

After resection, common treatment of pancreatic cancer as effective as chemotherapy drug dose

September 7 2010

Use of gemcitabine, a drug that can be effective in treating advanced and resected pancreatic cancer, did not result in improved overall survival after pancreatic cancer resection (surgical removal) compared to patients who received fluorouracil and folinic acid, another treatment regimen that has shown effectiveness, according to a study in the September 8 issue of *JAMA*.

"Pancreatic cancer is one of the major causes of cancer death globally, with a 5-year survival rate of less than 5 percent. The outlook for those patients who can undergo surgical resection is better, and in specialized centers, resection rates greater than 15 percent can be achieved. Although surgery cannot guarantee a cure, the 5-year survival does improve to around 10 percent following resection. There is a clear need to improve long-term survival in these patients," the authors write.

John P. Neoptolemos, M.D., of the University of Liverpool, U.K., and colleagues conducted a study to determine whether fluorouracil or gemcitabine is superior in terms of overall survival as adjuvant (supplemental) chemotherapy treatment following resection of pancreatic cancer. The European Study Group for Pancreatic Cancer (ESPAC)-3 trial was conducted in 159 pancreatic cancer centers in Europe, Australasia, Japan, and Canada. Included in ESPAC-3 version 2 (the trial was modified) were 1,088 patients with pancreatic ductal adenocarcinoma who had undergone cancer resection; patients were



randomized between July 2000 and January 2007 and underwent at least 2 years of follow-up. Patients received either fluorouracil plus folinic acid (leucovorin, an active metabolite of folic acid, which counteracts some of the toxic effects of some chemotherapy drugs) (n = 551) or gemcitabine (n = 537) for 6 months.

During the trial, 753 patients (69 percent) had died at the time of analysis (388 [70 percent] in the fluorouracil plus folinic acid group and 365 [68 percent] in the gemcitabine group). Median (midpoint) length of follow-up of 335 living patients was 34.2 months, equal across treatment groups. Overall, 282 of patients remaining alive (84 percent) had undergone follow-up for more than 2 years. Median survival for patients treated with fluorouracil plus folinic acid was 23.0 months and for patients treated with gemcitabine was 23.6 months.

Estimates of survival at 12 and 24 months were 78.5 percent and 48.1 percent, respectively, for the fluorouracil plus folinic acid group and 80.1 percent and 49.1 percent for the gemcitabine group. Analysis indicated no statistically significant difference in survival estimates between the treatment groups.

"Seventy-seven patients (14 percent) receiving fluorouracil plus folinic acid had 97 treatment-related serious adverse events, compared with 40 patients (7.5 percent) receiving gemcitabine, who had 52 events. There were no significant differences in either progression-free survival or global quality-of-life scores between the treatment groups," the authors write.

"In conclusion, gemcitabine did not result in improved overall survival compared with fluorouracil plus folinic acid in patients with resected pancreatic cancer."

More information: JAMA. 2010;304[10]:1073-1081.



Provided by JAMA and Archives Journals

Citation: After resection, common treatment of pancreatic cancer as effective as chemotherapy drug dose (2010, September 7) retrieved 22 November 2023 from https://medicalxpress.com/news/2010-09-resection-common-treatment-pancreatic-cancer.html

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