Conservative Treatment Versus Mastectomy in Early Breast Cancer: Patterns of Failure With 15 Years of Follow-Up Data

By Rodrigo Arriagada, Monique G. Lé, France Rochard, and Geneviève Contesso for the Institut Gustave-Roussy Breast Cancer Group

**Purposes:** A randomized trial was conducted to compare tumorectomy and breast irradiation with modified radical mastectomy. We have analyzed the patterns of failure in each arm of the trial and the prognostic factors that have an independent effect on treatment failures and overall survival.

**Patients and Methods:** The trial included 179 patients with breast cancer of up to 20 mm in diameter at macroscopic examination. Eighty-eight patients had conservative management and 91 a mastectomy. All patients had axillary dissection with frozen-section examination. For patients with positive axillary nodes (N+), a second randomization was performed: lymph node irradiation versus no further regional treatment. Patterns of failure were determined by a competing-risk approach and multivariate analysis. A prognostic score was determined by multivariate analysis.

During the last two decades, there has been increasing interest in nonmutilating treatment for women with early breast cancer. In addition to many uncontrolled series, six randomized trials have been published that compared limited surgery and radiotherapy with mastectomy. In all but one of these, no differences were found in the overall and relapse-free survival between the two treatment options.

One of the trials was conducted at the Institut Gustave-Roussy (IGR). The 5- and 10-year results were published in 1984 and 1989. We report here the long-term results, with a minimum follow-up time of 14 years for each patient. Patterns of failure were determined according to a competing-risk approach, which does not assume independence between analyzed events. Prognostic factors for survival and treatment failures were analyzed by a multivariate model.

**Results:** Overall survival, distant metastasis, contralateral breast cancer, new primary malignancy, and locoregional recurrence rates were not significantly different between the two surgical groups, or between lymph node irradiation groups. Most recurrences appeared during the first 10 years. Three distinct prognostic groups were determined taking into account age, tumor size, histologic grading, and number of positive axillary nodes.

**Conclusion:** Long-term results support conservative treatment with limited surgery and systematic breast irradiation as a safe procedure for the management of small breast cancers. Four easily obtainable clinical and histologic factors may be combined in a prognostic score that is highly predictive of overall and event-free survival.


**Trial Design**

The study design has been previously described. Briefly, between October 1972 and September 1979, all patients less than 70 years of age with a unilateral breast tumor classified T1a, N0, N1a, or N1b were considered eligible. They were informed of the two surgical treatment options. Nine patients refused a mastectomy and were not eligible for randomization. The other eligible patients first underwent tumor excision for diagnosis at frozen-section examination. When the tumor measured ≤20 mm at macroscopic examination, the patient was considered definitively eligible and the operative procedure was randomly allocated: modified radical mastectomy with no excision of pectoral muscles versus complete tumorectomy with a 2-cm margin of normal glandular tissue around the tumor mass.

A lower axillary dissection was performed in all patients, followed by frozen-section examination of at least seven lymph nodes. Complete axillary dissection was limited to patients who presented with at least one involved axillary lymph node.

All tumorectomized patients received, over 1 month, systemic breast irradiation at a dose of 45 Gy in 18 fractions (four fractions of 2.5 Gy/wk) using cobalt 60 photon beams. A boost dose of 15 Gy (six fractions of 10 days) was given to the tumor bed. Patients with histologically negative axillary nodes did not receive irradiation to nodal areas. For patients with positive axillary nodes (N+), a second randomization was performed to compare postoperative nodal irradiation versus no further treatment. When lymph node radiotherapy was performed, a total dose of 45 Gy (18 fractions over 1 month) was given to the axillary, supraclavicular, and internal mammary chain areas. Beam arrangements were previously described. In an attempt to increase the number of patients included in this second part of the study, nodal irradiation was also randomly allocated for all eligible N+ patients who had systematically undergone a tumorectomy between October 1979 and October 1980.

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Patients included in this trial did not receive any systemic adjuvant treatment such as chemotherapy or hormonal treatment.

