

Special Communication from the National Cancer Institute
**Survival After Breast-Sparing
 Surgery Versus Mastectomy**

On Oct. 14, the National Cancer Institute made the following summary of a meta-analysis of survival after breast-sparing surgery versus mastectomy available on PDQ, CancerFax, and Cancer Net computer information services.

To obtain a copy of this summary, including the chart, from CancerFax, use the handset on the fax machine to dial 1-800-624-2511 and after the voice prompt, request document number

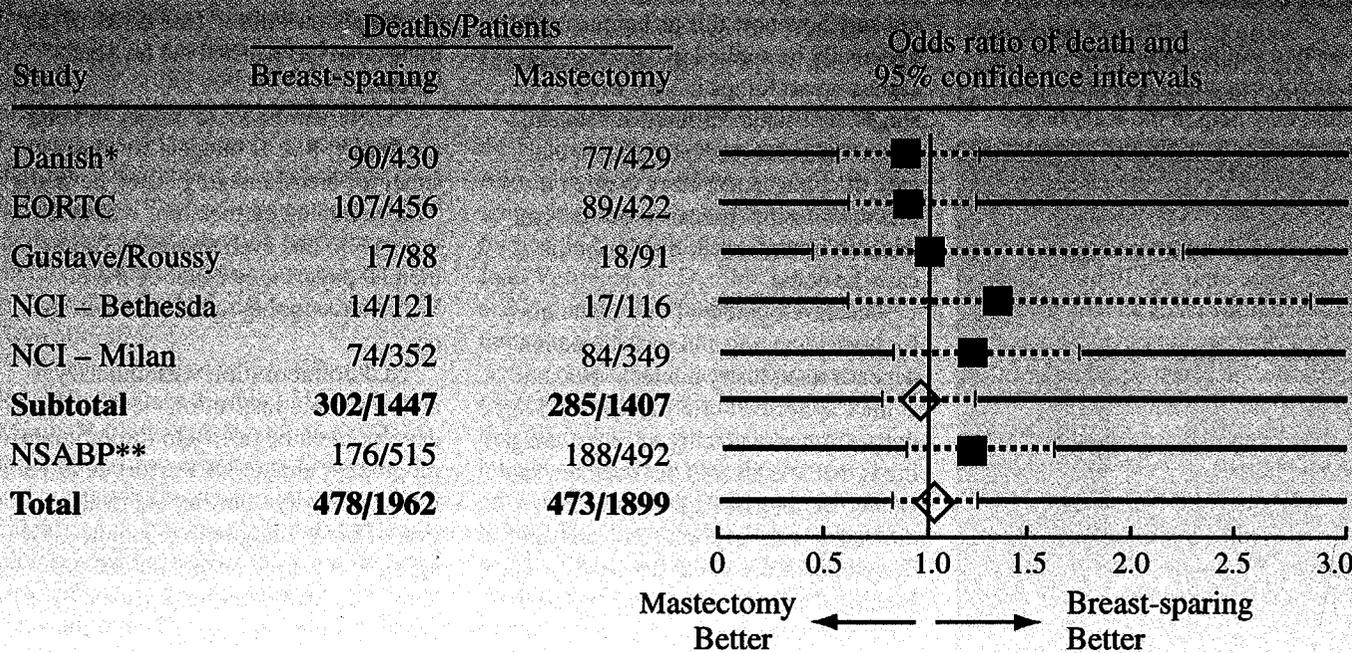
400020. The summary is reproduced here in its entirety.

The 1990 National Institutes of Health Consensus Development Conference on the Treatment of Early Stage Breast Cancer concluded that "Breast conservation treatment is an appropriate method of primary therapy for the majority of women with stage I and II breast cancer and is preferable because it provides survival equivalent to total

mastectomy and axillary dissection while preserving the breast."

The extensive review of the existing data that led the panelists to this conclusion in 1990 depended heavily on the National Surgical Adjuvant Breast and Bowel Project B-06 trial, the largest randomized test of mastectomy versus breast-sparing procedures. The submission of fraudulent data by one investigator in the B-06 trial created a need to validate the Consensus Conference conclusions. Fortunately, however, these conclusions did not depend entirely on the results of the B-06 trial alone. There have been five other randomized trials reported in the scientific literature that also support this con-

Breast-sparing Surgery vs. Mastectomy: Effect on Overall Survival



*Number of deaths estimated from survival rate.

