Eur J Cancer, Vol. 28A, No. 12, p. 2083, 1992.
Printed in Great Britain
0964–1947/92 $5.00 + 0.00
Pergamon Press Ltd

Letters

Adjuvant Tamoxifen in Postmenopausal Patients with Breast Cancer and Negative Axillary Lymph Nodes

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ADJUVANT TREATMENT with tamoxifen (10 mg tamoxifen twice daily for 1 year) has been investigated in a prospective randomised study. Between 1980 and 1985, 98 postmenopausal patients (age ≥ 50 years) with primary breast cancer and negative axillary lymph nodes were recruited. After modified radical mastectomy and radical axillary lymph node dissection, patients were randomised in two groups, one to receive 20 mg tamoxifen per day (n = 48), irrespective of the hormone receptor status (see below), and the control group with no postoperative adjuvant treatment (n = 50).

All relevant prognostic factors such as grading, tumour stage, postoperative radiotherapy, oestrogen and progesterone levels and age were equally distributed between treated and untreated women ($P > 0.1$). Likewise, oestrogen receptor (ER) levels were well-balanced between the two groups. 24 patients and 23 controls were hormone receptor positive (ER and/or progesterone receptor ≥ 10 fmol/mg), 15 patients and 18 controls were receptor negative and receptor levels were unknown in the rest of the patients (9 treated and 9 untreated women).

Survival probabilities from the date of primary surgery were calculated by the Kaplan–Meier method. Differences between groups were tested according to Mantel. The test of statistical significance for contingency tables was based on the usual chi-square value comparing observed and expected numbers of events.

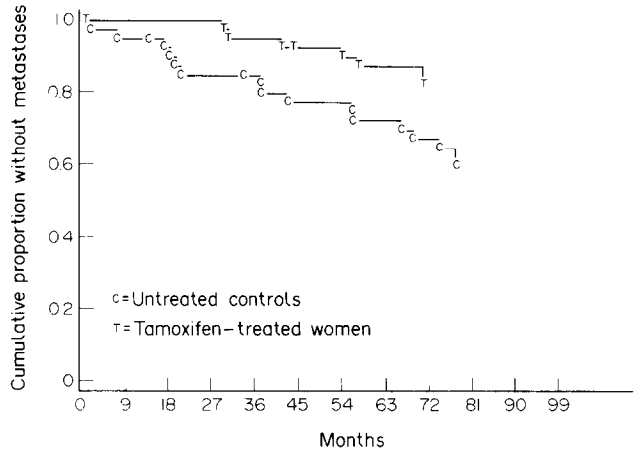

Fig. 1. Relapse-free survival of postmenopausal patients with breast cancer without axillary lymph node involvement: tamoxifen vs. no adjuvant therapy.

The results 6 years after the end of randomisation show a significantly lower incidence of metastases for the patients treated with tamoxifen: only 7 (7.2%) of 48 tamoxifen-treated patients had a recurrence of breast cancer, whereas 17 (17.5%) of the untreated control group had relapsed (P = 0.02).

The difference in duration of relapse-free survival was also significant, when the probability was calculated for a time period of 8 years, when 16.9% of the tamoxifen-treated patients had recurrence of disease, compared with 39% of the controls (P = 0.03) (Fig. 1). For a final survival analysis, a longer follow-up period will be necessary, although after 8 years survival probability was 95.4% for tamoxifen-treated women and 70.2% in the non-treated control group, thus presenting with an only borderline significance (P = 0.054).

We conclude that adjuvant treatment with 20 mg tamoxifen daily after surgery for postmenopausal patients with primary breast cancer and negative axillary lymph nodes led to a significant improvement in the process of disease. The duration of relapse-free survival was significantly longer and the incidence of tumour relapses was significantly lower.

These results further extend the positive data on the administration of tamoxifen in patients with lymph node-negative breast cancer [1, 2], in that its effectiveness was demonstrated over a very prolonged period of 6–11 years.

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Received 13 May 1992; accepted 26 May 1992.

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