Chemotherapy Regimen Extends Life by Nearly Twenty Months for People With Pancreatic Cancer

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ASCO Perspective

“Pancreatic cancer is notoriously aggressive and typically has a poor prognosis, so it is a major win to find that a new treatment regimen significantly improves survival for patients with this disease,” said ASCO Expert Andrew Epstein, MD.

CHICAGO – In a randomized phase III trial people with surgically removed pancreatic cancer who received mFOLFIRINOX, a chemotherapy regimen containing four different medicines, lived a median of 20 months longer and were cancer-free nine months longer than those who received the current standard of care, gemcitabine (Gemzar®).

The study will be featured in a press briefing today and presented at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting.

“For the first time, our trial shows a large benefit from adjuvant FOLFIRINOX chemotherapy
over standard chemotherapy with gemcitabine, showing we can help patients with pancreatic cancer live much longer,” said lead study author Thierry Conroy, MD, a medical oncologist and director of the Institut de Cancerologie de Lorraine in Nancy, one of the UNICANCER comprehensive cancer centers in France. “In addition, we were encouraged to see that the results were better than expected when we planned this trial.”

After pancreatic cancer surgery, adjuvant chemotherapy with gemcitabine can substantially prolong survival compared to surgery alone, as well as increase the number of patients who are cured, meaning patients who are healthy again and will probably not relapse from pancreatic cancer (at 5 years, about 21% with gemcitabine vs. 10% with surgery alone). Gemcitabine has been the standard adjuvant therapy for the past 10 years.

**About the Study**
The PRODIGE 24/CCTG PA.6 trial enrolled patients with non-metastatic pancreatic ductal adenocarcinoma (PDAC) who had surgery that removed all or nearly all of the tumor (meaning no cancer cells visible to the surgeon after surgery, but microscopic tumoral cells may have remained). PDAC is the most common type of pancreatic cancer and accounts for 90% of all cases. Surgery is possible in only 10-20% of patients with pancreatic cancer overall. In the United States, an estimated 55,400 people will be diagnosed with pancreatic cancer in 2018.

Three to 12 weeks after surgery, 493 patients were randomly assigned in France and in Canada to receive either gemcitabine or mFOLFIRINOX for six months. The mFOLFIRINOX regimen combines four chemotherapy medicines: oxaliplatin (Eloxatin®), leucovorin (folinic acid), irinotecan (Camptosar®), and 5-fluorouracil (Adrucil®). A very similar regimen is already used as an initial treatment for metastatic pancreatic cancer, and this study shows FOLFIRINOX can also benefit patients with earlier-stage disease.

**Key Findings**
At a median follow-up of 33.6 months, the median length of time without recurrence of pancreatic cancer (disease-free survival) was much longer in the mFOLFIRINOX group than in the gemcitabine group (21.6 months vs. 12.8 months), as was the median overall survival (54.4 months with mFOLFIRINOX vs. 35.0 months with gemcitabine). The benefit of the mFOLFIRINOX is observed in all subgroups of patients. mFOLFIRINOX also markedly extended
the time until metastases appeared (median 30.4 months vs. 17.0 months with gemcitabine).

Overall, more patients experienced severe side effects (mainly hematologic) in the mFOLFIRINOX group than in the gemcitabine group (76% vs. 53%), but the side effects were manageable, according to the authors. One treatment-related death occurred in the gemcitabine group, and none in the mFOLFIRINOX group.

The types of side effects also differed between the two groups. The most common side effects of gemcitabine were headache, fever, flu-like symptoms, swelling, and low white blood cell counts. Patients who received mFOLFIRINOX had more diarrhea, nausea, vomiting, and fatigue. There was no difference in the risk of febrile neutropenia (a dangerous complication characterized by fever and low white blood cell counts) between the two groups.

Past medical history of ischemic heart disease represents a risk with either regimen, but particularly mFOLFIRINOX. Patients should be assessed for underlying heart disease before starting this adjuvant treatment, a precaution that is routine for many people with cancer receiving surgery and chemotherapy.

**Next Steps**

The next step will be to explore the timing of chemotherapy. Patients may benefit from receiving chemotherapy before surgery (neoadjuvant chemotherapy) to shrink the tumor, to destroy undetectable micrometastases and increase the chance that the tumor can be completely removed through surgery. Dr. Conroy noted that mFOLFIRINOX appears to be a good candidate for neoadjuvant chemotherapy. Another option is to give half the cycles of chemotherapy before, and the other half after surgery (perioperative chemotherapy.) Ongoing clinical trials are already testing both of these approaches.

This study, sponsored by UNICANCER, Paris, France, received funding from the Institut National du Cancer in France, French national Ligue against cancer, Canadian Cancer society and “7 days in May,” a charity cycling event in Canada.

**Study at a Glance**

<table>
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<tr>
<th>Disease</th>
<th>Pancreatic Cancer</th>
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<td>Trial Phase, Type</td>
<td>Phase III, Randomized</td>
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Patients on Trial | 493
---|---
Intervention Tested | Adjuvant mFOLFIRINOX vs. gemcitabine (standard of care)
Primary Finding | mDFS 21.6 months with mFOLFIRINOX vs. 12.8 months with gemcitabine
Secondary Finding(s) | mOS 54.4 months with mFOLFIRINOX vs. 35 months with gemcitabine

View the full abstract.

For your readers:
- Guide to Pancreatic Cancer (Câncer de pancreas)
- Understanding Chemotherapy (Qué es la quimioterapia)

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