

Randomized Trial of Breast Irradiation Schedules After Lumpectomy for Women With Lymph Node-Negative Breast Cancer

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Background: Breast irradiation after lumpectomy is an integral component of breast-conserving therapy that reduces the local recurrence of breast cancer. Because an optimal fractionation schedule (radiation dose given in a specified number of fractions or treatment sessions over a defined time) for breast irradiation has not been uniformly accepted, we examined whether a 22-day fractionation schedule was as effective as the more traditional 35-day schedule in reducing recurrence. **Methods:** Women with invasive breast cancer who were treated by lumpectomy and had pathologically clear resection margins and negative axillary lymph nodes were randomly assigned to receive whole breast irradiation of 42.5 Gy in 16 fractions over 22 days (short arm) or whole breast irradiation of 50 Gy in 25 fractions over 35 days (long arm). The primary outcome was local recurrence of invasive breast cancer in the treated breast. Secondary outcomes included cosmetic outcome, assessed with the European Organisation for Research and Treatment of Cancer (EORTC) Cosmetic Rating System. All statistical tests were two-sided. **Results:** From April 1993 through September 1996, 1234 women were randomly assigned to treatment, 622 to the short arm and 612 to the long arm. Median follow-up was 69 months. Five-year local recurrence-free survival was 97.2% in the short arm and 96.8% in the long arm (absolute difference = 0.4%, 95% confidence interval [CI] = -1.5% to 2.4%). No difference in disease-free or overall survival rates was detected between study arms. The percentage of patients with an excellent or good global cosmetic outcome at 3 years was 76.8% in the short arm and 77.0% in the long arm; the corresponding data at 5 years were 76.8% and 77.4%, respectively (absolute difference = -0.6%, 95% CI = -6.5% to 5.5%). **Conclusion:** The more convenient 22-day fractionation schedule appears to be an acceptable alternative to the 35-day schedule. [J Natl Cancer Inst 2002;94:1143-50]

Breast-conserving surgery or lumpectomy is commonly recommended as the primary treatment for early breast cancer (1). Randomized controlled trials have demonstrated that breast irradiation after lumpectomy substantially reduces recurrence of cancer in the breast and thereby increases the likelihood of breast conservation (2-5). Although the role of breast irradiation after lumpectomy is widely accepted, there is no uniform agreement on which radiation therapy schedule should be used. Indeed, four national surveys of clinical practice in the United States, Canada, Britain, and France have identified variation in the radiation therapy schedules used to treat patients after lumpectomy (6-9). Several different radiation therapy schedules were used in randomized trials that established the efficacy of breast irradiation

compared with no irradiation following lumpectomy. The National Surgical Adjuvant Breast and Bowel Project (NSABP) B06 trial evaluated 50 Gy in 25 fractions to the whole breast (2). The Swedish trial evaluated 54 Gy in 27 fractions (3). The Ontario Clinical Oncology Group trial evaluated 40 Gy in 16 fractions (4). The Milan trial evaluated 50 Gy in 25 fractions (5). The latter two trials also included boost radiation (i.e., additional local radiation therapy) to the primary site. A schedule that is commonly used today in clinical practice is 50 Gy in 25 fractions to the whole breast, administered daily, Monday to Friday, over 35 days in fractions of 2 Gy per day (6,7). This schedule was used in all NSABP trials.

For a number of years, centers in the United Kingdom and Canada have used more rapid fractionation schedules for breast irradiation. This approach is based on the radiobiologic model that a larger dose per fraction given over a shorter period of time is just as effective as the more traditional longer schedule (10). Schedules used have ranged from 40 to 45 Gy in 15-20 fractions, administered over 19-22 days with fraction sizes of 2.3-2.7 Gy. Case series and cohort studies have reported acceptable local control rates and minimal acute and late morbidity (11-14).

We enrolled patients with lymph node-negative breast cancer who had received a lumpectomy in a randomized trial to determine whether 42.5 Gy in 16 fractions administered over 22 days to the whole breast, a treatment that is more convenient for patients and less resource intensive, was as effective as 50 Gy in 25 fractions administered over 35 days.