**Statistical Analysis**

Patterns and risk of failure were analyzed using three procedures: the log-rank test of censored curves of tumor events, a model that assumed competing risks, and a Cox's proportional hazards model adjusted on prognostic factors. The model that assumed competing risks included all events synonymous with relapse by using cumulative incidence functions. These incidence estimates were subdivided into separate components, which, when summed, represent the overall event rates. In this context, events are considered as competing events and the occurrence of one type of event does not censor the subsequent inclusion of other events. No assumption of independence is necessary. Event-specific cumulative incidence curves were estimated from the decomposition of the event-free survival curves, and a computer program (COMPETE), developed at IGR, was used for the calculations. Events analyzed were local recurrence (including breast or chest wall and lymph node recurrences), distant metastasis, contralateral breast cancer, new primary malignancies (defined as any site of second cancer except contralateral breast cancer and basal cell carcinoma), and death. The rates of the first events or first cause of failure obtained by this method are compared with total relapse rates in which other events, except death, are not taken into account.

Cox's proportional hazards model was used to estimate a prognostic score, for the total population, which included age at diagnosis (<35, 36 to 50, 51 to 65, and 66 to 70 years), microscopic size of the tumor (<10 mm, 10 to 11 mm), the three levels of a modified histologic Scarff-Bloom-Richardson-based grading system, and number of positive axillary lymph nodes (zero, one to three, and > four). This prognostic score was obtained by adding the regression coefficient associated with each prognostic factor. A study of the pattern of failure was performed using the model that assumed competing risks for each group of prognostic scores. The risks of death and other types of failure were also estimated by a model stratified on three levels of the previously computed prognostic score.

**Clinical and Histologic Findings**

The number of patients included in the first randomization was 179; 91 had a mastectomy and 88 a tumorectomy with breast irradiation. No differences could be detected between the two treatment groups in terms of age (mean, 51.4 v 51.8 years; P = .78), macroscopic tumor size (15.7 v 15.6 mm; P = .75), histologic grade (22% v 27% of patients had a grade III tumor; P = .50), and the number of positive axillary nodes (8% v 11% of patients had > four positive nodes; P = .80). Among 58 N+ patients included in the first randomization, 33 were randomized to receive nodal irradiation (15 from the mastectomy group and 18 from the conservative group). The mean follow-up time for the whole population was 14.5 years (SD 2.1).

**Survival Curves and Pattern of Failure Estimated by Conventional Log-Rank Test**

No difference was observed between the two surgical groups for the risks of death (P = .19), distant metastasis (P = .20), contralateral breast tumor (P = .63), and loco-regional recurrence (P = .44). Fifteen-year cumulative incidence rates in terms of the first cause of failure and total events according to treatment groups are listed in Table 1.

Overall survival and event-free survival curves are plotted in Fig 1. Similar results were observed in the two treatment groups. The relative risks of death and relapse were slightly higher for the mastectomy group than for the tumorectomy group (1.41 and 1.28 v 1; P = .19 and .23, respectively).

**Patterns of Failure Estimated by a Competing-Risk Approach**

Local recurrence and distant metastasis rates as the first cause of failure are plotted in Fig 2. The number of events was similar in the two treatment groups. The relative risks

<table>
<thead>
<tr>
<th>Table 1. Fifteen-Year Cumulative Incidence Rates (first cause of failure and total events) According to Treatment Groups</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of event</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Local recurrence</td>
</tr>
<tr>
<td>Distant metastasis</td>
</tr>
<tr>
<td>Contralateral breast</td>
</tr>
<tr>
<td>New primary malignancy</td>
</tr>
<tr>
<td>Intercurrent death</td>
</tr>
<tr>
<td>Any first event</td>
</tr>
<tr>
<td>Overall death</td>
</tr>
</tbody>
</table>

* Tumorectomy: conservative surgery group (88 patients).
† Mastectomy: radical surgery group (91 patients).
‡ RR: relative risk compared with the tumorectomy group defined as 1, using competitive-risk approach.
§ Gray test.
∥ Log-rank test.
* Complementary values of event-free and overall survival.
of local failure and distant metastasis were 1.40 and 1.40 for the mastectomy group compared with the tumorectomy group ($P = .48$ and .45, respectively).

