

Tumor Cellularity and Infiltrating Lymphocytes (CelTIL) as a Survival Surrogate in HER2-Positive Breast Cancer

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In early-stage HER2-positive breast cancer, biomarkers that guide de-escalation and/or escalation of systemic therapy are needed. CelTIL score is a novel, combined biomarker based on stromal tumor-infiltrating lymphocytes and tumor cellularity and determined in tumor biopsies at week 2 of anti-HER2 therapy only. We evaluated the prognostic value of CelTIL in 196 patients with early-stage HER2-positive disease treated with standard trastuzumab-based chemotherapy in the NeoALTTO phase III trial. Using a pre-specified CelTIL cutoff, a better 5-year event-free survival and overall survival was observed between CelTIL-high and CelTIL-low score with a 76.4% (95% confidence interval [CI] = 68.0%-85.0%) versus 59.7% (95% CI = 50.0%-72.0%) (hazard ratio = 0.40; 95% CI = 0.17 to 0.94), and 86.4% (95% CI = 80.0%-94.0%) vs 73.5% (95% CI = 64.0%-84.0%) (hazard ratio = 0.43; 95% CI = 0.20 to 0.92), respectively. Statistical significance was maintained after adjusting for baseline TILs, hormone receptor status, pre-treatment tumor size and nodal status, type of surgery, treatment arm, and pathological complete response. Further studies to support CelTIL as an early read-out biomarker to help de-escalate/escalate systemic therapy in HER2-positive breast cancer seem warranted.

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