PATIENTS AND METHODS

Study Patients

Women with invasive carcinoma of the breast treated by lumpectomy with pathologically negative axillary lymph nodes

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were eligible for the trial. Patients were excluded from the study for the following reasons: 1) level I and II axillary dissection not performed; 2) presence of invasive or intraductal carcinoma involving the inked margin of excision on pathologic examination; 3) presence of a tumor of more than 5 cm in diameter or clinical T4 disease; 4) presence of multicentric disease; 5) previous diagnosis of breast cancer; 6) presence of bilateral malignancy of the breast; 7) breast deemed too large to permit satisfactory radiation therapy (i.e., the maximum width of breast tissue >25 cm); 8) patient currently pregnant or lactating; 9) presence of serious nonmalignant disease (e.g., cardiovascular or pulmonary) that would preclude radiation treatment; 10) diagnosis of previous or concomitant malignancies of any type except squamous or basal cell carcinoma of the skin and carcinoma *in situ* of the cervix; 11) patient geographically inaccessible for follow-up; 12) presence of psychiatric or addictive disorders that would preclude informed consent or adherence to the protocol; 13) patient not treated with chemotherapy who was unable to commence radiation therapy within 16 weeks of the last surgical procedure on the breast; 14) patient treated with chemotherapy who was unable to commence radiation therapy within 8 weeks of the last dose of chemotherapy; and 15) patient enrolled in another clinical trial.

Consecutive eligible patients presenting at participating centers who met the inclusion criteria were registered. Participating centers included the Cancer Care Ontario Regional Cancer Centres in the cities of Hamilton, Toronto, Ottawa, Sudbury, London, Windsor, Kingston, and Thunder Bay; the Princess Margaret Hospital in Toronto; and the Montreal General Hospital. Reasons for noneligibility were documented. Written informed consent was obtained from eligible patients before assignment to treatment. The study protocol was approved by the institutional review board of each participating center.

Treatment Regimens

Patients were assigned to one of two regimens, according to a prescribed computer-generated central randomization schedule within strata defined by age (<50 years or ≥50 years), tumor size (≤2 cm or >2 cm), adjuvant systemic therapy (tamoxifen, any chemotherapy, or no therapy), and center. Before the randomization procedure, patients were assessed for adjuvant systemic therapy, according to the guidelines of each center. Suggested guidelines for premenopausal patients stated that chemotherapy should be considered if two of the following three tumor characteristics were present: tumor size of more than 2 cm, poorly differentiated tumor, or estrogen receptor-negative status. The guidelines for postmenopausal women stated that adjuvant tamoxifen therapy should be considered if the tumor was greater than 1 cm and had an estrogen receptor-positive status. Patients who received adjuvant chemotherapy completed chemotherapy before radiation therapy.

Patients were randomly assigned to receive whole breast irradiation of 42.5 Gy in 16 fractions over 22 days or to receive whole breast irradiation of 50 Gy in 25 fractions over 35 days. Radiation therapy was delivered daily, from Monday through Friday. The intention was to treat the breast at risk and the underlying chest wall. Patients were treated in the supine position with the ipsilateral arm raised above the shoulder and immobilized. The treatment volume was irradiated by two opposed tangential fields. The medial border was located at the midsternal line. The lateral border was at the midaxillary line to include

the breast with a 1- to 2-cm margin and to limit the amount of lung at the central plane to less than 3 cm. The superior border was located at a horizontal line drawn through the supersternal notch, and the inferior border was located at a horizontal line 1–2 cm below the inframammary fold. Wedge compensation was used to ensure a uniform dose distribution throughout the target volume. A contour was taken at the central plane, and a dose distribution was obtained. The treatment volume was treated uniformly to a given dose plus or minus 7%. The dose was prescribed at a point midway along the central plane, two thirds of the distance from the skin to the base of tangent fields. Portal films were obtained in the treatment position with a therapeutic beam to confirm adequate coverage. Patients were treated with a 4- to 6-megavolt linear accelerator or with cobalt-60 radiation. In this trial, no attempt was made to treat the axilla or the supraclavicular or internal mammary lymph nodes, and boost radiation was not used.

Follow-up Studies and Outcome Measures

After completion of radiation therapy, patients were seen every 6 months for 5 years and then yearly thereafter. At each follow-up visit, patients provided a medical history and underwent a physical examination. Bilateral mammograms were performed 6 months after radiation therapy and then yearly thereafter. Cosmetic outcome was assessed at baseline and at 3 and 5 years after randomization. Late radiation toxicity was assessed at 3 and 5 years after randomization.

