The effect of endocrine responsiveness on high-risk breast cancer treated with dose-intensive chemotherapy: results of International Breast Cancer Study Group Trial 15-95 after prolonged follow-up


BACKGROUND: The role of adjuvant dose-intensive chemotherapy and its efficacy according to baseline features has not yet been established. PATIENTS AND METHODS: Three hundred and forty-four patients were randomized to receive seven courses of standard-dose chemotherapy (SD-CT) or three cycles of dose-intensive epirubicin and cyclophosphamide (epirubicin 200 mg/m(2) plus cyclophosphamide 4 mg/m(2) with filgrastim and progenitor cell support). All patients were assigned tamoxifen at the completion of chemotherapy. The primary end point was disease-free survival (DFS). This paper updates the results and explores patterns of recurrence according to predicting baseline features. RESULTS: At 8.3-years median follow-up, patients assigned DI-EC had a significantly better DFS compared with those assigned SD-CT [8-year DFS percent 47% and 37%, respectively, hazard ratio (HR) 0.76; 95% confidence interval 0.58-1.00; P = 0.05]. Only patients with estrogen receptor (ER)-positive disease benefited from the DI-EC (HR 0.61; 95% confidence interval 0.39, 0.95; P = 0.03). CONCLUSIONS: After prolonged follow-up, DI-EC significantly improved DFS, but the effect was observed only in patients with ER-positive disease, leading to the hypothesis that efficacy of DI-EC may relate to its endocrine effects. Further studies designed to confirm the importance of endocrine responsiveness in patients treated with dose-intensive chemotherapy are encouraged.