Twelve locoregional recurrences occurred after conservative treatment and 15 after mastectomy. Most of them (10 in each group) were observed either in the breast or in the chest wall. The other sites of recurrences were the axilla (two in the tumorectomy group and four in the mastectomy group) and the supraclavicular area (one in the mastectomy group). There was no difference in the...
overall survival or metastasis-free rate after local recurrence between the two treatment groups.

Tumorectomy and breast irradiation produced a good cosmetic result in 92% of the cases, according to previously published definitions.\textsuperscript{29}

The cumulative incidence rates of tumor in the contralateral breast and a new primary malignancy are shown in Fig 3. There are no significant differences between these curves. New primary tumor sites were the floor of the mouth, colon, endometrium, ovary, kidney, myeloma, and two soft tissue sarcomas within the radiation fields for the mastectomy group, and the stomach, endometrium, colon, and thyroid for the tumorectomy group.

**Prognostic Score for Death**

We used the Cox model to estimate a prognostic score for death in the total population, from the four previously defined prognostic factors. Coefficient and corresponding risks of death associated with each class of these four selected prognostic factors are listed in Table 2. The prognostic score, obtained for each patient by adding their four beta coefficients, was strongly related to the risk of death. The 15-year survival rates for the three groups of prognostic scores were, respectively, 86% (95% confidence interval [CI], 77% to 94%), 73% (95% CI, 61% to 84%), and 45% (95% CI, 31% to 59%). The pattern of failure in each group of prognostic scores was also analyzed by the competing-risk approach (Table 3). The score is significantly predictive of tumor events and more specifically of distant metastases.

**Risk of Failure Estimated by the Cox Model, According to Type of Surgical Treatment**

The risks of death, local recurrence, distant metastasis, contralateral breast cancer, and other new primary malignancy were also estimated by the Cox model with stratification on the previously established prognostic score and adjustment on nodal irradiation (Table 4). In this model, the risks were slightly lower than those listed in Table 1, which indicates that both treatments led to similar results.

**Risk of Failure According to Nodal Irradiation**

The second part of the trial included only 58 N+ patients already randomized in the first part, and 14 additional N+ patients who had systematic conservative treatment after the interruption of the first randomization. Among the total of 72 patients, 41 received nodal irradiation and 31 did not. The proportion of patients treated by tumorectomy was 63% in the nodal irradiation group and 55% in the other group ($P = .46$). The two arms of this part of the trial were imbal-

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![Fig 3. Cumulative incidence of contralateral breast cancer ($P = .47$, Gray test) and new primary malignancies ($P = .55$, Gray test) as first cause of failure and according to treatment group.](image-url)
Table 2. Relative Risks of Death Associated With Four Prognostic Factors in a Multivariate Cox Model Including 179 Patients