The primary outcome for this study was any local recurrence of invasive cancer in the treated breast. Secondary outcomes were distant recurrence of invasive breast cancer, death, breast cosmesis, and late radiation toxicity. A histopathologic confirmation was required for any local recurrence and, if possible, for any first recurrence at other sites. Clinical and laboratory manifestations that suggested recurrent disease were fully investigated. The criterion for local disease recurrence was recurrent tumor within the treated breast. Criteria for distant disease recurrence included recurrent tumor in the regional lymph nodes (ipsilateral axilla, supraclavicular or internal mammary lymph nodes), bone (abnormal bone x-rays or bone scan), liver (abnormal liver scan, ultrasound, or computed tomography scan), lung (abnormal chest x-ray consistent with metastases), or central nervous system (abnormal computed tomography scan).

Cosmetic outcome was assessed by a trained clinical trials nurse who used the European Organisation for Research and Treatment of Cancer (EORTC) Cosmetic Rating System (15). Before the study began, clinical trials nurses at each center were trained by use of a guide and a set of training slides produced for this purpose. After an initial training session, nurses were encouraged to review the training package on a yearly basis. Nurses were asked to compare the treated breast with the untreated breast and grade a number of items including breast size and shape, location and shape of areola/nipple, skin color, breast edema, appearance of surgical scar, telangiectasia, and global cosmetic result. Items were graded on the following four-point scale: 0 = no difference or excellent, 1 = small difference or good, 2 = moderate difference or fair, and 3 = large difference or poor. For the purpose of this study, only global cosmetic outcome was reported.

Radiation toxicity was assessed by the clinical trials nurse who used the Radiation Therapy Oncology Group (RTOG)/EORTC late radiation morbidity scale (16). The effects of radiation

therapy on skin and subcutaneous tissue were graded on the following five-point scale: 0 = no toxicity, 1 = slight, 2 = moderate, 3 = marked, and 4 = severe.

Statistical Analysis

The sample size estimated for this trial, 600 patients per arm, was based on the ability to demonstrate that the experimental arm was not worse than the standard arm by 5% in local recurrence-free survival at 5 years, with an α value of .05 (one-sided) and a β value of .10. Local recurrence-free survival was defined as the time from randomization until local recurrence as a first event; patients were censored at distant recurrence, last contact date, or death, whichever occurred first. Disease-free survival was defined as the time from randomization until any recurrence or death. An event for the analysis of overall survival was death from any cause. For disease-free survival and overall survival, patients without a recurrence or death were censored at the date of last contact. The outcomes of local recurrence-free survival, disease-free survival, and overall survival were summarized as Kaplan–Meier survival curves. The local recurrence-free survival between the two treatment groups was compared with a two-sided 95% confidence interval (CI) for the survival difference at 5 years. For disease-free and overall survival end points, log-rank tests were performed.

For the three scales measuring breast cosmesis, skin toxicity, and subcutaneous toxicity, the results were dichotomized and described as proportions; for cosmesis, we used the proportion

with “excellent” or “good” results; and for toxicity, we used the proportion with no toxicity. All statistical tests were two-sided.

RESULTS

Study Population

Patients were recruited for the trial from April 1993 through September 1996; 3732 patients met our inclusion criteria. Of these, 1303 (35%) satisfied one or more of the exclusion criteria (Fig. 1). The remaining 2429 eligible patients were invited to participate in the trial, of whom 1234 (51%) accepted through the process of informed consent. Of these 1234 patients, 622 patients were randomly assigned to receive 42.5 Gy in 16 fractions, and 612 patients were randomly assigned to receive 50 Gy in 25 fractions. Median follow-up was 69 months.

The treatment groups were reasonably comparable in terms of baseline characteristics including age, tumor size, estrogen receptor status, tumor grade (17), and use of adjuvant systemic therapy (Table 1).

During this study, four patients did not receive radiation therapy (one in the short arm and three in the long arm), four patients did not complete radiation therapy (two in the short arm and two in the long arm), and 12 patients crossed over to the alternate arm (five in the short arm and seven in the long arm). The following intention-to-treat analysis was based on all randomly assigned patients.

Fig. 1. CONSORT trial flow diagram.

