

Radiation Can Be Safely Omitted for Select Patients With Locally Advanced Rectal Cancer

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New research from Dana-Farber Brigham Cancer Center and Memorial Sloan Kettering Cancer Center finds that radiation can be safely omitted in select patients with locally advanced rectal cancer

New data led by researchers at Dana-Farber Brigham Cancer Center and Memorial Sloan Kettering Cancer Center (MSK) and featured in the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting press program and simultaneously published in [The New England Journal of Medicine](#) (NEJM) and the Journal of Clinical Oncology [June 4] indicates that some patients with locally advanced rectal cancer with tumors that respond to chemotherapy can safely forego radiation before surgery.

Omitting radiation therapy from these patients' treatment plan can reduce short- and long-term side effects while providing similar outcomes in disease-free survival and overall survival.

The findings will be presented in the meeting's press and plenary sessions on June 4, 2023, by [Deb Schrag, MD, MPH](#) from MSK. [Harvey Mamon, MD, PhD](#), of Dana-Farber Brigham Cancer Center is the senior author of the study.

In 2023, [an estimated 47,000](#) people will be diagnosed with rectal cancer in the United States. Advances in treatment and early detection for colorectal cancer have led to a steady decrease in mortality rates, with the 5-year relative survival rate for locally advanced rectal cancer at 74%.

The phase III PROSPECT trial enrolled 1,194 patients from June 2012 to December 2018 with rectal cancer that had spread to nearby tissue or lymph nodes. Patients were randomly assigned to receive one of two treatment arms before a mesorectal excision, which is surgery to remove tumors in the rectum, bowel, and surrounding tissue. The first arm received the standard treatment of six weeks of chemoradiation therapy given before surgery, while the second arm received 12 weeks of the chemotherapy combination FOLFOX with chemoradiation therapy administered only if/when tumors did not shrink by 20% or more.

"The results of this practice changing study show that it is safe and effective to treat some locally

advanced rectal cancer with preoperative chemotherapy and use chemoradiation therapy selectively, rather than administer chemoradiation to all patients. This gives patients a new standard of care that has the potential to reduce side effects and, in some cases, may make treatment more convenient,” said Schrag, the lead author and Chair of the Department of Medicine at MSK. “Both the experimental ‘chemotherapy first approach’ and the standard ‘chemoradiation’ first approach achieved similar results in terms of overall survival, disease-free survival, and local recurrence. This empowers patients with treatment options and allows them to select the approach that is the best fit.”

After five years, there was no statistically significant difference between the two treatment arms in any of the endpoints studied, meaning that radiation therapy can be safely omitted before surgery if the tumor responds to treatment with FOLFOX chemotherapy. Additional highlights of the study include:

- Disease-free survival at five years was comparable, with 78.6% for patients who received preoperative chemoradiation therapy in the control group and 80.8% for patients who received preoperative chemotherapy with selective use of chemoradiation only if they did not respond to or tolerate the chemotherapy in the intervention group.
- Other endpoints, such as overall survival, the rate of radical resection, and pathologic complete response, were also comparable.
- 91% of patients who were randomized to the experimental group receiving FOLFOX did not require chemoradiation before surgery.
- When tumors respond to six cycles of preoperative FOLFOX chemotherapy, chemoradiation therapy can be safely omitted before rectal cancer surgery.

“In the current era of an increasing prevalence of early-onset colorectal cancer, this is particularly welcome news for women of child-bearing age who wish to preserve fertility,” said Mamon, Chief of Gastrointestinal Radiation Oncology at Dana-Farber Brigham Cancer Center. Mamon notes that the trial will continue to follow the participants for eight years and that the biospecimens contributed by patients are being interrogated to understand which tumors respond better to FOLFOX and which to chemoradiation. For now, he advises that, “the take-home message is that both treatments have similar outcomes with different toxicity profiles, and patients should work closely with their physicians to individualize their treatment plan.”

The study was funded by the Alliance for Clinical Trials in Oncology, one of the National Cancer Institute’s clinical trial consortia and recruited patients from over 200 practice sites primarily in the US, but also Canada and Switzerland.

This [news release](#) was published by Dana-Farber Cancer Institute on June 4, 2023.

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