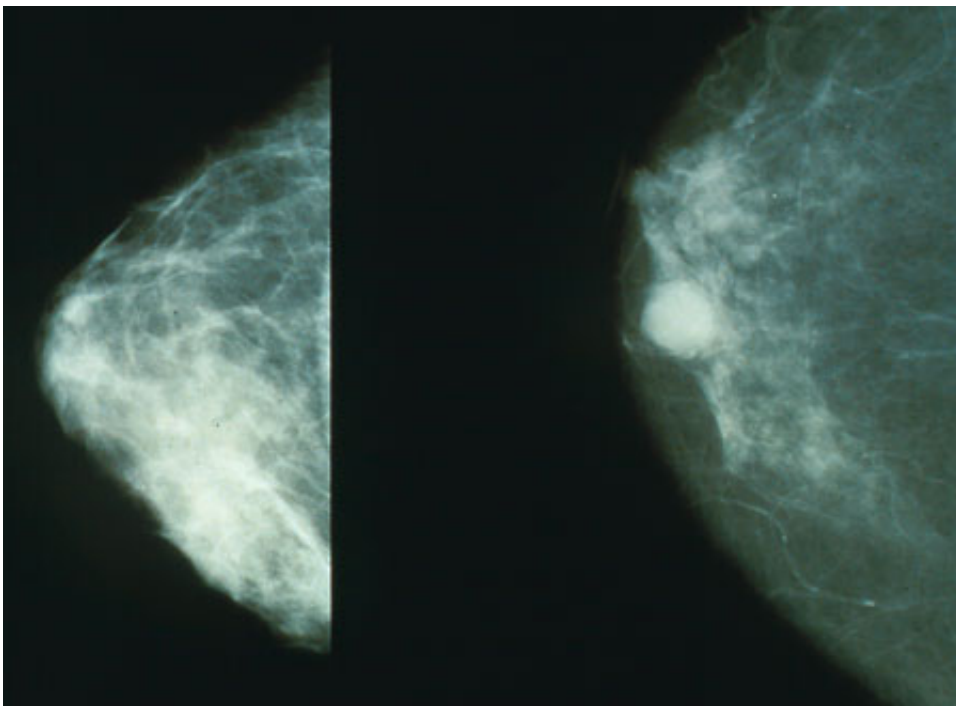


Short-course radiation as effective for patients who opt for breast reconstruction after mastectomy

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Mammograms showing a normal breast (left) and a breast with cancer (right).
Credit: Public Domain

In a first-of-its-kind study, people with breast cancer who underwent implant-based breast reconstruction immediately following a mastectomy reported that getting fewer, higher doses of radiation was just as effective as standard radiation, did not increase side effects and

saved them time and money. There also was a small improvement in quality of life for women under 45 who received the shortened treatment regimen.

The FABREC study is the first prospective randomized study comparing [quality-of-life](#) and [clinical outcomes](#) following accelerated versus conventional [radiation therapy](#) specifically for [patients](#) with post-mastectomy implant- or tissue-based breast reconstruction. Findings will be presented today at the [American Society for Radiation Oncology \(ASTRO\) Annual Meeting](#).

"Both the accelerated and standard courses of [treatment](#) were equally effective at preventing the cancer from returning and had the same level of side effects. But with shortening the treatment from five weeks to three, patients experienced fewer treatment disruptions, a lower financial burden and other meaningful improvements to their lives," said senior study author Rinaa Punglia, MD, MPH, FASTRO, an associate professor of [radiation](#) oncology at Dana-Farber Brigham Cancer Center in Boston.

Breast cancer is the second most diagnosed cancer for women in the U.S. About 40% of people with [breast cancer](#) have mastectomies and of that group, 62% undergo immediate reconstruction. Reconstruction using tissue expanders or breast implants has grown in popularity in recent years.

