Abiraterone acetate delays quality of life decline in men with metastatic prostate cancer

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Abiraterone acetate, a recently FDA-approved drug used to treat men with metastatic castration-resistant prostate cancer, significantly delays progression of pain and quality of life deterioration when taken in conjunction with prednisone.

The study, published Sept. 24 in *Lancet Oncology*, was led by Ethan Basch, MD, director of the Cancer Outcomes Research Program at the University of North Carolina Lineberger Comprehensive Cancer Center. Researchers measured the pain and quality of life impact of abiraterone acetate, an orally prescribed treatment marketed under the trade name Zytiga, when administered to 1,088 patients with metastatic castration-resistant prostate cancer at 151 sites in the U.S., Europe, Canada and Australia. The randomized trial enrolled patients who had experienced little or no pain at the outset, prescribing abiraterone acetate and prednisone to 546 of the enrollees and placebo plus prednisone to the remainder.

"The majority of men with metastatic prostate cancer experience pain that is often debilitating and can have a profound impact on their ability to function, sleep, work, and their enjoyment of life. Pain is a central problem in prostate cancer and managing pain remains a major challenge," said Dr. Basch.

The design of the study emphasized the importance of patient reported-

outcomes in evaluating new treatments. In previous publications, Dr. Basch has shown the importance of evaluating how treatments impact how people feel and function during drug development.

"Patients with cancer experience many symptoms related to their disease and to drug side effects, but this information is generally neither measured rigorously in clinical trials nor included in U.S. drug labels. As a result, patients often have incomplete information about how they may expect to feel with a new therapy. This study addresses this information gap towards better-informed decisions," said Dr. Basch.

Abiraterone acetate was approved by the Food and Drug Administration (FDA) in 2011. The drug, which was found to increase survival in patients by an average of four months, is in routine clinical use in the United States and Europe.

The study tracked the progression of pain intensity, the time until patients needed opiates to control pain, and patients' quality of life using validated questionnaires. Patients reported their pain intensity on a scale of one to 10 as well as the amount that pain interfered with their sleep, mood and ability to conduct daily activities via the Brief Pain Inventory.

The combination of abiraterone acetate and prednisone significantly prolonged the time until clinically meaningful worsening of pain intensity as well as quality of life deterioration compared to patients receiving the placebo and prednisone. Patients reported a more than eight-month delay in progression of pain, and a more than four-month delay in quality of life deterioration. Significant improvements were also seen in how pain interferes with daily activities, and time until opiate use.

Pain is a significant predictor of overall survival, and the ability to delay suffering represents a meaningful clinical benefit to patients, according

to Dr. Basch. The delay of pain also allows patients to forgo the use of opiates and other pain medications for longer periods, a benefit since those medications also cause negative side effects that deteriorate quality of life.

"The design of this study provides a path forward for future research to utilize patient-centered endpoints," said Dr. Basch. "Not only does it provide essential information about the properties of abiraterone acetate, but it demonstrates the feasibility of rigorously measuring symptoms in a large multi-national study. It also helps identify areas of needed future methodological research."

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