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No. of Patients</th>
<th>Beta Coefficient</th>
<th>SE</th>
<th>RR</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 35</td>
<td>7</td>
<td>0.9195</td>
<td>0.5618</td>
<td>2.5</td>
<td>.003</td>
</tr>
<tr>
<td>36-50</td>
<td>78</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>.01</td>
</tr>
<tr>
<td>51-65</td>
<td>81</td>
<td>-0.2307</td>
<td>0.3259</td>
<td>0.8</td>
<td></td>
</tr>
<tr>
<td>66+</td>
<td>13</td>
<td>1.2255</td>
<td>0.4269</td>
<td>3.4</td>
<td></td>
</tr>
<tr>
<td>Clinical size of tumor (mm)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 20</td>
<td>79</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>.001</td>
</tr>
<tr>
<td>&gt; 20</td>
<td>100</td>
<td>1.0197</td>
<td>0.3024</td>
<td>2.8</td>
<td></td>
</tr>
<tr>
<td>Histologic grading</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>56</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>.01</td>
</tr>
<tr>
<td>II</td>
<td>80</td>
<td>1.0015</td>
<td>0.3743</td>
<td>2.7</td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>43</td>
<td>1.0059</td>
<td>0.4020</td>
<td>3.1</td>
<td></td>
</tr>
<tr>
<td>No. of positive axillary nodes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>121</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>1-3</td>
<td>39</td>
<td>0.0126</td>
<td>0.3460</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>4+</td>
<td>19</td>
<td>1.2829</td>
<td>0.3945</td>
<td>3.6</td>
<td></td>
</tr>
<tr>
<td>Prognostic score†</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 1.000</td>
<td>64</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>10^-4</td>
</tr>
<tr>
<td>1.001-2.000</td>
<td>60</td>
<td>0.5742</td>
<td>0.3870</td>
<td>1.8</td>
<td></td>
</tr>
<tr>
<td>2.001+</td>
<td>55</td>
<td>1.4997</td>
<td>0.3557</td>
<td>4.5</td>
<td></td>
</tr>
</tbody>
</table>

*Reference category.
†Sum of corresponding beta coefficients for each patient. For example, a 67-year-old patient with a tumor of 15 mm, grade I, and 2 involved axillary nodes will have a prognostic score of 2.2578 (1.2255 + 1.0197 + 0 + 0.0126).

Table 4. Risks of Failure According to Type of Surgical Treatment, Estimated by the Cox Model

<table>
<thead>
<tr>
<th>No. of Events</th>
<th>Type of Event</th>
<th>Tumorectomy</th>
<th>Mastectomy</th>
<th>RR*</th>
<th>95% CI</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>24</td>
<td>33</td>
<td>1.20</td>
<td>0.70-2.05</td>
<td>.51</td>
<td></td>
</tr>
<tr>
<td>Local recurrence</td>
<td>12</td>
<td>15</td>
<td>1.22</td>
<td>0.56-2.64</td>
<td>.62</td>
<td></td>
</tr>
<tr>
<td>Distant metastasis</td>
<td>23</td>
<td>32</td>
<td>1.24</td>
<td>0.72-2.15</td>
<td>.45</td>
<td></td>
</tr>
<tr>
<td>Contralateral breast</td>
<td>12</td>
<td>10</td>
<td>0.76</td>
<td>0.33-1.79</td>
<td>.53</td>
<td></td>
</tr>
<tr>
<td>New primary malignancy</td>
<td>4</td>
<td>8</td>
<td>2.01</td>
<td>0.61-6.95</td>
<td>.25</td>
<td></td>
</tr>
</tbody>
</table>

NOTE. Cox model adjusted on 3 levels of prognostic score (Table 2) with stratification on nodal irradiation. *The reference category is the tumorectomy group.

Table 3. Fifteen-Year Cumulative Incidence Rates (first cause of failure and total events) According to Prognostic Score Groups

<table>
<thead>
<tr>
<th>Type of Event</th>
<th>Group 1 (n = 64)</th>
<th>Group 2 (n = 60)</th>
<th>Group 3 (n = 55)</th>
<th>P*</th>
<th>Group 1 (n = 64)</th>
<th>Group 2 (n = 60)</th>
<th>Group 3 (n = 55)</th>
<th>P*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local recurrence</td>
<td>5</td>
<td>17</td>
<td>15</td>
<td>.12</td>
<td>7</td>
<td>19</td>
<td>22</td>
<td>.057</td>
</tr>
<tr>
<td>Distant metastasis</td>
<td>8</td>
<td>22</td>
<td>26</td>
<td>0.045</td>
<td>14</td>
<td>34</td>
<td>47</td>
<td>.0003</td>
</tr>
<tr>
<td>Contralateral breast</td>
<td>16</td>
<td>3</td>
<td>15</td>
<td>.12</td>
<td>17</td>
<td>4</td>
<td>20</td>
<td>.06</td>
</tr>
<tr>
<td>New primary malignancy</td>
<td>7</td>
<td>5</td>
<td>6</td>
<td>.96</td>
<td>7</td>
<td>9</td>
<td>6</td>
<td>.87</td>
</tr>
<tr>
<td>Intercurrent death</td>
<td>2</td>
<td>3</td>
<td>6</td>
<td>.44</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Any first event†</td>
<td>37</td>
<td>50</td>
<td>66</td>
<td>.002</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Overall death†</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td></td>
<td>15</td>
<td>27</td>
<td>56</td>
<td>&lt; 10^-5</td>
</tr>
</tbody>
</table>

