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## ■ Grapefruit juice boosts drug's anti-cancer effects

April 20, 2009

In a small, early clinical trial, researchers at the University of Chicago Medical Center have found that combining eight ounces of grapefruit juice with the drug rapamycin can increase drug levels, allowing lower doses of the drug to be given. They also showed that the combination can be effective in treating various types of cancer.

For two decades, pharmacists have pasted do-not-take-with-grapefruit-juice stickers on various pill bottles because it can interfere with the enzymes that break down and eliminate certain drugs. This interference makes the drugs more potent. In data presented at the AACR 100th Annual Meeting 2009, the Chicago researchers examine ways to exploit this fruit's medication-altering properties.

"Grapefruit juice can increase blood levels of certain drugs three to five times," said study director Ezra Cohen, MD, a cancer specialist at the University of Chicago Medical Center. "This has always been considered a hazard. We wanted to see if, and how much, it could amplify the availability, and perhaps the efficacy of rapamycin, a drug with promise for cancer treatment."

This trial was designed to test "whether we could use this to boost rapamycin's bioavailability to the patient's advantage, to determine how much the juice altered drug levels, and to assess its impact on anti-cancer activity and side effects," he said.

The study followed 28 patients with advanced solid tumors, for which there is no effective treatment. The dose of the drug increased with each group of five patients, from 15 milligrams up to 35. Patients took the drug by mouth, as a liquid, once a week.

Beginning in week two, they washed it down with a glass of grapefruit juice (*Citrus paradisi*), taken immediately after the rapamycin and then once a day for the rest of the week.

Twenty-five participants remained in the study long enough to be evaluated. Seven of those 25 (28 percent) had stable disease, with little or no tumor growth. One patient (4 percent) had a partial response, with the tumor shrinking by about 30 percent. That patient is still doing well more than a year after beginning the trial.

"My first cancer doctor gave me five years to live," said that patient, Albina Duggan of Bourbonnais, IL. "That time runs out

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next July."

Duggan, mother of four, has a rare cancer, an epithelioid hemangioendothelioma that originated in the liver and subsequently spread to two vertebrae in the neck and to the lymph nodes. She had surgery and radiation therapy and was evaluated for a liver transplant, but evidence of cancer beyond the liver made her ineligible for a transplant. She "shopped around" for other therapies and was able to keep the disease in check for a year with sorafenib, a drug approved for kidney and liver cancers.

After a year of stable disease, however, her tumor began growing again and she had to look for an alternative therapy. Her doctors at the University of Chicago offered three clinical trials. The most appealing to her was the rapamycin plus grapefruit juice study. She took her first dose March 11, 2008, and is still on the drug-juice combination.

"My tumor is smaller and it's no longer growing. I feel fine. I can do whatever I like and I have no real side effects," she said. "What's not to like?"

Trial subjects do not like the taste of rapamycin. "It's not pleasant," Duggan admitted. She has also tired of grapefruit juice.

Many patients in the study did report side effects. More than half experienced elevated blood sugar levels, diarrhea, low white blood cell counts or fatigue.

Duggan, more fortunate than most, has had milder side effects, including fragile toe and finger nails and curly hair. "I now have very curly hair," she said, "seriously curly. I have to adjust to it."

Rapamycin, also known as sirolimus, was originally developed to suppress the immune system, preventing rejection in patients receiving a transplanted kidney. Cancer specialists became interested in the drug when they learned that it disrupted a biochemical pathway involved in the development of the new blood vessels that tumors need to grow. But the drug is expensive and poorly absorbed. Less than 15 percent of rapamycin is absorbed when taken by mouth.

This study showed that substances known as furanocoumarins, plentiful in some forms of grapefruit juice, can decrease the breakdown of rapamycin. This makes the drug reach higher levels in the bloodstream, two to four times the levels seen without a juice boost, and thus increases the amount of the drug that reaches its targets.

"That means more of the drug hits the target, so we need less of the drug," said Cohen.

Many of the newer cancer medications, precisely focused on specific targets, are now taken as pills rather than intravenously. Some of these drugs, including rapamycin, can cost thousands of dollars a month. Hence, "this is an opportunity for real savings," Cohen said. "A daily glass of juice could lower the cost by 50 percent."

The study will be presented at the AACR's 100<sup>th</sup> Annual Meeting in Denver in a session on "Late-Breaking Research: Clinical Research 1: Phase I-III Clinical Trials," Poster Section 27, from 1 to 5 p.m. on Monday, April 20, 2009.

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