

Radioimmunotherapy, Gemcitabine combination shows early promise for metastatic pancreatic ductal cancer

May 20 2014

A combination of several small doses of an investigational radioimmunotherapy and the chemotherapy gemcitabine had superior outcomes compared with radioimmunotherapy alone in patients with metastatic pancreatic ductal cancer, according to phase Ib clinical trial data presented at the AACR special conference on Pancreatic Cancer: Innovations in Research and Treatment, held May 18-21.

"Radiation therapy is an effective therapy against most cancers, including [pancreatic cancer](#)," said Vincent J. Picozzi Jr., M.D., director of the Pancreas Center of Excellence at the Virginia Mason Medical Center's Digestive Disease Institute. "However, an antibody that can recognize a target found only on most pancreatic [cancer cells](#) and that can carry a radioactive source with it has the potential to kill cancer cells throughout the body, as opposed to conventional [radiation therapy](#), which is delivered as a 'beam' to a specific area of the body."

One such radioimmunotherapy, 90Y-clivatuzumab tetraxetan, was used in this trial: PAM4 is the antibody and yttrium-90 (90Y) is the source of radiotherapy, and they are held together by a linker.

"The antibody binds to a protein called MUC5ac, which is a protein found on the surface of most pancreatic cancer cells, but not normal cells," explained Picozzi. "90Y, a radioactive form of yttrium that emits radiation over a distance of about a quarter of an inch, is attached to this

antibody.

"We found that 90Y-clivatuzumab tetraxetan, when used with low-dose gemcitabine, is a safe, low-side-effect therapy that can prolong survival for at least some [patients](#) with metastatic pancreatic cancer, even when no chemotherapy options exist," he added. "Our studies imply that radiolabelled antibodies are safe to use in advanced pancreatic cancer, and that it may be possible to attach other anticancer agents besides 90Y to clivatuzumab tetraxetan to fight pancreatic cancer."

In this trial, 58 patients, median age 63.5 years, including 33 males, who received at least two prior therapies, were randomly assigned to either arm A (29 patients) or arm B (29 patients). Patients from both arms received 6.5 mCi/m² 90Y-clivatuzumab tetraxetan for three weeks, divided into multiple smaller doses per cycle. Patients from arm A also received low-dose gemcitabine for one week and then in combination with the radioimmunotherapy for three weeks in each cycle. Patients received treatment for up to nine cycles, with four-week delays in between. The goal was to determine the safety and efficacy of this approach in this advanced population and evaluate the contribution of low-radiosensitizing doses of gemcitabine to the regimen.

Twenty-seven and 26 patients from arms A and B, respectively, completed at least one cycle of treatment. Patients terminated treatment due to disease progression or clinical deterioration, but 12 and 11 patients from arms A and B, respectively, completed two or more cycles of treatment.

The investigators found that the patients from arm A were 45 percent more likely to live longer, compared with patients from arm B. For patients who received only one treatment cycle, there was little survival difference between arm A and arm B. However, the overall survival was 7.9 months and 3.4 months, respectively, for patients from arm A and

arm B who received multiple cycles of treatment.

In arm A, two patients had partial responses, and three patients are still alive 13 and 15 months after the start of their treatment.

Side effects were minimal, and the only clinically significant side effect that occurred with any frequency was reduction in blood counts, said Picozzi.

A larger, randomized phase III trial is underway to confirm these results.

"Patients are experiencing gradually increasing success in treating pancreatic cancer, even in advanced disease," said Picozzi. "There are a variety of new approaches being developed for the treatment of pancreatic cancer, among the most promising of which is using the immune system in various ways to fight it."

Provided by American Association for Cancer Research

Citation: Radioimmunotherapy, Gemcitabine combination shows early promise for metastatic pancreatic ductal cancer (2014, May 20) retrieved 10 April 2024 from <https://medicalxpress.com/news/2014-05-radioimmunotherapy-gemcitabine-combination-early-metastatic.html>

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