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Dose-dense sequential adjuvant chemotherapy with epirubicin, paclitaxel and CMF in high-risk breast cancer.

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Source

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Abstract

Dose-dense sequential chemotherapy appears to be a promising approach in the management of patients with operable breast cancer. We evaluated the tolerability of such a novel chemotherapeutic regimen in high-risk patients. From February 1995 until September 1997, 49 women with histologically confirmed breast cancer and > or =10 involved axillary nodes were treated postoperatively with three cycles of epirubicin (110 mg/m(2)) followed by three cycles of paclitaxel (250 mg/m(2) in a 3-hour infusion) followed by three cycles of 'intensified' CMF (cyclophosphamide 840 mg/m(2), methotrexate 57 mg/m(2), fluorouracil 840 mg/m(2); E-T-CMF). All cycles were repeated every 2 weeks with G-CSF support. Ovarian ablation with monthly injections of triptorelin for 1 year was performed in premenopausal patients and tamoxifen was prescribed for 5 years to all women with positive receptor status after the completion of chemotherapy. A total of 456 cycles of chemotherapy were administered, 363 (80%) of them at full dose. Forty-seven (96%) patients received all 9 cycles of chemotherapy. Relative dose intensity of epirubicin was 0.98, of paclitaxel 0.97, of cyclophosphamide 0.99, of methotrexate 0.98 and of fluorouracil 0.99. Grade 3--4 toxicities included anemia (8%), leukopenia (8%), peripheral neuropathy (6%), neutropenia (4%), thrombocytopenia (4%), stomatitis (2%), diarrhea (2%), fatigue (2%) and hypersensitivity reaction (2%). Febrile neutropenia occurred in 2 patients. Alopecia was universal. After a median follow-up of 3 years, 11 women (22%) relapsed and 4 (8%) died. The 3-year actuarial disease-free survival rate was 72% and the 3-year overall survival rate 90%. The E-T-CMF regimen is well tolerated, as adjuvant treatment, in patients with operable breast cancer with promising activity and deserves further evaluation in phase III studies.