

## Chemotherapy drug improves survival following surgery for pancreatic cancer

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Among patients with pancreatic cancer who had surgery for removal of the cancer, treatment with the drug gemcitabine for 6 months resulted in increased overall survival as well as disease-free survival, compared with observation alone, according to a study in the October 9 issue of *JAMA*.

"Pancreatic cancer is a disease with a poor prognosis, mainly because of the inability to detect the tumor at an early stage, its high potential for early dissemination, and its relatively poor sensitivity to chemotherapy or radiation therapy," according to background information in the article. Even after complete removal of the tumor, the vast majority of patients relapse within 2 years, leading to a 5-year survival rate of less than 25 percent. No consensus has been reached on a standard treatment approach for additional therapy. Gemcitabine-based chemotherapy is standard treatment for advanced pancreatic cancer, but its effect on survival after surgery has not previously been demonstrated.

Helmut Oettle, M.D., Ph.D., of the Charite-Universitatsmedizin Berlin, Germany, and colleagues conducted follow-up of a randomized trial that previously reported improvement in disease-free survival with adjuvant (in addition to surgery) gemcitabine therapy to determine if this treatment improved overall survival. Patients with macroscopically (observation made by the unaided eye) completely removed pancreatic cancer entered the study between July 1998 and December 2004 in 88 hospitals in Germany and Austria; follow-up ended in September 2012. Patients were randomly assigned to either adjuvant gemcitabine treatment for 6 months or to observation alone.



A total of 368 patients were randomized, and 354 were eligible for intention-to-treat-analysis. By September 2012, 308 patients (87.0 percent) had relapsed. The median (midpoint) follow-up time was 136 months (11.3 years). The median disease-free survival was 13.4 months in the treatment group compared with 6.7 months in the observation group.

By the end of the follow-up period, 316 patients (89.3 percent) had died and 38 patients were still alive, 23 in the treatment group and 15 in the observation group. The researchers found a statistically significant difference in overall survival between the study groups, with a median of 22.8 months in the gemcitabine group compared with 20.2 months in the observation group. There was also a statistically significant absolute 10.3 percent improvement in the 5-year overall survival rate (20.7 percent vs. 10.4 percent) and a 4.5 percent improvement in the 10-year survival rate (12.2 percent vs. 7.7 percent), compared with observation alone.

"[These] data show that among patients with macroscopic complete removal of pancreatic cancer, the use of adjuvant gemcitabine for 6 months compared with observation resulted in increased overall survival as well as disease-free <u>survival</u>. These findings support the use of gemcitabine in this setting," the authors conclude.

More information: doi:10.1001/jama.2013.279201

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