Breast-conserving surgery plus radiation therapy was as effective as mastectomy

Objective
To compare the effectiveness of breast-conserving surgery plus radiation therapy with that of modified radical mastectomy in patients with early-stage breast cancer.

Design
Randomised controlled trial with median 10-year follow-up.

Setting
U.S. National Cancer Institute.

Patients
247 women (median age 50 y) with stage I or II invasive carcinoma of the breast were enrolled. Exclusion criteria were previous cancer, metastasis, multiple invasive lesions, concurrent or previous cancer in the contralateral breast, Paget disease, pregnancy, or lactation. 237 patients (96%) were randomly assigned, and follow-up was complete for 234 patients.

Intervention
Patients were stratified by age (< 50 y vs ≥ 50 y) and nodal status (positive vs negative) and assigned to Patey modified radical mastectomy with complete axillary dissection (n = 116) or to breast conservation therapy that included excision of all gross tumour, complete axillary dissection, and radiation therapy (4500 to 5040 cGy for 5 weeks) (n = 121). Patients with positive nodes received adjuvant chemotherapy with doxorubicin, 30 to 40 mg/m² on day 1, and cyclophosphamide, 150 to 200 mg/m² on days 3 to 6 every 4 weeks for 1 year. For the last 2 years of enrollment, postmenopausal women with positive nodes also received tamoxifen, 20 mg 2 times/d for 5 years.

Main Outcome Measures
Overall survival, disease-free survival, and local or regional recurrence.

Main Results
At 10 years, patients who had mastectomy or received breast conservation therapy did not differ for overall survival (75% vs 77%, P = 0.89) or for disease-free survival (69% vs 72%, P = 0.93). Local or regional recurrence occurred in 10 patients (9%) who had mastectomy and in 20 patients (17%) who received breast conservation therapy. After recurrences that were successfully treated by mastectomy were censored from the analysis, the rate of local or regional recurrence was 9% for patients in the mastectomy group and 4% for patients in the breast conservation group (P = 0.16). Patient age did not affect outcomes.

Conclusion
Radical mastectomy and breast-conserving surgery plus radiation therapy had similar overall survival and disease-free survival rates in patients with early-stage breast cancer.

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Commentary
The results from this single-institution trial by Jacobson and colleagues are consistent with those of earlier randomised studies showing that overall survival of patients with operable breast cancer is similar whether local treatment is mastectomy or breast conservation therapy. The rate of local recurrence confined to the breast in patients treated by breast conservation was 18% at 10 years. This is higher than the rate in patients assigned to wide local excision and radiotherapy in the National Surgical Adjuvant Breast Project B-06 trial (12% at 9 years) (1) and is near the upper end of the range (0% to 21%) of studies reported in the literature (2, 3). This may be because of the inclusion of larger tumours (up to 5 cm) and patients who had positive histologic margins. The cosmetic implications of these larger excisions and reoperations and the overall quality of life of patients is not well studied, nor were they included in this investigation.

Some comfort can be derived from the fact that these data confirm the safety of breast-conserving surgery plus radiation where long-term survival is concerned. Better information about cosmetic function and quality of life is required to aid in the appropriate selection of therapy in the individual patient.

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References