

WEB EXCLUSIVES

Avastin Falls Short in Early-Stage Colon Cancer

BY MELISSA WEBER

Adding Avastin (bevacizumab) to standard chemotherapy after surgery failed to extend the time early-stage colon cancer patients were free of recurrence. “The hope was because bevacizumab in metastatic colon cancer can prolong survival, by adding it to a regimen in early-stage colon cancer, we could increase the rate of cure,” said lead investigator Norman Wolmark, MD, of Allegheny General Hospital in Pittsburgh, at a press briefing. “We failed.”

The phase III study randomly assigned 2,710 patients with stage 2 or stage 3 colon cancer to receive six months of FOLFOX chemotherapy (5-FU, leucovorin, and Eloxatin [oxaliplatin]) alone or in combination with Avastin. Patients in the Avastin arm received an additional six months of the drug. After a median follow-up of three years, 77.4 percent of patients in the Avastin group were free of disease compared with 75.5 percent who received chemotherapy alone. This slight difference was found to be statistically insignificant, meaning it could have occurred by chance.

Although the study established that the experimental regimen doesn't work, it offered some useful information, Wolmark told reporters. During the 12 months that Avastin was given, investigators saw a favorable effect: 94.3 percent of patients taking Avastin were free of disease after one year versus 90.7 percent in the chemotherapy-only arm. “Once the bevacizumab was stopped, that effect disappeared,” said Wolmark. “So, clearly, strong consideration should be given to clinical trials that use bevacizumab for periods of time well beyond the one year that was used in [our study]. We hope to start a trial in the not-too-distant future where we do use bevacizumab for a period of two years.

Results are expected within the next year from a similar phase III trial, known as AVANT, which is comparing FOLFOX alone, FOLFOX plus Avastin, and Avastin plus XELOX (Xeloda [capecitabine] and Eloxatin) in early-stage colon cancer. “We certainly hope for the sake of our patients that it will be a grand hoorah,” Wolmark said at the briefing. “Unfortunately, I suspect it will simply confirm the observations we saw [in our study]—that bevacizumab's only effective while it's given.”

Following Wolmark's presentation to his peers on Sunday, Lee Ellis, of M.D. Anderson Cancer Center in Houston, offered insight for the cancer professionals in attendance. Ellis reiterated Wolmark's hope that the AVANT trial is positive when data are analyzed, but he cautioned that if AVANT is negative, researchers should not conduct studies looking at longer duration and should instead look to

new agents for early-stage colon cancer after surgery. He added that long-term use of Avastin would result in increased costs, risk of side effects, and patient inconvenience (Avastin is administered intravenously every three weeks).