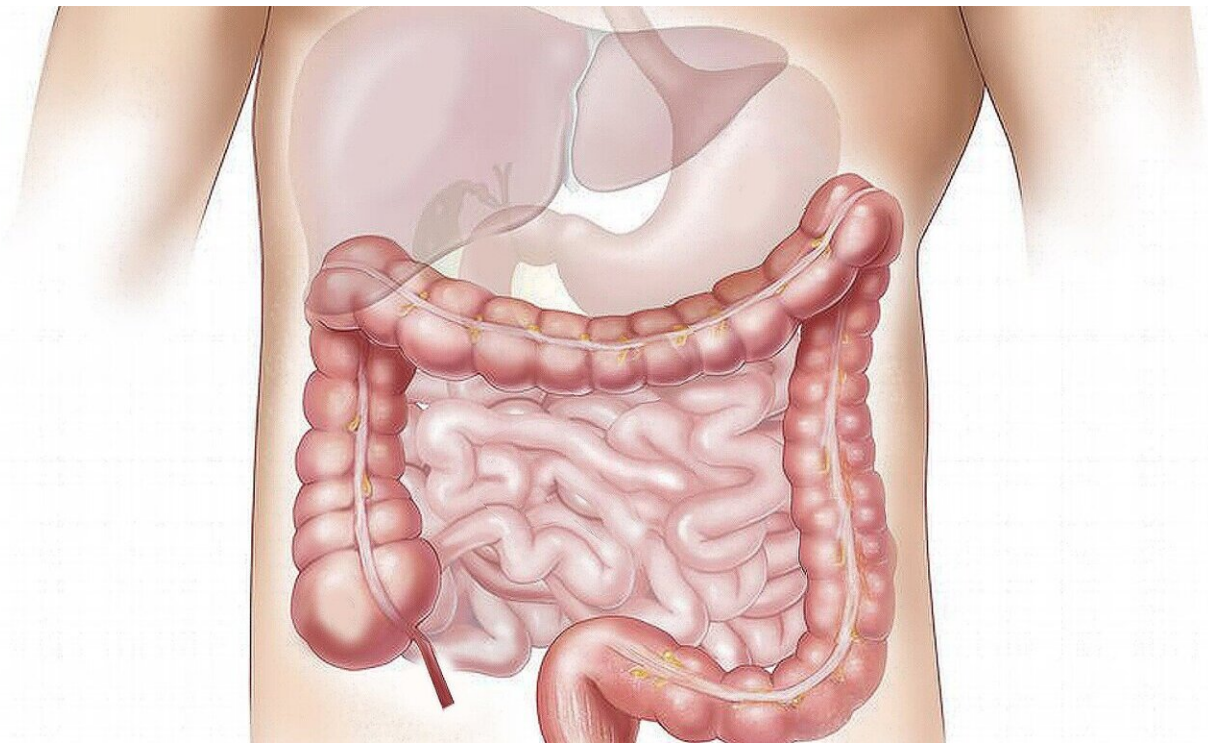


Anti-inflammatory drug celecoxib could reduce risk of colon cancer recurrence for a subset of patients

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An analysis of data from a randomized clinical trial for patients with stage 3 colon cancer found that those with PIK3CA mutations who took celecoxib, an anti-inflammatory drug, after surgery lived significantly

longer and had longer disease-free survival compared to those without the mutation. The study, highlighting a potential breakthrough in personalized cancer treatment, was led by clinical investigators at Dana-Farber Cancer Institute and Brigham and Women's Hospital.

These findings are the first clinical trial results to validate previous observations that adjuvant anti-inflammatory prostaglandin inhibitors, such as celecoxib, improve survival for PIK3CA-mutated colon cancer.

The results are [published](#) in the *Journal of Clinical Oncology*.

"These findings strengthen a growing body of evidence suggesting that prostaglandin inhibitors could benefit a subgroup of patients with colon cancer," says Jeffrey Meyerhardt, MD, MPH, senior author and co-director of the Colon and Rectal Cancer Center at Dana-Farber Cancer Institute. "They suggest a potential personalized approach to additional therapy for patients with early-stage colon cancer."

After primary treatment for stage 3 colon cancer, patients typically receive adjuvant chemotherapy intended to reduce the risk of the cancer returning. In a subset of these patients, the cancer returns, and those patients have few treatment options. Through [collaborative research](#) across Dana-Farber and BWH, researchers are looking for ways to improve adjuvant therapies and stave off recurrence.

To investigate the use of celecoxib on disease-free survival in patients with stage 3 colon cancer, Meyerhardt and colleagues initiated a [randomized clinical trial](#), the Alliance 80702 trial, in 2010. The trial enrolled 2,526 patients between 2010 and 2015. After treatment, patients were randomized to receive [adjuvant chemotherapy](#) with fluorouracil, leucovorin, and oxaliplatin (FOLFOX) for three or six months with or without daily celecoxib for three years. Those taking celecoxib showed a moderate benefit, but [the results](#), which were

published in 2021, were not statistically significant.

During the execution of that trial, new evidence suggested that [anti-inflammatory drugs](#) might benefit some patients with colon cancer, but not others. For instance, in 2012 Dana-Farber researchers [observed a signal](#) in the Nurses' Health Study and Health Professionals Follow-up Study, a long-term observational study of a broad spectrum of individuals. Patients in the study with colon cancer who regularly used aspirin, also an anti-inflammatory with a similar mechanism of action to celecoxib, had longer survival, but only if they had PIK3CA-mutated colon cancer. Other [observational studies](#) conducted since then have supported this association.

"We needed to do a subgroup analysis of the Alliance 80702 trial data to determine if PIK3CA mutations are a predictor of response to celecoxib," says first author Jonathan Nowak, MD, Ph.D., a molecular and gastrointestinal pathologist at Brigham and Women's Hospital and Dana-Farber and investigator in the Hale Family Center for Pancreatic Cancer Research at Dana-Farber.

In this new study, Meyerhardt, Nowak, and colleagues performed comprehensive genetic sequencing called whole exome sequencing on 1200 tumor samples from patients from the Alliance 80702 trial. They found that 22% of patients had tumors with PIK3CA mutations. The patients with PIK3CA-mutated tumors who received celecoxib lived significantly longer overall compared to patients without PIK3CA mutations who received celecoxib.

In this analysis, a patient's risk of dying was reduced by about 50%, and by about 60% when excluding patients who were using [low-dose aspirin](#) for reasons not related to their cancer treatment. Disease-free survival was also improved but did not reach statistical significance.

"If these results are confirmed in other ongoing studies, it will be important for physicians to understand the genetics within the tumors of patients with early-stage [colon cancer](#) to determine which patients may benefit from [celecoxib](#) in addition to other standard treatments," says Meyerhardt.

More information: Jonathan Nowak et al, Improved survival with adjuvant COX-2 inhibition in PIK3CA-activated stage III colon cancer: CALGB/SWOG 80702 (Alliance), *Journal of Clinical Oncology* (2024). ascopubs.org/doi/abs/10.1200/JCO.23.01680

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