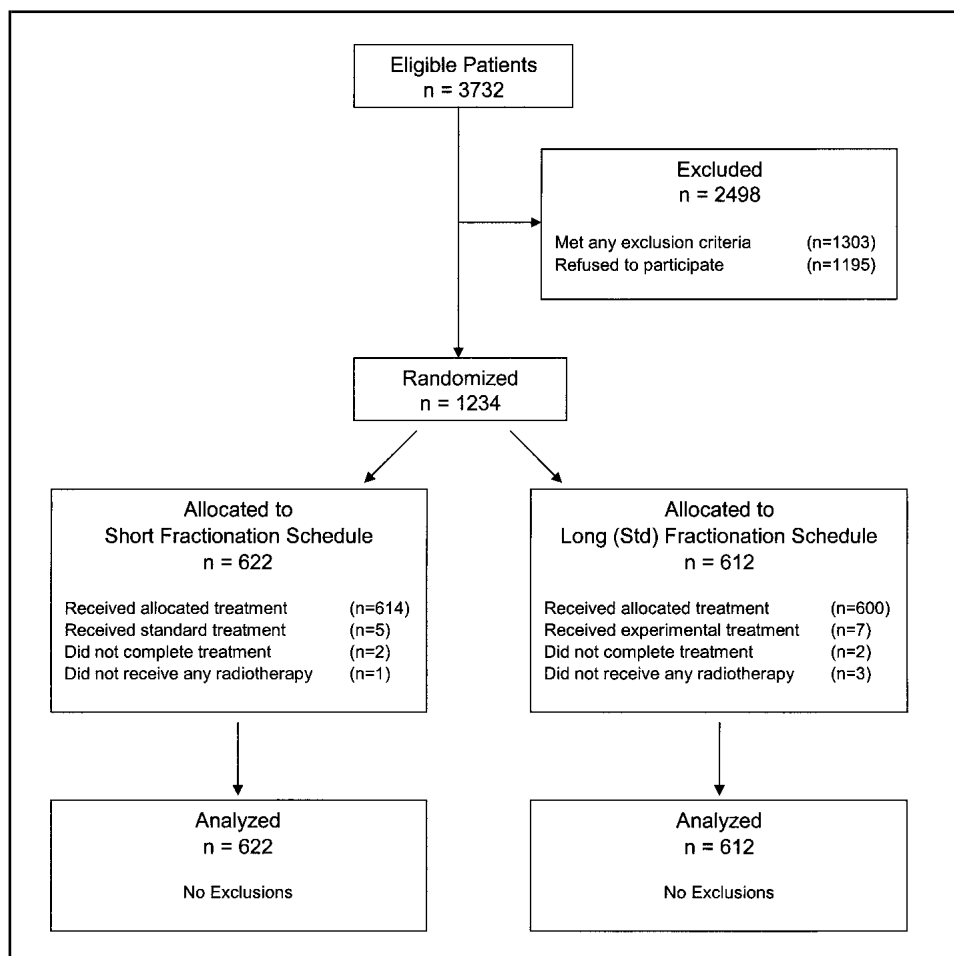


Table 1. Baseline characteristics

Characteristic	No. of patients in short arm (%) (n = 622)	No. of patients in long arm (%) (n = 612)
Age		
<50 y	157 (25)	148 (24)
50–59 y	186 (30)	155 (25)
60–69 y	181 (29)	200 (33)
≥70 y	98 (16)	109 (18)
Tumor size		
≤1 cm	183 (29)	192 (31)
>1–2 cm	317 (51)	302 (49)
>2 cm	122 (20)	118 (19)
Tumor grade*		
I	215 (35)	209 (34)
II	244 (39)	236 (39)
III	117 (19)	116 (19)
Unknown	46 (7)	51 (8)
Estrogen receptor status		
Positive	440 (71)	434 (71)
Negative	165 (27)	157 (26)
Unknown	17 (3)	21 (3)
Systemic therapy		
None	298 (48)	295 (48)
Tamoxifen	254 (41)	251 (41)
Chemotherapy	70 (11)	66 (11)

*Tumor grade is as previously described (17).

Local Recurrence-Free Survival

Forty-four patients experienced a local breast cancer recurrence as a first event: 21 in the short treatment arm and 23 in the long treatment arm. Local recurrence-free survival was similar in both treatment arms (Fig. 2). At 5 years, local recurrence-free survival was 97.2% in the short arm and 96.8% in the long arm. The absolute difference at 5 years was 0.4% (95% CI = -1.5% to 2.4%). The 5-year local recurrence rates for patient groups

based on age, tumor size, and adjuvant systemic therapy are presented in Table 2. In addition, there were seven cases of noninvasive (ductal carcinoma *in situ*) local recurrences, four in the short arm and three in the long arm.

Disease-Free and Overall Survival

Any recurrence or death was noted as a first event—91 events were identified in the short treatment arm (21 local recurrences, eight regional recurrences, 48 distant recurrences, and 14 deaths), and 79 events were identified in the long treatment arm (23 local recurrences, six regional recurrences, 26 distant recurrences, and 24 deaths). Overall, there were 48 deaths in the short arm and 51 deaths in the long arm. By use of a two-sided log-rank test, no statistically significant differences were detected for disease-free survival ($P = .37$; Fig. 3) or overall survival ($P = .78$; Fig. 4).

