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912 – Impact of delays in updating breast cancer brazilian clinical protocols and therapeutic guidelines on pathologic complete response

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Introduction: Pathologic complete response (pCR) after neoadjuvant chemotherapy is associated with improved outcomes in breast cancer. In the Brazilian Unified Health System, delays in updating the Clinical Protocols and Therapeutic Guidelines (PCDT) limit access to modern therapies. Trastuzumab is the only anti-human epidermal growth factor receptor 2 (HER2) therapy available in the neoadjuvant setting. Although incorporated in 2012, access remains uneven. The 2024 PCDT update included trastuzumab emtansine (T-DM1) for HER2+ patients with residual disease; however, dual HER2 blockade and pembrolizumab are still unavailable, potentially impacting pCR rates.

Methods: This cross-sectional study included 286 women who underwent surgery after neoadjuvant chemotherapy between 2018 and 2021. Tumors were classified by molecular subtype. Trastuzumab use and the number of doses were recorded in HER2+ patients. pCR was defined as the absence of invasive disease in the breast and axilla.

Results: Mean age was 51 years; 58% had stage III disease. Overall pCR rate was 22%. Higher rates were observed in HER2/hormone receptor (HR)– (48.8%), triple-negative (26.1%), and HER2/HR+ (25%) tumors, while HR+ tumors had 8.5% ($p < 0.05$). Among HER2+ patients, 63.3% received trastuzumab, but only 31.6% received ≥ 4 doses. pCR rates according to the number of trastuzumab doses were 56%, 50%, 25%, and 20% for ≥ 4 , 3, 2, and 1 doses, respectively. In HER2/HR– tumors, the difference in pCR rates between no trastuzumab and ≥ 4 doses was 45.3 percentage points. In 66.7% of cases, the time from request to first dose exceeded three months. After a median follow-up of 4.3 years, pCR was associated with lower rates of metastasis (11.1% vs. 36.3%) and no deaths; 22.4% of patients with residual disease died ($p < 0.001$).

Conclusion: pCR rates were lower than those reported in clinical trials, reflecting outdated regimens and inconsistent access to trastuzumab. Under the 2024 PCDT criteria, inadequate neoadjuvant therapy may limit eligibility for T-DM1, reinforcing disparities between policy and real-world care.

Ethics: Research Ethics Committee Approval (CAAE 76014923.2.0000.0047).

Keywords: breast neoplasms; neoadjuvant therapy; pathologic complete response; health services accessibility; Brazil.