CHEMOTHERAPY

Metastatic breast cancer—optimal front-line therapy

The optimal first-line chemotherapy regimen for patients with metastatic breast cancer remains to be defined. Researchers from Japan conducted a randomized, multicenter, phase III, clinical trial to compare doxorubicin plus cyclophosphamide, single-agent docetaxel and an alternating regimen of doxorubicin plus cyclophosphamide and docetaxel as first-line therapy in patients with metastatic breast cancer. “[The] results demonstrate that single-agent docetaxel is the most promising candidate for first-line chemotherapy”, says N. Katsumata, lead author of the study.

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In total, 441 patients with metastatic breast cancer who were resistant to endocrine therapy were randomly assigned to receive either six cycles of alternating doxorubicin plus cyclophosphamide and docetaxel (40 mg/m² and 500 mg/m², respectively, *n* = 146), docetaxel (60 mg/m², *n* = 147), or alternating doxorubicin plus cyclophosphamide and docetaxel (three cycles each, *n* = 148), every 3 weeks. Patients’ characteristics, such as age, performance status, disease status, estrogen receptor status, previous treatment and metastatic sites, were well balanced among the treatment groups.

Response rates of 30%, 41% and 35% were observed for patients treated with doxorubicin plus cyclophosphamide, docetaxel, and the alternating doxorubicin plus cyclophosphamide and docetaxel regimen, respectively. The median time to treatment failure, the primary end point of the study, and median overall survival were not significantly different for patients in the three treatment groups. The

researchers, however, found a trend toward better response and overall survival for patients treated with docetaxel compared with doxorubicin plus cyclophosphamide. Patients were allowed to cross over from the doxorubicin plus cyclophosphamide arm to the docetaxel arm and vice versa if treatment failure or disease progression occurred during or after treatment.

Toxic effects such as grade 3 or 4 leukopenia and neutropenia occurred in the docetaxel group and the alternating anthracycline and docetaxel group, whereas nonhematologic toxic effects were mild in all groups. Grade 3 or 4 nausea occurred more frequently in patients who received the combination regimens than those who received docetaxel alone.

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Original article Katsumata, N. *et al.* Phase III trial of doxorubicin plus cyclophosphamide (AC), docetaxel, and alternating AC and docetaxel, as front-line chemotherapy for metastatic breast cancer: Japan Clinical Oncology Group trial (JCOG9802). *Ann. Oncol.* **20**, 1210–1215 (2009).