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'MICRO'-CHEMO AND CANCER PILL COMBO TESTED IN LIVER CANCER PATIENTS

A combination of an oral drug, called sorafenib, and a method for injecting microbeads of chemotherapy directly into tumors has been proven safe for liver cancer patients and may improve outcomes for those who have these fast-growing, deadly tumors whose numbers are on the rise in the U.S.

Reporting in the Sept. 12 online version of the *Journal of Clinical Oncology*, Johns Hopkins investigators tested the combination in 35 patients with advanced, inoperable liver cancer. Both sorafenib and the chemotherapy drug used in this study, doxorubicin, have independently – but not in combination -- been approved to treat liver cancer.

Combining the right therapies at the right time is an intense focus of study among cancer experts, and Johns Hopkins interventional radiologist Jean-Francois Geschwind, M.D., saw promise in the two therapies tested in the current study.

“Both therapies have increased survival rates in advanced liver cancer, and combining them may push those survival rates further,” says Geschwind, professor of radiology, surgery and oncology at Johns Hopkins.

For the study, Geschwind employed a method called chemoembolization that uses catheters the size of a single hair to deliver microbeads filled with high concentrations of the chemotherapy drug, doxorubicin, directly to the tumor. The chemotherapy seeps out of the microbead for at least three weeks.

Sorafenib, approved for its ability to block a key pathway, depriving tumors of blood vessels, was given twice daily to patients one week before their chemoembolization procedure. “The idea is to block blood vessel formation in these cancers, which typically peaks 24 to 36 hours after chemoembolization. This may help prolong the chemotherapy’s impact.” says Geschwind.

Patients treated with the combination had no more side effects than reported for sorafenib or chemoembolization alone, according to Geschwind. Common side effects included fatigue, skin reactions in hands and feet, and body rash.

Patients in the study were admitted to the hospital overnight for their chemoembolization treatment. The patients continued oral sorafenib twice daily until their disease progressed. For the study, Geschwind says that patients received up to four chemoembolization treatments within a six-month period.

Primary liver cancer incidence is rising in the U.S., says Geschwind, because of increasing rates of hepatitis C infections, which cause liver inflammation and are major risk factors for liver cancer.

Liver cancer tends to grow rapidly and without specific symptoms. Measures of a liver cancer marker called alpha-fetoprotein are elevated in only half of patients, adds Geschwind, making it difficult to find the disease early.

When the cancer is confined to the liver, doctors can transplant or remove the liver, but three-quarters of patients are not eligible for surgery. Without treatment, median survival of these inoperable patients is typically less than nine months. Chemoembolization procedures add 10 to 15 months of survival.

A phase III trial comparing chemoembolization with or without sorafenib is under way at Johns Hopkins and 100 other sites in the U.S. "We're on the path to improving the standard of care for liver cancer," says Geschwind.

The study was funded by Bayer Health-Care and Onyx Pharmaceuticals, manufacturer of sorafenib, and Biocompatibles, makers of the microbeads.

Researchers involved in the study include Timothy Pawlik, Diane Reyes, David Cosgrove, and Ihab Kamel, Nikhil Bhagat of Johns Hopkins.

Pawlik and Geschwind are consultants to Bayer HealthCare Pharmaceuticals, and Geschwind is a consultant to Biocompatibles. The terms of these arrangements are being managed by the Johns Hopkins University in accordance to its conflict-of-interest policies.

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