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First line combination chemotherapy with docetaxel and vinorelbine in advanced breast cancer. A phase II study.

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Source

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Abstract

We evaluated the efficacy and tolerance of the combination of docetaxel and vinorelbine as first line treatment in metastatic breast cancer (MBC). These agents have different mechanisms of action and both are active in advanced breast cancer. Thirty-nine chemotherapy-naive for metastatic disease patients were treated on an out-patient basis with vinorelbine 20 mg/m2 i.v. on days 1 and 8 and docetaxel 85 mg/m2 i.v. on day 8, every 3 weeks. Twenty-one (53.8%) patients had locoregional disease, 30 (76.9%) had distant metastases and 20 (51.3%) had visceral metastases. The intent-to-treat objective response rate (RR) was 48.75% (19 out of 39 patients; 95% confidence interval (CI), 32.4% to 65.2%). Four patients (10.25%) achieved a complete response (CR) (95% CI, 2.9% to 24.2%) and 15 (38.5%) a partial response (PR) (95% CI, 23.4% to 55.4%). The median duration of response was 4 months, the median time to progression (TTP) was 6 months and the median survival-time was 11.3 months. Grade 3 and/or 4 (3/4) anemia and thrombocytopenia occurred in 7.7% and 5.1% of patients, respectively. Twelve (30.7%) patients developed grade 3/4 neutropenia and 7 (17.9 %) were complicated with fever. Grade 3/4 diarrhea, nausea-vomiting, fatigue and constipation were not a problem. Alopecia was universal. Grade 3/4 neurotoxicity was evident in 2.6% of patients. None of the patients developed allergic reaction or fluid retention. There was one treatment-related death due to grade 4 neutropenia and sepsis. CONCLUSION: This combination of docetaxel and vinorelbine, a non-anthracycline-containing regimen, is a moderately effective regimen for the treatment of chemotherapy-naive breast cancer patients with metastases, causing only mild to moderate toxicity.