Cosmetic Outcome

Cosmetic outcome was assessed by use of the EORTC Cosmetic Rating System as excellent, good, fair, or poor at baseline and at 3 and 5 years. Cosmetic assessment was completed in 1220 patients at baseline, in 1013 patients at 3 years, and in 735 patients at 5 years. At baseline before radiation therapy, the groups were comparable—with 83.8% of patients in the short arm and 82.6% in the long arm being rated as excellent or good. At 3 years, the percentages of patients with an excellent or good cosmetic outcome were 76.8% in the short arm and 77.0% in the long arm. At 5 years, the percentages were 76.8% and 77.4%, respectively (absolute difference = -0.6, 95% CI = -6.5% to 5.5%).

Radiation Toxicity

The percentages of patients with late radiation toxicity of the skin or subcutaneous tissue at 3 and 5 years after randomization

Fig. 2. Local recurrence-free survival in the study groups. The hypothesis that the short arm is worse than the long arm by 5% or more at 5 years is rejected ($P < .001$).

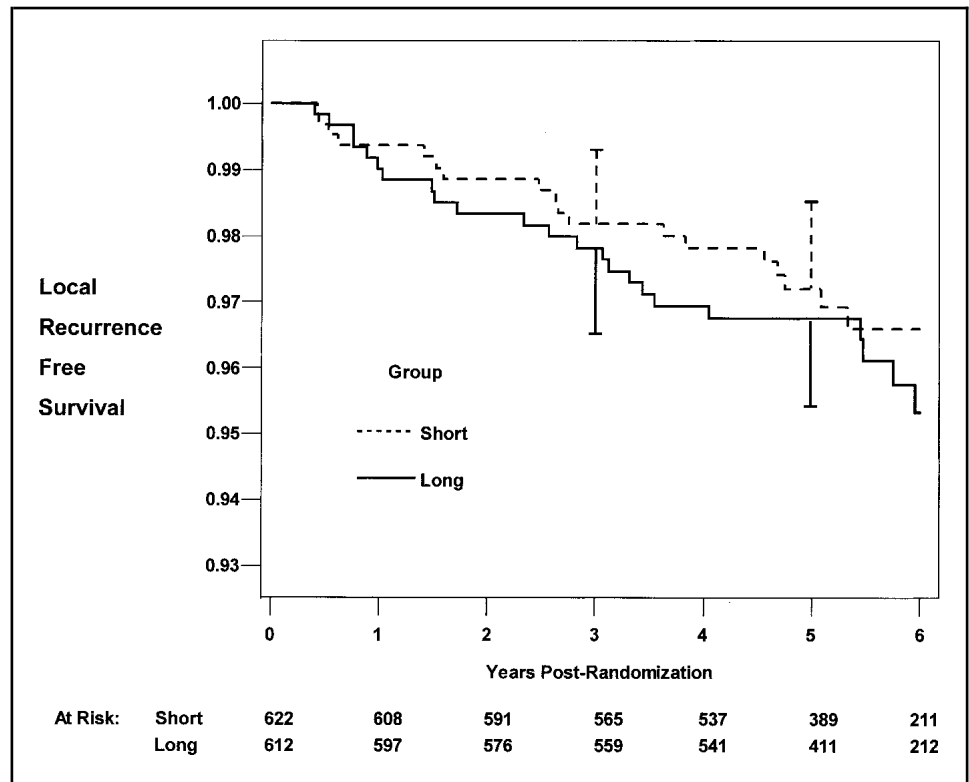
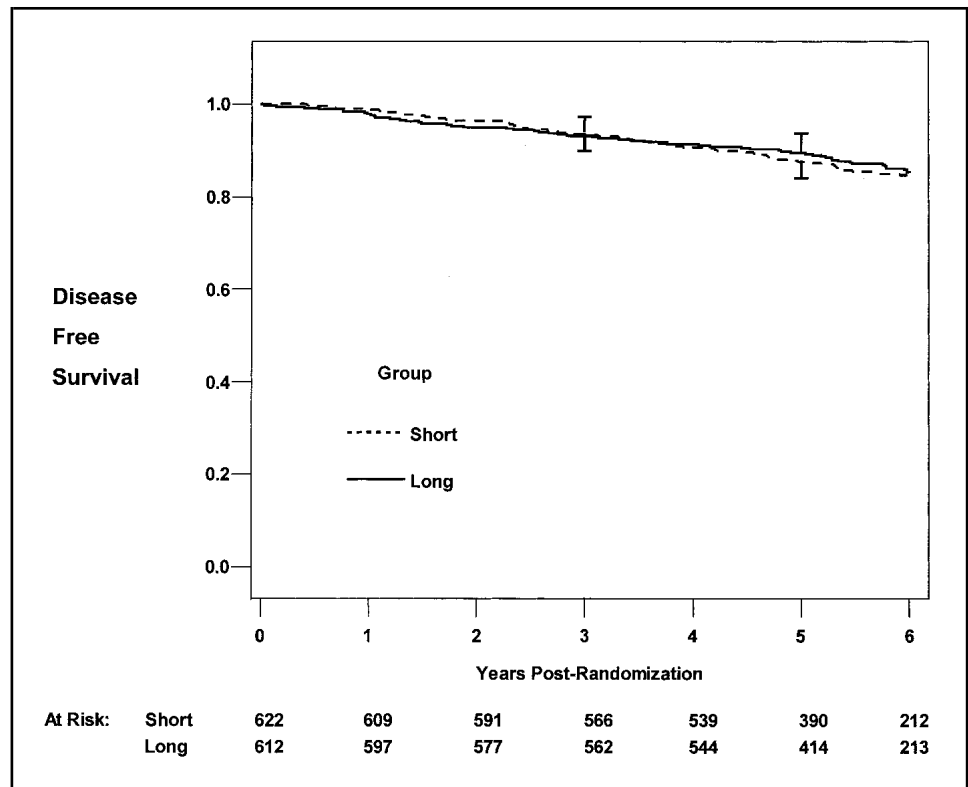


