https://doi.org/10.29289/259453942025V35S1031

Grade 1 hormone receptor-positive early breast cancer: is Oncotype DX necessary?

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Introduction: The Oncotype DX (ODX) genomic risk score (RS) is a key tool for guiding adjuvant chemotherapy decisions in early-stage hormone receptor-positive and human epidermal growth factor receptor-type 2-negative (HR+/HER2-), breast cancer. Since some genes assessed in RS tests are linked to proliferation, its utility in low-proliferation tumors, such as histologic grade 1 (G1) or those with low Ki67-index, remains uncertain. **Objective:** This study aimed to evaluate ODX role in G1 tumors. **Methods:** GBECAM-0520, a multicentric real-world data study, assessed ODX's usefulness in G1 HR+/HER2- breast cancer. Conducted across nine Brazilian cancer centers (2009–2024), key endpoints included the prevalence of high genomic RS and invasive disease-free survival. **Results:** Among 1,059 HR+/HER2- breast cancer patients undergoing ODX, 194 had G1 tumors. The median age was 51 years (range 31–72), and 49% were pre-menopausal. Most had non-special type carcinoma (80%) and Ki67 <20% (76%). Tumor stages were 32% T1b, 44% T1c, and 14% T2, while nodal status was 75% N0, 9% N1mic, and 15% N1. Based on the Adjuvant! algorithm, 90% (n=174) had low clinical risk. ODX results showed 22% low, 71% intermediate, and 6% high RS. With a median 51-month follow-up, six patients recurred—five locoregionally and one distantly; one died without recurrence. All recurrences occurred in the intermediate RS group; no events were seen in the high-risk group. Recurrence rates were 3.4% for Ki67 <20% and 4.9% for Ki67 ≥20%. The estimated 5-year invasive disease-free survival rate was 98.4% (95% confidence interval 93.7–99.6). **Conclusion:** For G1 breast cancer with low clinical risk, ODX's utility and cost-effectiveness may be limited. Careful clinical risk assessment is crucial for optimizing genomic RS testing and resource allocation.

Keywords: breast neoplasms; genomics; adjuvant chemotherapy; neoplasm grading.