

Taking prostate cancer drug with low-fat breakfast can be effective and less expensive, study finds

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Taking one-fourth the standard dose of a widely used drug for prostate cancer with a low-fat breakfast can be as effective - and four times less expensive - as taking the standard dose as recommended: on an empty stomach.

The study, a multi-center, randomized, phase-II clinical trial to be presented at ASCO's 2017 Genitourinary Cancers Symposium in Orlando, FL, found that the 36 patients who took 250 milligrams of the drug with a low-fat breakfast had outcomes that were virtually identical to the 36 patients who took the standard dose, 1,000 milligrams of the drug on an empty stomach.

The finding has significant financial implications. The drug, abiraterone acetate - marketed as ZYTIGA® - now retails for more than \$9,000 per month. Even patients with blue-ribbon health insurance can have co-pays ranging from \$1,000 to \$3,000 per month.

Patients taking abiraterone acetate typically stay on the medication for 12 to 18 months. Since 2011, according to the manufacturer's website, more than 100,000 patients in the United States alone have filled prescriptions for abiraterone.

If each of those 100,000 patients had taken the drug for 12 months and, theoretically, paid the list price out of pocket but took the lower dose with food, the 75-percent cost reduction could have saved them more than \$6 billion.

Seventy-two patients from multiple centers in the United States and Singapore participated in the study. Patients aged 52 to 89 years (median 74) with advanced prostate cancer whose disease had progressed despite standard initial hormonal therapy, were randomly assigned to take the standard dose on an empty stomach or the low dose with breakfast.

The primary objective of the study was to compare the change in blood levels

of prostate specific antigen (PSA), a measure of disease burden and progression. Despite a 75-percent difference in dose, there was no difference in abiraterone activity as measured by variation in PSA levels between the two groups of patients. The time to disease progression also was nearly identical for both arms of the study, about 14 months.

Patients who took the drug with food appeared to have an additional benefit. They were less likely to complain about stomach discomfort than those who took the drug as recommended. The drug's label recommends fasting for 2 hours before and 1 hour after swallowing the medication. Taking the medication with breakfast is therefore logistically easier for patients.

"We know this drug is absorbed much more efficiently when taken with food," said study director Russell Szmulewitz, MD, assistant professor of medicine at the University of Chicago and a specialist in medical treatment of patients with advanced prostate cancer. "It's inefficient, even wasteful, to take this medicine while fasting, which is how the drug's label says to take it."

"Given the pharmaco-economic implications," he added, "our results warrant consideration by doctors who care for prostate cancer patients as well as payers."

Many drugs taken by mouth have a "food effect," which can alter how the drug is absorbed. Abiraterone has one of the most dramatic food effects. Blood levels of the drug can be up to 17 times higher when taken with a high-fat meal. Taking the drug with a low-fat meal is more predictable. It increases blood levels four to seven fold.

"This is a widely prescribed drug, a mainstay for patients with prostate cancer," Szmulewitz said. "It is a great medication that has shifted the standard of care."

Patients with early stage prostate cancer patients are usually treated initially with hormone therapy, drugs that disrupt the production of male hormones such as testosterone, which promotes tumor growth. This can slow or halt progression of the disease.

Over time, however, cancer cells adapt. They develop the ability to grow and spread without relying on hormones, a stage known as castration-resistant

prostate cancer. Historically, those patients were treated with chemotherapy, which can have significant side effects.

Abiraterone, approved for treatment of metastatic prostate cancer in April, 2011, added a new layer to the sequence. It "sits between hormone therapy and chemotherapy," Szmulewitz explained. "It delays disease progression, improves survival and delays deterioration of quality of life." When its effects diminish, they shift to a similar, competing drug or move on to chemotherapy.

Patients who take abiraterone for prostate cancer should not "conduct such experiments on their own," Szmulewitz warned. "This was a relatively small study, too small to show with confidence that the lower dose is as effective. It gives us preliminary but far from definitive evidence. Physicians should use their discretion, based on patient needs."

The study shows that patients with genuine concerns about costs could, with careful guidance and regular follow-up from their doctors, consider the smaller dose taken with a low-fat breakfast. This would enable them to spread the cost of one month's of pills over four months, a per-patient savings of up to \$7,500 each month.

The American Cancer Society estimates that 161,360 men will be diagnosed with prostate cancer in 2017 and 26,730 men will die from the disease. "If we could reduce the cost of medication for this stage of the disease by a few thousand dollars each month simply by having patients take it with food," Szmulewitz said, "that would be significant."

Source:

University of Chicago Medical Center