Roughly one-third of patients who get mastectomies also need radiation therapy to the [chest wall](#) and [lymph nodes](#), to help prevent their cancer from returning. While standard radiation therapy generally occurs over a period of five weeks, research has shown a shorter course of treatment can be just as effective at preventing the cancer from returning in women who have undergone breast-conserving surgery. Prior research also shows the shorter regimen does not increase side effects and can improve quality of life for these patients.

FABREC is the first study to compare the shorter and longer courses of post-mastectomy radiation specifically for people who had their breasts reconstructed immediately following mastectomy. Investigators also compared results for people under 45 years old to those 45 and older.

"Our main goal was to look at patient-reported outcomes, especially in terms of patient well-being," said lead study author, Julia Wong, MD, FASTRO, also an associate professor of radiation oncology at Dana-Farber Brigham Cancer Center. "We often focus on cancer outcomes, but there are a lot of quality-of-life issues involved in having a mastectomy and reconstructive surgery, a combination a lot of patients are now choosing. We have to look at how these treatments affect patients."

The multi-center trial involved 400 participants treated at 16 U.S. health centers who underwent mastectomies followed by immediate breast reconstruction using a tissue expander or implant. Patients were randomly assigned to receive either conventional radiation consisting of 25 fractions across five weeks (50 Gy total; n=201) or hypofractionated radiation consisting of 16 fractions across roughly three weeks (42.56 Gy total; n=199).

All patients were diagnosed with stage 0 to 3 breast cancer with tumors of any size but not growing into the chest wall or skin. The median age was 47 years. Patients completed questionnaires about their physical well-being and quality of life at baseline and at six, 12 and 18 months following treatment. Median follow-up was 40.4 months.

Patients in both groups reported similar levels of physical well-being six months after treatment, the primary endpoint of the study ($p=0.71$). There were some differences between the groups at baseline, including higher energy levels reported by those randomized to receive hypofractionated radiation ($p=0.02$). Dr. Puniglia said this finding likely

reflects their positive reactions to the shortened treatment.

"In our protocol, patients could complete their baseline questionnaire either before or after randomization, as long as it was before they started radiation. And so, patients could be aware of their treatment arm when they answered the questions," she said. "It seems patients felt more energetic because they knew they would be done with treatment faster."

Treatment breaks, which are associated with worse outcomes in breast cancer, were significantly fewer (2.7% vs. 7.7% with conventional treatment, $p=0.03$) and shorter with the accelerated treatment (average 2.8 days vs. 3.3 with conventional treatment, $p=0.03$). Patients who needed unpaid time off work also reported taking 50 fewer hours of unpaid leave (73.7 hours vs. 125.8 hours, $p=0.046$).

There were small improvements in quality-of-life scores among younger patients treated with hypofractionated radiation. Patients younger than 45 reported feeling less bothered by treatment-related side effects ($p=0.045$) with the accelerated treatments. They also reported better physical well-being ($p=0.049$).

There were no differences in the rates of recurrence or side effects between the two groups. Two people (one in each arm) experienced a local recurrence, and 23 (12 in the conventional arm, 11 in the hypofractionated arm) had [cancer](#) return to distant sites. Four patients (two in each arm) died during the study period; all were diagnosed with distant metastases.

The overall rates of chest wall toxicity were lower in both arms than rates previously reported with implant-based reconstruction, said Dr. Wong. Twenty patients in the hypofractionated group and 19 in the conventional group had toxicity in the chest wall area. The analysis found several factors predicted chest wall toxicity on univariate analysis,

including higher body mass index (HR=1.02, p=0.003), having a post-operative infection (HR=3.14, p=0.01), whether lymph nodes needed to be dissected (HR=2.07, p=0.03), having more lymph nodes removed (HR=1.05, p=0.01), having a tissue expander versus an implant (HR=3.32, p=0.04), and using preoperative endocrine therapy (HR=2.99, p=0.001).

Though they had hoped to see more dramatic results, the researchers were happy that delivering higher doses of radiation in less time did not increase side effects. "In fact, overall, the rates of chest wall toxicity were lower in both arms than what's been seen historically, which is likely because of improvements over time in technique," said Dr. Wong.

Provided by American Society for Radiation Oncology

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