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Docetaxel and gemcitabine in anthracycline-resistant advanced breast cancer: a Hellenic Cooperative Oncology Group Phase II study.

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Source

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Abstract

A phase II study was conducted to evaluate the activity and toxicity profile of the combination of docetaxel and gemcitabine in anthracycline-resistant advanced breast cancer (ABC). Thirty-nine eligible patients with a median performance status of 1 (range, 0-2) were enrolled in the study. Treatment consisted of docetaxel 75 mg/m2 in a 1-hr infusion on day 1 preceded by gemcitabine 1000 mg/m2 over 30 min on days 1 and 8. One hundred eighty-one treatment cycles were administered, 113 (62.4%) of them at full dose. Relative dose intensity of gemcitabine and of docetaxel was 0.73 and 0.85, respectively. More common grade 3-4 toxicities included neutropenia (49%), anemia (10%), fatigue (10%), nausea/vomiting (8%), and alopecia (77%). Seven patients were hospitalized for febrile neutropenia. Granulocyte colony-stimulating factor (G-CSF) administration was required in 90% of patients. Overall, 14 patients (36%) responded, 3 (7.5%) of them completely. Median duration of response was 10.3 months (range, 4.6-17.5+). Median time to progression was 7 months (range, 0.2-17.5+) and median survival 12.7 months (range, 2-20.5+). In conclusion, the combination of docetaxel and gemcitabine, as used in the present study, has moderate activity in anthracycline-resistant ABC. Future studies should incorporate prophylactic administration of G-CSF to reduce the incidence of febrile neutropenia and maintain dose intensity.