

PROSPECT trial expands treatment options for patients with resectable rectal cancer

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The American Society for Radiation Oncology (ASTRO)



Gastrointestinal Cancers Resource Panel issued the following statement today regarding the <u>PROSPECT clinical trial</u> for patients with rectal cancer:

"The PROSPECT trial was designed to see if the <u>standard treatment</u> for locally advanced rectal <u>cancer</u>—pre-operative <u>radiation</u> therapy combined with low-dose chemotherapy—could be selectively replaced by more aggressive chemotherapy, known as FOLFOX, without radiation for patients who had a good initial response to chemotherapy. The assumption was that if chemotherapy alone was equally effective at treating the cancer, radiation therapy could be omitted. Patients in the trial were carefully monitored for treatment-related side effects and overall quality of life, in addition to cancer-related outcomes such as disease-free survival and length of time without cancer recurrence.

"The trial demonstrated that cancer-related outcomes were very similar between the two study groups, but contrary to many news reports, the conclusion was not that radiation therapy should be omitted. Why? In this study [published in the *Journal of Clinical Oncology*], the rate of significant side effects was actually higher with chemotherapy alone (41%) than with chemotherapy and radiation therapy combined (23%). The increased toxicities in patients who received chemotherapy alone included anxiety, appetite loss, constipation, depression, difficulty swallowing, shortness of breath, edema, fatigue, mouth sores, nausea, vomiting and neuropathy. With additional follow-up, these symptoms improved, but we are still awaiting outcomes on longer-term side effects, particularly neuropathy.

"While the trial did not explicitly conclude that radiation therapy should be omitted, it did confirm that patients now have an additional option of FOLFOX instead of chemoradiotherapy, depending on which toxicity profile they perceive as least disruptive. In the trial, patients' overall quality of life measurements were very similar with either treatment.



"It is also worth noting that the trial was deliberately limited to patients with a relatively narrow spectrum of rectal cancer stages, and the results do not apply to patients with large tumors, tumors low in the rectum near the anus or tumors with multiple enlarged lymph nodes. The chemotherapy arm included selective use of radiation, which was needed in 10% of patients, so even if patients choose chemotherapy alone, there is a 10% chance radiation may be needed, depending on how well the tumor responds to chemotherapy.

"Understanding the context of the trial is also essential. The goal of all cancer treatments is to maximize efficacy while minimizing side effects. There have been three standard treatments for <u>rectal cancer</u>: chemotherapy, radiation therapy and surgery. In PROSPECT, the goal was to selectively omit radiation, while continuing both chemotherapy and surgery. In parallel, there have been <u>other studies</u> of omitting surgery, while retaining chemotherapy and radiation. Selective omission of surgery is an increasingly popular approach which may also improve patient quality of life through <u>organ preservation</u>. For patients whose goal is to avoid surgery, both <u>chemotherapy</u> and <u>radiation therapy</u> are still required."

More information: Ethan Basch et al, Patient-Reported Outcomes During and After Treatment for Locally Advanced Rectal Cancer in the PROSPECT Trial (Alliance N1048), *Journal of Clinical Oncology* (2023). DOI: 10.1200/JCO.23.00903

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