<0.001). This prognostic impact was mostly attributable to luminal-B tumors. pN status, Ki-67, local and central grade, tumor size, and RS were univariate prognostic factors for EFS. In multivariate analysis, only central G3, pN status, and RS (fractionally ranked) remained significant predictors for poor EFS.

Conclusion: As shown for the first time by a prospective trial, patients with RS 0–11 treated by ET alone have an excellent 3^y EFS. Using the 2013 St. Gallen Criteria central review identified about 1/3 of CT candidates as low risk. Highest clinical utility of RS was observed in the luminal-B subgroup. The excellent outcome of patients with RS 12–25 receiving CT suggests potential CT overtreatment in this group. This issue is addressed by the ongoing WSG-ADAPT trial.