Table 2. Actuarial rates of local recurrence at 5 years by treatment group according to stratification factors

Variable	Short arm		Long arm		Absolute difference, % (95% confidence interval)
	No. of patients	5-y local recurrence rate, %	No. of patients	5-y local recurrence rate, %	
Age					
<50 y	157	3.6	148	7.2	3.6 (-1.7 to 9.0)
50-59 y	186	2.9	155	2.6	-0.2 (-3.6 to 3.3)
60-69 y	181	3.1	200	1.0	-2.1 (-5.1 to 0.9)
≥70 y	98	1.0	109	2.9	1.9 (-1.9 to 5.7)
Tumor size					
≤1 cm	183	1.7	192	1.6	-0.1 (-2.7 to 2.5)
>1-2 cm	317	2.1	302	3.5	1.4 (-1.4 to 6.1)
>2 cm	122	6.4	118	5.4	-1.1 (-7.3 to 5.2)
Systemic therapy					
No	298	3.0	295	3.9	0.9 (-2.2 to 4.0)
Yes	324	2.6	317	2.6	0.0 (-2.5 to 2.7)

Fig. 3. Disease-free survival in the study groups (two sided log-rank test, $P = .37$).



are listed in Table 3. In this study, no grade 4 toxicity was observed. The incidence of grade 2 or 3 toxicity was very low in both treatment arms. At 5 years, the percentages of patients with no skin toxicity were 87% in the short arm and 82% in the long arm. For subcutaneous tissue, the percentages were 66% and 60%, respectively. The absolute difference for skin toxicity was 5% (95% CI = -0.3% to 10%); the absolute difference for subcutaneous tissue toxicity was 6% (95% CI = -1.2% to 13%). In addition to skin and subcutaneous tissue toxicity, there were four cases of radiation pneumonitis (two in the short arm and two in the long arm) and one case of rib fracture (in the long arm) attributed to radiation therapy.

DISCUSSION

Breast irradiation after lumpectomy is usually given daily for 5-6 weeks. Results of this trial demonstrate that a shorter fractionation schedule of 42.5 Gy in 16 fractions over 22 days is as

effective as the more traditional schedule of 50 Gy in 25 fractions over 35 days in terms of preventing recurrence of cancer in the breast. The rates of local recurrence at 5 years were low and similar in both treatment arms. The 95% CI for the absolute difference between rates of local recurrence at 5 years indicated that treatment with the shorter schedule was unlikely to be worse than treatment with the longer schedule. In this trial, no difference was detected in disease-free and overall survival between treatment groups. Furthermore, the overall survival at 5 years for this population of women with lymph node-negative breast cancer was excellent.

Radiation therapy may cause skin telangiectasia and thickening of subcutaneous tissue that may adversely affect the cosmetic outcome of the treated breast (18,19). Breast cosmesis was used in this trial as a measure of late radiation toxicity. Approximately 75% of patients demonstrated a good or excellent cosmetic outcome at 3 and 5 years, and no difference was detected

Fig. 4. Overall survival in the study groups (two-sided log-rank test, $P = .78$).

