Take With Food: Study Tests Lowering Dose of Prostate Cancer Drug

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Findings from a new clinical trial suggest that a much smaller dose of the cancer drug abiraterone (Zytiga) taken with a low-fat breakfast may be as effective as the full dose taken on an empty stomach, as directed on the drug's label.

It's unclear from the study whether, over the long term, patients taking the lower dose will do as well as those taking the full dose in terms of how long they live overall. But as concern continues to mount about the increasing cost of cancer drugs, the trial's findings raise the prospect that something as simple as taking some cancer drugs with food may help to address the issue.

In the small clinical trial, Mark Ratain, MD, of the University of Chicago, and his colleagues tested whether they could exploit what is known as the food effect to reduce the needed dose of abiraterone, a standard treatment for men with metastatic prostate cancer.

Men who took one-quarter of the normally prescribed dose of abiraterone with food had similar reductions in prostate-specific antigen (PSA) levels—a biomarker used to track prostate cancer progression—as men who took the full dose on an empty stomach, they reported March 28 in the Journal of Clinical Oncology.

Although it is effective in slowing the progression of metastatic cancer, abiraterone is one of the most expensive drugs on the market, explained William Figg, Sr., PharmD, of NCI's Center for Cancer Research, an investigator on the study. "We're trying to find ways to offset the exorbitant cost of these cancer drugs, and this is one potential approach," Figg said.

Full Stomach, Smaller Dose

Many drugs that are given by mouth have a food effect: when a drug is taken with a meal instead of on an empty stomach, the body can absorb more of it. This is because the fat molecules found in food carry the drug efficiently through the stomach and intestines, Ratain explained. So less of the drug is needed when taken with food to produce the same concentration in the bloodstream.

Drugs with a strong food effect are often tested in a way that intentionally diminishes this effect, he continued. This is done to reduce the potential variability in dose between participants that

could arise due to what types of and how much food different people eat.

And so, although the food effect of abiraterone has long been recognized, the large clinical trials that led to the drug's approval required that participants take it on an empty stomach. As a result, the drug's label directs patients to take it without food.

The new trial tested the opposite approach. The researchers randomly assigned 72 men with metastatic prostate cancer that had progressed on other standard therapies to take either the label-directed dose of abiraterone without food or one-quarter of that dose with a low-fat breakfast of the patients' choice.

After 12 weeks of treatment, the men in both groups had similar blood PSA levels, showing that both groups received enough of a dose to hit the drug's target, explained Ratain.

Although levels of abiraterone in patients' blood dipped lower between doses in men who took the lower dose with food than in men who took it on an empty stomach, this did not seem to influence responses to the drug. However, blood concentrations of abiraterone varied more widely between participants in men who took it on an empty stomach, the researchers found.

In both groups, men lived for an average of about 9 months without their disease progressing.

Larger studies are needed to measure whether the effects of abiraterone can be maintained in the long term when given at a reduced dose with food, wrote the study authors.

In an editorial that accompanied the trial results, Jill Kolesar, PharmD, of the University of Kentucky, and Glenn Liu, MD, of the University of Wisconsin, cautioned doctors, patients, and insurance providers against making dosing decisions based on a small trial with limited follow-up.

The use of PSA testing to measure the effects of abiraterone could introduce extra uncertainty in a small trial, as results of PSA testing can normally vary between hospitals by as much as 20 percent, Kolesar and Liu wrote. In addition, they explained, the long-term repercussions of the lower levels of abiraterone in patients' blood seen between doses in the food-effect group are not known.

But although the results of the trial are preliminary, Ratain thinks it could point to a reasonable strategy for patients who would otherwise not be able to take the drug at all because of cost, as long as they remain under careful supervision by their doctor.

Other Methods to Manipulate Drug Dose

The idea of harnessing the food effect is not new, said Ratain.

Previous studies have showed that giving pazopanib (Votrient), which is used to treat kidney cancer and sarcoma, with food doubles the amount of the drug that makes its way into the

bloodstream. A trial of ibrutinib (Imbruvica) in patients with chronic lymphocytic leukemia showed that about one-third more of a dose of ibrutinib is processed by the body when it's taken with food.

"The way [some] drugs are labeled and marketed today may not be optimal from a patient perspective," Ratain commented.

The food effect is not the only method under study to decrease the required doses of some drugs. Other trials are testing medications that slow metabolism—the rate at which the body breaks down a drug—along with cancer drugs, noted Figg.

Other potential approaches that could be tested, Ratain said, include taking cancer drugs that naturally break down slowly in the body less often than directed by the label, or using shorter courses of some drugs.

Ratain and other US researchers recently founded a nonprofit organization, the Value in Cancer Care Consortium, to support more trials of cost-reduction strategies in oncology.

With newer drugs that hold the promise of ever-more-personalized treatment reaching the market, many patients are now prescribed drugs that cost more than $100,000 per year. Even with insurance, people will often face out-of-pocket costs of more than $10,000 annually for these treatments.

"We view the abiraterone study as proof of concept," Ratain said, "and we're now thinking about [trying these approaches] to reduce the cost of other drugs."

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