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## TWENTY-YEAR FOLLOW-UP OF A RANDOMIZED STUDY COMPARING BREAST-CONSERVING SURGERY WITH RADICAL MASTECTOMY FOR EARLY BREAST CANCER

UMBERTO VERONESI, M.D., NATALE CASCINELLI, M.D., LUIGI MARIANI, M.D., MARCO GRECO, M.D.,  
ROBERTO SACCOZZI, M.D., ALBERTO LUINI, M.D., MARISEL AGUILAR, M.D., AND ETTORE MARUBINI, PH.D.

### ABSTRACT

**Background** We conducted 20 years of follow-up of women enrolled in a randomized trial to compare the efficacy of radical (Halsted) mastectomy with that of breast-conserving surgery.

**Methods** From 1973 to 1980, 701 women with breast cancers measuring no more than 2 cm in diameter were randomly assigned to undergo radical mastectomy (349 patients) or breast-conserving surgery (quadrantectomy) followed by radiotherapy to the ipsilateral mammary tissue (352 patients). After 1976, patients in both groups who had positive axillary nodes also received adjuvant chemotherapy with cyclophosphamide, methotrexate, and fluorouracil.

**Results** Thirty women in the group that underwent breast-conserving therapy had a recurrence of tumor in the same breast, whereas eight women in the radical-mastectomy group had local recurrences ( $P < 0.001$ ). The crude cumulative incidence of these events was 8.8 percent and 2.3 percent, respectively, after 20 years. In contrast, there was no significant difference between the two groups in the rates of contralateral-breast carcinomas, distant metastases, or second primary cancers. After a median follow-up of 20 years, the rate of death from all causes was 41.7 percent in the group that underwent breast-conserving surgery and 41.2 percent in the radical-mastectomy group ( $P = 1.0$ ). The respective rates of death from breast cancer were 26.1 percent and 24.3 percent ( $P = 0.8$ ).

**Conclusions** The long-term survival rate among women who undergo breast-conserving surgery is the same as that among women who undergo radical mastectomy. Breast-conserving surgery is therefore the treatment of choice for women with relatively small breast cancers. (N Engl J Med 2002;347:1227-32.)

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**T**HE radical mastectomy introduced by Halsted<sup>1</sup> was the treatment of choice for breast cancer of any size or type, regardless of the patient's age, for 80 years. Apart from a few modifications, such as enlarging the extent of the dissection to include the internal mammary nodes or reducing it to spare the pectoralis muscles, the Halsted mastectomy was performed as originally described throughout this period. The possibility of attempting a surgical procedure that would conserve the breast was not widely considered during those years.<sup>2,3</sup>

In 1969, a randomized study to compare radical mastectomy with breast-conserving surgery, which was termed "quadrantectomy," was approved by the World Health Organization Committee of Investigators for Evaluation of Methods of Diagnosis and Treatment of Breast Cancer.<sup>4</sup> The recruitment of patients began at the Milan Cancer Institute in 1973, after the new procedure was standardized, and preliminary data showing that survival rates were equal after radical and breast-conserving surgery were published in 1977<sup>5</sup> and 1981.<sup>6</sup>

The main criticism of the data was that they were too preliminary; patients with small breast cancers must be followed for a very long time, even decades, to ensure that the evaluation of the efficacy of any new treatment is accurate. We carefully monitored the 701 women in the trial for up to 29 years, and we now report the results.

### METHODS

#### Study Design

Enrollment in the trial began in 1973 and ended in May 1980 after the recruitment of 701 patients who had breast cancers with

From the Department of Senology, European Institute of Oncology (U.V., A.L., M.A.); the Departments of Senology (N.C., M.G., R.S.) and Biometrics (L.M.), Istituto Nazionale per lo Studio e la Cura dei Tumori; and the Institute of Medical Statistics and Biometry, Università degli Studi (E.M.) — all in Milan, Italy. Address reprint requests to Dr. Veronesi at the European Institute of Oncology, 435 Via G. Ripamonti, I-20141 Milan, Italy, or at [umberto.veronesi@ieo.it](mailto:umberto.veronesi@ieo.it).