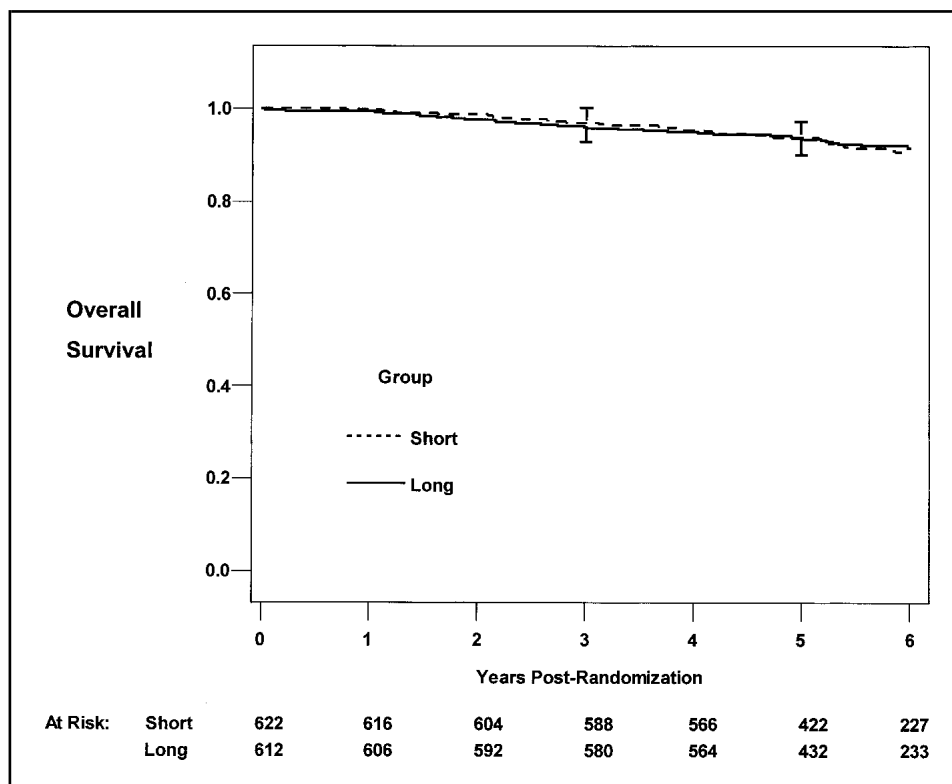


Table 3. Radiation Therapy Oncology Group (RTOG)/European Organisation for Research and Treatment of Cancer (EORTC) late radiation morbidity (grade %) by site and time

Site	Grade	% at 3 y		% at 5 y	
		Short arm (n = 515)	Long arm (n = 492)	Short arm (n = 394)	Long arm (n = 358)
Skin	0	90	87	87	82
	1	8	11	10	15
	2/3	2	2	3	3
Subcutaneous tissue	0	69	63	66	60
	1	27	32	29	33
	2/3	4	5	5	7

between treatment groups. The incidence of late radiation toxicity on skin and subcutaneous tissue was uncommon in both treatment arms, although patients in the short arm fared about 5% better. Given that most of the toxic effects of radiation therapy would be expected by 5 years, further differences between groups in skin and subcutaneous tissue toxicity are unlikely to occur with longer follow-up (20,21).

Long-term studies of breast irradiation have shown a variable effect on the incidence of ischemic heart disease. Two previous studies showed no increase in fatal or nonfatal myocardial infarction with left-sided breast irradiation (22,23). In a retrospective cohort study using a cancer registry database, Paszat et al. (24) observed a 1% increase in the rate of fatal myocardial infarction at 10 years with left-sided breast irradiation. This increase was associated with radiation therapy delivered with fraction sizes greater than 2.0 Gy. No data were available in this study on the volume of heart that was irradiated. In a study by Vallis et al. (25), a similar cohort of breast cancer patients treated with fraction sizes of 2.5 Gy were carefully evaluated by

individual chart review and adjudication of outcomes for the development of fatal or nonfatal myocardial infarction. At a median follow-up of 10.2 years, no increase in myocardial events was observed for patients treated with left-sided breast irradiation. Nonetheless, in our study we will follow patients to detect any long-term cardiac toxicity.