*Log-rank test.
†Complementary values of event-free and overall survival.

Discussion

More than 15 years after the initial treatment of early breast cancer, no detrimental effects in terms of survival, event-free survival, distant metastasis, contralateral breast cancer, or locoregional relapse rates were observed in patients treated by a conservative approach compared with those treated by a modified radical mastectomy. The event-free survival rates were even higher, although non-significantly, in the tumorectomy group than in the mastectomy group. This trend may be related to the prevention of local recurrences by systematic irradiation of the breast. Most of local recurrences and distant metastases developed within the first 10 years of follow-up evaluation, especially in the tumorectomy group, for which both described prognostic score to take these differences into account. In this population, the 15-year survival rates according to the prognostic score were as follows: 84% (95% CI, 61% to 94%), 72% (95% CI, 50% to 87%), and 50% (95% CI, 32% to 68%). The risks of failure in the stratified Cox model, adjusted on the type of surgery, are listed in Table 5. Differences are not significant.
the 10-year and 15-year first cause of failure rates were 9% for local recurrences and 16% for distant metastases. The respective rates in the mastectomy group were slightly higher at 15 years. These rates were 13% and 14% for local recurrences, and 17% and 20% for distant metastases.

These results support the hypothesis that a conservative procedure does not reduce the chances of survival for patients with a small breast tumor. They are consistent with those published for five other trials.3,5,10,12,14 Only the British trials31 showed worse results for the wide-excision treatment group than for the control group, both for stage I and II patients. However, these trials differed from others essentially for the following reasons: (1) the wide-excision group had no axillary dissection, but irradiation of the axilla; (2) a low radiation dose was delivered to both the breast and the axilla; and (3) these trials also included T2 and T3 tumors. It is possible, therefore, that conservative surgery may not be adequate enough to ensure long-term control in such large tumors. However, the National Surgical Adjuvant Breast and Bowel Project (NSABP), National Cancer Institute, and European Organization for the Research and Treatment of Cancer trials10,12,14 provide some evidence that conservative management could be extended to patients with tumors between 2 and 5 cm. The NSABP trial also randomized breast irradiation in the tumorectomy group. Results showed an increased risk of local recurrence in the nonirradiated group, as observed in other similar trials.30-32 This increased risk could have a greater prognostic impact, since the occurrence of a local recurrence may be predictive of an increased risk of distant metastases.33,34

In summary, most of the results of the randomized trials demonstrate that conservative treatment with breast irradiation is a safe procedure for the management of small breast cancers, in terms of long-term local control and overall survival. The only ominous risk is the development of radiation-induced soft tissue sarcomas, but this event remains exceptional. In a larger series previously reported, the cumulative incidence was estimated at 0.2% at 10 years.35 Meanwhile, it is impossible to define the population of patients at very low risk (5% at 10 years) of developing a local recurrence in the absence of breast irradiation during initial treatment. Standard treatment should therefore continue to include breast irradiation until more specific results are available.

The use of preoperative treatment with chemotherapy and/or radiotherapy allowing tumor shrinkage and breast conservation in cases of large T2-3 tumors needs to be evaluated in randomized trials,36,37 but a longer follow-up time is necessary to determine the actual long-term risk of local recurrence. The results of the present study and of other published randomized trials offer a safe basis for conservative management of small breast tumors with limited surgery and systemic breast irradiation.

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REFERENCES


