

Evaluation of the prognostic and predictive value of p53 and Bcl-2 in breast cancer patients participating in a randomized study with dose-dense sequential adjuvant chemotherapy.

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Abstract

PURPOSE:

To assess the prognostic and predictive significance of p53 and Bcl-2 protein expression in high risk patients with breast cancer treated with dose-dense sequential chemotherapy.

PATIENTS AND METHODS:

From June 1997 until November 2000, 595 patients were randomized to three cycles of epirubicin (E) 110 mg/m² followed by three cycles of paclitaxel (P) 250 mg/m² followed by three cycles of 'intensified' CMF (cyclophosphamide 840 mg/m², methotrexate 47 mg/m² and fluorouracil 840 mg/m²) or to four cycles of E, followed by four cycles of CMF. p53 and Bcl-2 expression was investigated by immunohistochemistry in 392 and 397 patients respectively.

RESULTS:

Positive expression of p53 was detected in 104 (26.5%) patients and was significantly associated with negative hormonal status, worse histologic grade, higher incidence of disease relapse and higher rate of death. p53 positive expression was a significant negative predictor of overall survival (OS) (P = 0.002) and disease-free survival (DFS) (P = 0.001). Negative expression of Bcl-2 was detected in 203 (51%) patients and was significantly associated with negative hormonal status. Multivariate analysis revealed that, positive p53 expression, higher number of positive nodes and worse tumor grade were related to significantly poorer OS and DFS.

CONCLUSIONS:

For both treatments, p53 positive expression was a significant negative prognostic factor for OS and DFS while Bcl-2 was not. No predictive ability of p53 status or Bcl-2 status for paclitaxel treatment was evident.