More Aggressive Approach Shows Promise for Locally Advanced Liver Cancer

Sintilimab plus chemotherapy infused into a liver artery may offer the chance for a cure.

July 12, 2021 By Liz Highleyman

The experimental checkpoint inhibitor sintilimab plus chemotherapy infused directly into the hepatic artery led to good outcomes for people with locally advanced hepatocellular carcinoma (HCC), the most common type of liver cancer, according to a presentation at the 2021 International Liver Congress.

This treatment "offers a chance for advanced HCC to be cured," Li Xu, MD, PhD, of Sun Yat-sen University Cancer Center in China, said during a conference press briefing.

Hepatitis B, hepatitis C, fatty liver disease, heavy alcohol use and other causes can lead to serious liver disease, including cirrhosis and liver cancer. HCC is often diagnosed late and is difficult to treat. In general, it responds poorly to traditional chemotherapy but immunotherapy has produced good outcomes in several studies.

Xu and her colleagues tested the experimental PD-1 checkpoint inhibitor sintilimab plus hepatic arterial infusion chemotherapy (HAIC) using a regimen known as FOLFOX in people with locally advanced HCC that had invaded the hepatic blood supply but had not yet spread beyond the liver

Sintilimab is a monoclonal antibody that helps the immune system fight cancer. PD-1 is a checkpoint protein on T-cells that regulates immune function. Some tumors can hijack PD-1 to turn off immune responses against them; PD-1 checkpoint inhibitors can restore T-cell activity. The Food and Drug Administration is now considering approval of sintilimab for lung cancer.

Liver cancer is common in China, most often due to hepatitis B. Chinese experts favor a more aggressive approach to treatment, according to Xu. While surgery is usually not considered for people with advanced HCC in the United States, surgical resection is an option in China for patients with vascular invasion but no metastasis outside the liver.

This analysis included 30 people with locally advanced HCC; one withdrew from the study. More than 90% were men, the median age was 51 years and most had hepatitis B; just over half had a

single tumor while the rest had multiple nodules.

The participants received FOLFOX HAIC plus IV infusions of sintilimab every three weeks. They were assessed after two cycles, and if their tumors shrank, they were considered for surgery. Those who underwent surgery continued to received sintilimab every three weeks until they experienced disease progression or unacceptable side effects or completed 16 cycles. Those who were not eligible for surgery after the first two cycles of treatment received another two cycles and were reassessed.

Thirteen patients experienced partial tumor shrinkage, for an overall response rate of 45%. Another 11 had stable disease, yielding a disease control rate of 83%. Nearly three quarters (21 out of 29) became eligible for surgery, mostly after the first two treatment cycles. Of these, 19 underwent hepatectomy (partial removal of the liver) while two received radiofrequency ablation (a procedure that uses radio waves to destroy tumors). Four patients went on to achieve a pathological complete response, or full remission.

Among all treated patients, the median progression-free survival (PFS) time was 15.7 months, and the 12-month PFS rate—meaning they were still alive without disease progression—was 58%. The median PFS was just 5.5 months for patients who did not undergo surgery but it was not reached in the surgery group because a majority were still responding. The 12-month overall survival rate was 82%.

Xu said that these outcomes for people with advanced liver cancer were “almost equal” to outcomes for people with early and middle-stage HCC in other studies.

The therapy was generally safe, but side effects were common. About 90% of participants experienced some treatment-related adverse events, but these were mostly mild to moderate. Four people had severe (Grade 3 to 4) adverse events and one stopped treatment for this reason. This patient experienced severe immune-related liver dysfunction, which can result when checkpoint inhibitors restore immune activity.

FOLFOX HAIC plus sintilimab is a “safe and successful conversion therapy” that provides “outstanding progression-free survival,” Xu concluded. Although most patients in this study had hepatitis B, she suggested the same approach might be beneficial for people with other causes of liver cancer.

“We highly recommend that investigators in other countries do some trials of these new strategies,” she said. “Maybe more and more patients with advanced HCC could be cured.”

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