BREAST CANCER FEWER THERAPY CYCLES IS BETTER

For patients with early stage low-risk breast cancer, the optimum duration of adjuvant therapy remains to be defined. Previous trials have indicated that four cycles of anthracycline-based treatment was comparable to six cycles of cyclophosphamide, methotrexate and 5-fluorouracil. However, these trials never tested four cycles versus six cycles of chemotherapy using identical schedules and dose per cycle of treatment. Now, a large study, designed to improve survival and reduce toxicity for women with early stage low-risk disease, has confirmed that six cycles of doxorubicin and cyclophosphamide (AC) or paclitaxel therapy is not superior to four cycles of treatment. Thus, women can now be spared the toxicity associated with the additional two cycles of chemotherapy.

Lawrence Shulman and colleagues conducted a randomized, phase III, 2×2 factorial trial to address two questions: first, whether six treatment cycles is better than four; and second, whether singleagent paclitaxel is equivalent to AC. A total of 3,171 women were enrolled, and the median follow-up period was 5.3 years. After adjusting for tumour size, number of positive nodes, hormonal and menopausal status, Shulman's team demonstrated that six cycles of AC or paclitaxel were no better than four cycles at improving relapsefree and overall survival. Haematological toxicity was the most noted adverse event for the AC regimen and neuropathy was more common with paclitaxel. As expected, toxicities were more common with six treatment cycles than four.

Shulman summarizes the key results, "our study demonstrates that there is no survival advantage to receiving six cycles of chemotherapy, as compared to four, and toxicity is lower in women receiving only four cycles." Data from this trial to address whether paclitaxel is less toxic than AC are still pending, but as Shulman notes, "it will be important to obtain these data as this will help us define the optimal chemotherapy for these patients, as we know that four cycles of chemotherapy is sufficient. Future studies assessing alternative chemotherapy should be designed around a four-cycle structure."

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Original article Shulman, L. N. *et al.* Six cycles of doxorubicin and cyclophosphamide or paclitaxel are not superior to four cycles as adjuvant chemotherapy for breast cancer in women with zero to three positive axillary nodes: Cancer and Leukemia Group B 40101. *J. Clin. Oncol.* doi:10.1200/JC0.2011.40.6405