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Randomized adjuvant trial to evaluate the addition of tamoxifen and PSK to chemotherapy in patients with primary breast cancer. 5-Year results from the Nishi-Nippon Group of the Adjuvant Chemoendocrine Therapy for Breast Cancer Organization.

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Abstract

BACKGROUND: A randomized adjuvant trial was conducted from October 1982 to January 1985 to evaluate the addition of tamoxifen (TAM) to combination chemotherapy with perioperative mitomycin C (MMC) and ftorafur (FT) for patients with estrogen receptor (ER)-positive tumors and the addition of PSK, a biologic response modifier, to MMC+FT chemotherapy for patients with ER-negative tumors in operable Stage IIA, IIB, and IIIA cancer. The doses used were 20 mg of oral TAM daily, 600 mg of oral FT daily, and 3 g of oral PSK daily for 2 years. Intravenous MMC (13 mg/m2) was given on the day of operation. METHODS: A total of 967 patients were entered and randomized by stratification based on ER status and staging (1978 International Union Against Cancer [UICC] criteria at the time of trial execution). Of 967 patients, 914 (94.5%) were evaluable. At 5-year follow-up, significant prolonged overall survival (OS) and relapse-free survival (RFS) times were seen with the addition of TAM in patients with ER-positive and Stage IIIA T3N0 cancer (1987 UICC-American Joint Committee on Cancer [AJCC] criteria); however, no significant survival benefit from TAM was seen in patients with ER-positive and Stage IIA T2N1 cancer. There was no significant difference between regimens, with or without PSK, in patients with ER-negative disease. RESULTS: Results of subset analyses suggested a benefit from TAM in postmenopausal patients with ER-positive and Stage IIA T2N1 cancer and a benefit from PSK in patients with node-negative, ER-negative, and Stage IIA T2N1 cancer. CONCLUSIONS: The 5-year results of the current trial showed a survival advantage by the addition of TAM to chemotherapy in patients with ER-positive and Stage IIIA T3N0 cancer.

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