To our knowledge, this is the first randomized trial to compare a rapid fractionation schedule with a longer traditional schedule for breast irradiation after lumpectomy. The rapid schedule had been used extensively in clinical practice, was shown to have limited morbidity in a prospective study (13), and was supported by radiobiologic models (10). It was compared with a commonly used schedule—50 Gy in 25 fractions—that was used in a number of trials establishing the role of breast irradiation and continues to be used by many cooperative groups (e.g., NSABP, RTOG, and EORTC) in ongoing trials. Radiation therapy was delivered by a modern approach, and important outcomes including local recurrence, long-term cosmesis, and toxicity were assessed in a rigorous fashion.

Results from our study support the use of a modest increase in daily fraction size for breast irradiation when the total dose and overall treatment time is reduced. Concerns that have been raised in the literature about rapid fractionation schedules relate to two issues: the association of a large dose per fraction with the increased risk of late normal tissue toxicity and the reduction in total dose and potential for decreased effect on tumor control (26). The first concern arises from reports in older, retrospective case series (27,28). These studies were poorly controlled, with small patient numbers, and used older radiation therapy techniques. In particular, radiation therapy was delivered with large doses per fraction (≥ 3 Gy) without a reduction in the overall total dose. Radiobiologic models predict that normal tissue toxicity is not increased when the increase in fraction size is modest and the total dose is reduced (10). Similar models also suggest

that rapid schedules may be equally efficacious if the reduction in total dose is accompanied by a shorter overall treatment time (29) or if the tumor is more sensitive to a larger daily dose (30). This approach is supported by data from randomized trials that compared hypofractionated radiation therapy with more conventional radiation therapy in women with early breast cancer (31–33). In these three trials, no difference was detected in late radiation morbidity or local recurrence.

Although it was not possible to blind the assessment of outcome in this study, we did take care to minimize bias. All local recurrences required histologic confirmation, and all recurrences were adjudicated blindly. Cosmetic outcome was assessed by a clinical trials nurse using a validated scale. Nurses were trained regularly in assessment techniques with a package of training slides and a guide specifically developed for this study. Although nurses were not formally blinded to treatment group allocation for practical issues, they were encouraged to remain unaware of allocation, and this was very difficult to recall 3 and 5 years after randomization.

In our trial, additional boost radiation to the lumpectomy site was not used, because data from randomized trials supporting its efficacy were not available. Since the completion of this study, results from randomized trials indicate that boost radiation has a modest impact on local recurrence at the expense of cosmetic outcome (34,35). In the recently published EORTC trial, the rates of local recurrence at 5 years were 7.3% in the arm receiving breast irradiation alone and 4.3% in the arm receiving the boost radiation (35). The observed local recurrence rates in our trial were lower: 3.2% in the long arm and 2.8% in the short arm. Although there are limitations to cross-study comparisons, there are some important differences between the two studies. The EORTC trial was conducted in women with negative (78%), positive (21%), or unknown (1%) axillary lymph node status, whereas we enrolled only women with a negative axillary lymph node status. In the EORTC trial, 28% of women received adjuvant systemic therapy, whereas in our trial 52% of women received systemic therapy. In the EORTC study, the benefit of boost radiation appeared mainly in women 50 years of age or younger; in these women, the rate of local recurrence was high—as high as 20% in women who were aged younger than 40 years. In our trial, no difference was detected between groups including younger women; in younger women, the rates of local recurrence were low, especially for women treated with the shorter course of radiation therapy (i.e., 3.6%). For such women, we would postulate that the benefit achieved with boost radiation would be of a relatively small magnitude. Although Bartelink et al. (35) recommend boost treatment for all women who are younger than 50 years old, in our view, this remains an area for future study.

Our results support the use of a shorter fractionation schedule for irradiation of women with lymph node-negative breast cancer treated by lumpectomy. The results are not applicable to women with very large breasts (i.e., with widths >25 cm). The irradiation of such women has been associated with poor cosmetic results, even with conventional fractionation, and alternative techniques may be considered (36).

The results of this study have important implications for women with breast cancer and the health care system. Previous research suggests that the inconvenience of prolonged daily treatments makes a substantial contribution to the decreased quality of life experienced by women with breast cancer treated

with radiation therapy (37). A shorter fractionation schedule will lessen the burden of treatment for women, many of whom may also receive adjuvant chemotherapy, and will have important quality-of-life benefits with respect to convenience and less time away from home and work. Currently, radiation therapy for breast cancer accounts for up to 25%–30% of all radiation therapy delivered (38). The shorter schedule also will permit more efficient use of resources, in that up to 50% more women can be treated with existing equipment and personnel.

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NOTES

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