**A randomized study of epirubicin monotherapy every four or every two weeks in advanced breast cancer. A Hellenic Cooperative Oncology Group study.**

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**Source**

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**Abstract**

**PURPOSE:**

To evaluate the impact on the response rate in patients with advanced breast cancer (ABC) of the doubling of the dose intensity (DI) of epirubicin monotherapy.

**PATIENTS AND METHODS:**

From January 1991 until April 1996, 167 patients with ABC were randomized to receive epirubicin (110 mg/m2) either every four (81 patients, group A) or every two weeks (86 patients, group B). Filgrastim (5 micrograms/kg/daily) was administered prophylactically on days 2-12 of each cycle.

**RESULTS:**

The two groups were equally balanced in terms of major patient and tumor characteristics. Even though the median cumulative dose of epirubicin was identical in the two groups (651 mg/m2), the median DI of epirubicin was doubled in group B (27.2 vs. 52.9 mg/m2/wk, respectively). The complete response (CR) rate was significantly increased in group B (5%, 95% CI: 0.16%-9.84% vs. 17%, 95% CI: 8.9%-25.08%, P = 0.011), although overall response rates were similar (49% vs. 53%, P = 0.5957). Also, there was no significant difference in the incidence of grade 3-4 toxicity between the two groups. After a median follow-up of 25 months (range, 0.43-43.3+) no significant difference was observed in the duration of response (median, 10 months vs. 8.5 months, P = 0.5130), time to progression (median, 7.2 months vs. 7.4 months, P = 0.2970) or survival (median, 14.6 months vs. 14.9 months, P = 0.4483). Logistic regression analysis showed that performance status was a significant variable for response (P = 0.0068) and multivariate analysis using the Cox proportional hazards model revealed that performance status was significant for survival (P = 0.0049), while the presence of multiple metastases (P = 0.0020) was significant for time to progression.

**CONCLUSION:**

Doubling the planned DI of epirubicin monotherapy significantly increases the CR rate but has no influence on time to progression or survival in patients with ABC.