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Stage I human epidermal growth factor receptor-type 2-positive breast cancer: is systemic therapy required?

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Introduction: Recent SEER (USA Surveillance, Epidemiology, and End Results) data suggest that patients with tumors ≤1 cm achieve excellent outcomes regardless of chemotherapy use. **Objective:** This study aimed to evaluate the clinical characteristics, treatment patterns, and outcomes of patients with human epidermal growth factor receptor-type 2 positive (HER2+) stage I breast cancer. **Methods:** A cohort of stage I HER2+ breast cancer patients treated between 2008 and 2023 at a large cancer center in Brazil was assessed for progression-free survival based on anti-HER2 adjuvant therapy use and related factors via Cox regression. **Results:** A total of 115 patients with stage I HER2+ breast cancer were identified, with a median age of 55 years (range 22–80). Most tumors were pT1c (65.7%), while 14.9% were pT1mic/pT1a, and 19.2% were pT1b. Tumor grade distribution was 8.3% grade 1; 52.3% grade 2; and 39.4% grade 3. Additionally, 78.3% had high Ki67 (>20%), 65.8% were estrogen receptor positive, and 51.8% were progesterone receptor positive. Systemic therapy with chemotherapy plus trastuzumab (Ch+T) was administered to 93 patients (80.8%). No significant differences in baseline characteristics were observed between patients who received or did not receive Ch+T, except for tumor stage. Specifically, 27.7% of patients with pT1mic/pT1a, 72.7% with pT1b, and 94.7% with pT1c received Ch+T ($p<0.001$). After a median follow-up of 80 months, eight recurrences and five deaths (two unrelated to breast cancer) were recorded. Five new primary non-breast tumors were identified. The 7-year progression-free survival rate was 93.3% for patients who received Ch+T and 95.0% for those who did not (HR 2.15; 95% confidence interval [CI] 0.27–17.02, $p=0.467$). In Cox regression, no factors, including tumor stage, grade, Ki67 index, estrogen and progesterone receptors expression, and systemic treatment, were associated with recurrence risk. **Conclusion:** Patients with HER2+ stage I breast cancer had an excellent prognosis, with low recurrence rates. These findings align with SEER data, supporting de-escalation strategies. Larger studies are needed to confirm outcomes of subcentimetric tumors not receiving systemic therapy.

Keywords: breast neoplasms; ErbB-2 receptor.