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HEALTH JOURNAL

# Alternative Way to Treat Early-Stage Breast Cancer With Radiation

A single-dose technique costs less than traditional radiation treatment but with a higher risk of recurrence



Options for breast-cancer radiation are proliferating and so are controversies over which forms are best at reducing the risk of recurrence with the fewest side effects and least cost. WSJ's Melinda Beck joins Lunch Break to discuss. Professors Jeffrey S. Tobias (left) and Jayant Vaidya (right), at University College London Hospitals with the device they pioneered to administer a single dose of radiation during lumpectomy surgery. Photo: Ramesh Pydiah



By **MELINDA BECK**

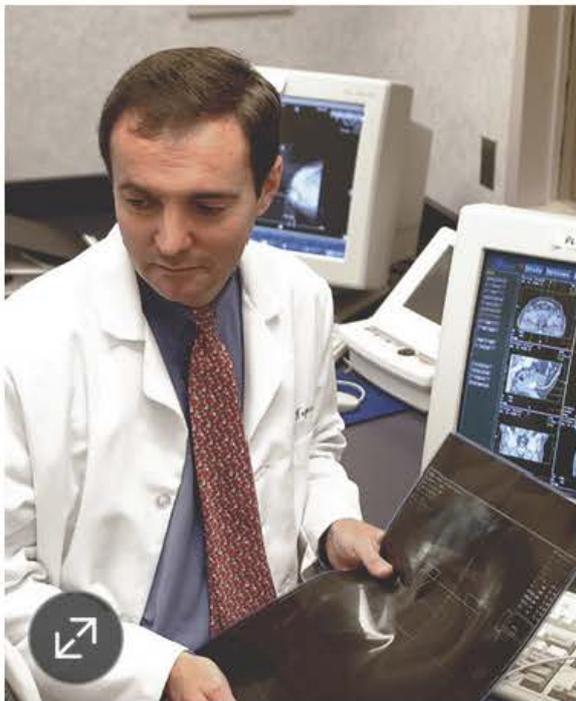
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**2 COMMENTS**

Breast-cancer specialists are sharply divided over a new radiation technique that costs less and is more convenient than conventional therapy.

The technique, known as intraoperative radiation therapy, or IORT, involves administering a single dose of radiation at the same time a patient is having lumpectomy surgery to remove a tumor. [A large, randomized controlled trial](#) concluded that IORT has fewer side effects and appears to prevent the return of cancer nearly as well as traditional treatment, in which patients undergo radiation sessions five days a week for up to seven weeks.

Oncologists with opposing opinions have been debating that conclusion in letters and editorials in major medical journals, including the *Lancet* and *BMJ*. Some critics point out that the study found women who had IORT face twice the risk of a cancer recurrence compared with traditional radiation (3.3% versus 1.3% over five years).



David Wazer, chairman of radiation oncology at Brown and Tufts medical schools, is a vocal critic of the new IORT technique, which administers a single dose of radiation at the same time a patient is having lumpectomy surgery. *PHOTO: WILLIAM MURPHY*

Some also criticize the design of the IORT study and say patients haven't been followed long enough to draw conclusions. "A lot of us are scratching our heads as to why [IORT] would be appropriate," says David Wazer, chair of radiation oncology at Brown and Tufts medical schools and [a vocal critic](#).

Yet proponents of IORT say the risk of recurrence with either radiation treatment over five years is tiny, and IORT's advantages could outweigh the higher risk of recurrence for some patients.

"A lot of women who hear about this option make an informed decision to use it," says Stephen Grobmyer,

director of the breast center at the Cleveland Clinic, which is collecting data on nearly 1,000 patients who have had the treatment at 19 U.S. centers.

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At many radiation centers, a big portion of revenue comes from delivering lengthy courses of treatment to breast-cancer patients. “Depending on your perspective, [moving to a single treatment during surgery] is either a significant threat or a quantum leap forward,” Anthony Zietman, editor in chief of the International Journal of Radiation Oncology, wrote [in an editorial](#) this month.

Radiation has revolutionized breast-cancer treatment since the 1980s, allowing older women with small, early-stage tumors to opt for lumpectomies rather than mastectomies. Survival rates are similar, because radiation helps destroy any stray cancer cells left behind. About 60% of the more than 200,000 women in the U.S. diagnosed annually with early-stage breast cancer undergo lumpectomy with radiation.

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#### RADIATION OPTIONS

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Options for breast-cancer radiation are proliferating as radiation oncologists seek to maximize cancer control while minimizing damage to surrounding tissue. Some of the main techniques:

- **Whole-breast external beam:** The standard therapy targets a high-energy beam from a linear accelerator at the entire breast, typically with 25 to 33 treatments given over five to seven weeks. A newer version called **hypofractionated radiation therapy** delivers higher doses in fewer sessions, generally over three to four weeks.
- **Partial breast irradiation:** This method delivers radiation only to the area around the tumor site, either from an external beam or from inside the breast itself, known as **brachytherapy**. The most common approach involves inserting a balloon or other device into the lumpectomy cavity to hold tiny radioactive pellets for a few minutes at a time, twice daily over five days.
- **Intraoperative radiation therapy (IORT):** A single concentrated dose of radiation is given directly to the tumor site during the lumpectomy surgery. IORT can use low-energy photons or high-energy electrons.
- **Proton beam:** Another form of whole-breast external radiation using a proton accelerator that is theoretically more precise than standard therapy. This is still considered experimental for breast cancer and available at only a few centers in the U.S.

