E11. Update of the worldwide evidence on the adjuvant treatment of breast cancer

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In early breast cancer, all clinically apparent disease can be removed surgically. Following such surgery, adjuvant systemic treatments involving various cytotoxic, hormonal or other therapies may be considered. Before the 1980s, despite many trials of different adjuvant therapies, there was substantial uncertainty as to the net effects of such treatments, particularly on long-term survival, because none of the trials individually was large enough to provide reliable answers. In 1983–1985, the Clinical Trial Service Unit (CTSU) established the Early Breast Cancer Trialists' Collaborative Group (EBCTCG) to bring together updated data on each woman randomised into all trials of the treatment of early breast cancer, in an "overview", or series of systematic reviews. These meta-analyses provide definitive evidence on the long-term effects of widely practicable adjuvant treatments on recurrence, second cancer and mortality, which could not be obtained by other means. The fourth cycle of data collection (involving 200,000 women in over 300 randomised trials, done by 250 trial groups) was presented to the EBCTCG for discussion in September 2000. Analyses were available for 10,000 women who were randomised in trials directly comparing different types of surgery; 10,000 in trials of ovarian ablation or suppression; 20,000 in trials of radiotherapy; 50,000 in trials of polychemotherapy (including trials of polychemotherapy versus control and direct comparisons of different polychemotherapy regimens); and 80,000 in trials of tamoxifen (50,000 in trials of tamoxifen versus control and 30,000 in trials of different durations of tamoxifen). These results underlay the November 2000 United States (US) National Institute of Health (NIH) Consensus Development Conference recommendation that (i) a few courses of anthracycline-based chemotherapy (e.g. doxorubicin, cyclophosphamide (AC), 5-fluorouracil, doxorubicin, cyclophosphamide (FAC), etc) is standard adjuvant chemotherapy for women aged under 70 years (unless they have a very small primary and no evidence of nodal involvement); (ii) 5 years of tamoxifen is standard adjuvant hormonal therapy for all women with an oestrogen receptor (ER)+, or ER untested, primary, irrespective of age, tumour size or nodal involvement (and irrespective of what other therapies have been given); and (iii) high priority should be given to comparisons of 5 years of adjuvant tamoxifen versus longer (e.g. 10 years of tamoxifen: the aim of such trials would be to discover whether one decade of hormonal treatment provides important protection against recurrence not only in the first, but also in the second decade after diagnosis).