**St. Luc Hospital data excluded (J Natl Cancer Inst 86:487-489, 1994).

clusion. In order to further evaluate these different therapeutic options, the authors performed a literature review of these trials and used this information to conduct a meta-analysis.

The five published studies, excluding B-06, include trials from the following organizations:

- (1) Danish Breast Cancer Group (*Monogr J Natl Cancer Inst* 11:19-25, 1992);
- (2) European Organization for Research on Treatment for Cancer (*Monogr J Natl Cancer Inst* 11:15-18, 1992);
- (3) Gustave-Roussy (*Radiother Oncol* 14:177-184, 1989);
- (4) National Cancer Institute-Bethesda (*Monogr J Natl Cancer Inst* 11:27-32, 1992), and
- (5) National Cancer Institute-Milan (*Eur J Cancer* 6:668-670, 1990).

These five trials have a total of 1,447 patients randomized to conservative surgery and breast irradiation versus 1,407 patients randomized to mastectomy (see table on previous page). The results of this meta-analysis demonstrate that, without the B-06 trial, both types of treatment yield equivalent results in terms of overall survival.

Odds Ratio

The odds ratio of comparing the likelihood of death for patients who received mastectomy compared to patients who received breast-sparing surgery is 0.964, which approaches equivalent results, with a 95% confidence interval of 0.804 to 1.157. Thus, even without the B-06 trial, there is substantial evidence that breast-sparing procedures and mastectomy are comparable.

If the conservative surgery and breast irradiation arm (minus patients treated at St. Luc Hospital) and the mastectomy arm (minus patients treated at St. Luc Hospital) from the NSABP

B-06 trial are included in the analysis, then there are a total of 1,962 patients treated with conservative surgery and breast irradiation versus 1,899 patients treated with mastectomy. The addition of the B-06 patients does not change the overall results, although the statistical power of the conclusion are strengthened. The odds ratio of death comparing mastectomy to breast-sparing surgery is 1.035, which is still nearly equivalent, with a 95% confidence interval of 0.892 to 1.200.

Whenever a trial is designed to prove equivalence between two treatment options, the sample size should be large enough to ensure the critical difference is outside the 95% confidence interval. However, the use of meta-analysis to combine results from similar trials does increase the sample size and allow us to infer that, even in the worst-case scenario, survival after mastectomy cannot be more than 11% better than that seen with breast conservation. This tight confidence interval makes it unlikely that meaningful differences exist between breast-sparing procedures and mastectomy.

— Jeffrey Abrams, M.D., Timothy Chen, Ph.D., and Ruthann Giusti, M.D., from NCI's Division of Cancer Treatment.

In an effort to further educate patients and review persisting questions concerning the treatment of early stage breast cancer with the medical and lay communities, NCI scheduled a workshop for Nov. 15, entitled, "An Appraisal of Clinical Research for the Treatment of Early Breast Cancer." As part of the workshop, a forum for both medical care providers and concerned members of the lay community, a re-analysis of the B-06 trial was presented using only cases that have undergone extensive re-audit by NCI staff.

More and Stiffer Mammography Clinic Regulations On the Way

Now that mammography clinic staff have dusted themselves off from meeting the Food and Drug Administration's Oct. 1 deadline to comply with the Mammography Quality Standards Act, they may have to gear up for even more regulatory changes as soon as 1995.

In an attempt to reach the 44% of women age 50 or over who do not get mammograms — and to improve mammography quality overall — the U.S. Department of Health and Human Services announced its clinical practice guideline on mammography last month.

Improving Standards

Coming on the heels of the MQSA deadline, the timing of the announcement emphasized the cooperation of several government agencies in improving mammography standards. Food and Drug Administration Commissioner David A. Kessler, M.D., J.D., said FDA will use the clinical guideline for its final set of clinic certification regulations, to be issued for public commentary in 1995.

The DHHS clinical practice guideline, "Quality Determinants of Mammography," which clinics follow voluntarily, includes aspects that FDA could regulate, such as x-ray equipment specifications, as well as intangible aspects outside FDA's purview, such as sensitivity in communicating mammogram results.