Radiation’s side effects include fatigue, skin redness and blistering. In rare cases, it can damage patients’ hearts, lungs and rib cages. Weeks of treatment are disruptive for women who work, care for children or live far from radiation centers. About one-third of women who begin radiation don’t finish their

prescribed courses, studies show.

Experts have developed new methods to maximize the effectiveness of radiation treatments while minimizing the inconvenience and damage to healthy tissue. One approach delivers fewer but higher doses of radiation over three to four weeks. Several new technologies target only the tumor site instead of the whole breast. Some versions deliver radiation from inside the breast, using high-dose radioactive pellets held in place by balloon catheters for brief periods, a technique called brachytherapy.

To date, however, only conventional, whole-breast external-beam radiation has a long record of safety and effectiveness, which is why some radiation oncologists say they are reluctant to abandon it.

Use of IORT for breast-cancer patients, with just a single radiation dose during surgery, started in Europe in the late 1990s. In 2000, developers of one method called targeted intraoperative radiotherapy, or TARGIT, organized a clinical trial to compare it with traditional radiation. They enrolled 3,451 women from 33 centers in 11 countries, including the U.S.; about half the participants received IORT and the rest got conventional therapy.

In a paper published in the *Lancet* last year, the investigators calculated that the five-year risk of cancer recurrence was 3.3% for the women who had IORT, compared with 1.3% for the control group—a margin that was within the trial's predetermined definition of “non-inferiority.”

The women who had IORT had fewer severe skin problems. There was no significant difference in the risk of death in either group.

Critics of the trial say the median follow-up was only 29 months, not five years. They also say the design of the trial made a true comparison impossible.

Because not all the information about a tumor is known at the time of a lumpectomy, about 20% of the study participants who had IORT were later found to be at higher risk based on a final pathology report and were given conventional radiation as well. Those women were still considered in the IORT group for the study, which some critics say skewed the findings.

The investigators say the trial was designed all along to assess the strategy of

giving IORT to women with early-stage cancers and adding conventional radiation for those deemed at higher risk later.

“We’ve analyzed this four different ways, and every way we get the same answer: There isn’t much difference in efficacy, but it is significantly less toxic, and significantly more convenient,” says Jayant Vaidya, a professor of surgery and oncology at University College London, and lead investigator in the trial. Dr. Vaidya says he and other investigators receive travel expenses and speaking fees from Carl Zeiss Meditec Inc., the German maker of the radiation equipment.

Dr. Vaidya says some 260 medical centers world-wide now offer IORT. The Australian government last month approved it for its national health system, and Britain’s health authority is meeting to consider it this week.

In the U.S., Medicare and most private insurers cover IORT. On average, Medicare pays hospitals \$7,461 for IORT, including the lumpectomy, compared with \$10,870 for six weeks of conventional radiation or \$6,312 for a three-week course, with an additional \$2,000 to \$3,500 for the surgery, according to James Hugh, senior vice president at American Medical Accounting and Consulting Inc., a healthcare billing and consulting firm.

About 60 U.S. medical centers are using the device used in the TARGIT trial, according to Dr. Vaidya.

“We’re confident of it. We haven’t had any issues at all,” says Michael Alvarado, a breast-cancer surgeon at the University of California, San Francisco, and one of the TARGIT trial investigators. He says UCSF offers IORT only to patients who fit select criteria and informs them that they have a slightly higher risk of recurrence and could need more radiation later.

Many breast-cancer experts say additional follow-up data from the TARGIT trial in coming years may settle some of the disputes. A separate trial in Italy is evaluating another form of IORT and a large randomized trial is underway in the U.S. to compare partial breast radiation using a balloon catheter with conventional radiation, but results won’t be available for several years.

In the meantime, experts say women diagnosed with early breast cancer should consult centers that offer a variety of options and weigh the pros and cons for

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themselves.

When Deborah Affonsa, a 56-year-old utility executive in San Francisco, was diagnosed with early-stage breast cancer a year ago, she chose to have IORT at UCSF, in part because “the risk seemed negligible and the convenience seemed huge,” she says. “I had this done on a Friday and I was back at work on Monday.”

**Write to** Melinda Beck at [HealthJournal@wsj.com](mailto:HealthJournal@wsj.com)

### **Corrections & Amplifications**

The Cleveland Clinic is collecting data on nearly 1,000 patients who have had the IORT treatment at 19 U.S. centers. An earlier version of this article incorrectly said data was being collected at 10 centers.

