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Global study sets new risk-based standard to personalize chemotherapy for colon cancer

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After surgery for lymph-node positive colon cancer (stage III), some patients may only need half of the long-standing standard course of chemotherapy. In an analysis of six clinical trials with over 12,800 patients, 3 months of chemotherapy was nearly as effective as 6 months in patients with relatively lower recurrence risk and caused fewer side effects, particularly nerve damage.

These data will be presented in ASCO's Plenary Session, which features four abstracts deemed to have the greatest potential to impact patient care, out of the more than 5,000 abstracts featured as part of the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting.

Chemotherapy lowers the chance of cancer recurrence after colon cancer surgery. Since 2004, the standard (adjuvant) treatment after surgery has been a combination of chemotherapies (FOLFOX or CAPOX), given over a period of six months.

The goal of this study, which pooled data from 6 studies conducted in North America, Europe, and Asia, was to determine if 3 months of chemotherapy was as effective as 6 months. While the primary endpoint was not proven statistically, a shorter, 3-month course of chemotherapy was associated with a less than 1% lower chance of being colon cancer free at 3 years compared to the standard 6-month course (74.6% vs. 75.5%). In patients considered at low risk of cancer recurrence (60% of patients in the study), the difference was even smaller (83.1% in patients receiving a 3-month course vs. 83.3% in patients receiving a 6-month

course).

"Our findings could apply to about 400,000 colon cancer patients worldwide every year. For 60% of these patients, who have lower risk for cancer recurrence, 3 months of chemotherapy will likely become the new standard of care," said senior study author Axel Grothey, MD, an oncologist at the Mayo Clinic Cancer Center in Rochester, Minn. "Patients with higher risk colon cancer, however, should discuss these results with their doctor to see if a shorter course of therapy would be right for them, taking into account their preference, age, and ability to tolerate chemotherapy."

A key side effect of one of the chemotherapies in the regimen - oxaliplatin - is nerve damage, which can result in permanent numbness, tingling, and pain. The longer a patient receives oxaliplatin, the greater the chance for severe and long-lasting nerve damage. Nerve damage (numbness/tingling of the hands and feet) was substantially less common in patients receiving a 3-month course of chemotherapy vs. a 6-month month course (15% vs. 45% with FOLFOX and 17% vs. 48% with CAPOX).

"Many side effects of chemotherapy, such as hair loss, go away over time, but nerve damage is a side effect some patients have to deal with for the rest of their lives," said Dr. Grothey.

About the Study

This study is a prospective, pre-planned analysis of pooled data from six concurrent, phase III clinical trials conducted in 12 countries. It was established more than 10 years ago as so-called IDEA collaboration (International Duration Evaluation of Adjuvant therapy). A steering committee oversaw the study design, and an independent statistical center reviewed the results from all six clinical trials (findings from

three of which are being presented at the ASCO Annual Meeting). The study received public funding only.

"We needed this large number of patients to answer the study question, but at the time this study began in 2007 it was not possible to run one study of that size anywhere in the world," said Dr. Grothey. "With more than 12,834 patients, this is the largest collaboration of its kind in oncology."

Key Findings

Patients were followed for a median time of 39 months. For all patients combined, the rate of disease-free survival at 3 years was slightly lower with 3 months of chemotherapy than with 6 months of chemotherapy (74.6% vs. 75.5%). The type of chemotherapy regimen selected affected the difference in 3-year disease-free survival between the 3-month and 6-month treatment duration (75.9% vs. 74.8% with CAPOX and 73.6% vs 76.0% with FOLFOX), although the difference was relatively small in both cases.

In the subset of patients with lower risk colon cancer (defined as cancer spread to 1-3 lymph nodes and not completely through the bowel wall), the disease-free survival rate at 3 years was almost identical for those who received 3 (83.1%) and 6 months of chemotherapy (83.3%).

The rate of clinically meaningful (grade 2 or greater) nerve damage differed depending on the type of chemotherapy regimen received, but was consistently higher for people who received 6 months versus 3 months of chemotherapy (45% vs. 15% with FOLFOX and 48% vs. 17% with CAPOX).

"Aside from nerve damage, longer chemotherapy also means more diarrhea and fatigue, more doctor appointments, blood draws, and time

away from work and social interactions," said Dr. Grothey.

"This is extremely important work that will affect the lives of many of my patients hopefully tomorrow, and will allow us to provide a more personalized approach to our patients with colon cancer. Although addressing the question, 'can we give less treatment?' is of major importance to patients and their doctors, it is rare to see this type of study. Given that these questions are unlikely to be of interest to the pharmaceutical industry, federal support for these trials is critical," said Dr. Baxter.

More information:
abstracts.asco.org/199/AbstView_199_188616.html

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