Abiraterone May Be More Effective in Black Men With Advanced Prostate Cancer Than in White Men

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ASCO Perspective
“Racial and ethnic minorities continue to be underrepresented in clinical trials. This study should serve as a call for the entire cancer research community to make trials much more inclusive. When it comes to cancer treatments, people are not all alike, and it’s important to understand how different groups respond to different therapies,” said ASCO Expert Robert Dreicer, MD, MS, MACP, FASCO.

CHICAGO – In a prospective clinical trial of 100 men with metastatic castration-resistant prostate cancer, the response to the hormone treatment abiraterone (Zytiga®) was greater and longer lasting in black men than in white men. Black men were more likely to have a decline in prostate-serum antigen (PSA) -- a sign of prostate cancer response -- and had a 5-month longer median time to PSA worsening than white men (16.6 vs. 11.5 months).

This is the first prospective study to compare outcomes of abiraterone for advanced prostate
cancer in black men and white men, according to the authors. The findings confirm prior retrospective observations suggesting a stronger cancer response to abiraterone in black men.

The study will be featured in a press briefing today and presented at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting.

“Black men are more than twice as likely to die of prostate cancer than white men and are generally thought to have worse prostate cancer outcomes. Our study suggests that when black men and white men with advanced prostate cancer are given the same hormone treatment, this is not the case,” said lead study author Daniel George, MD, professor of medicine and surgery at Duke University in Durham, NC. “Our research underscores the importance of specifically studying genetically diverse populations and raising awareness of these results, so that everyone who can benefit from abiraterone is offered this treatment.”

In most clinical trials, the percentage of minority participants, including black patients, is disproportionately lower than the representation of the same racial group in the general population (black men were also underrepresented in the clinical trial that led to the approval of abiraterone for this indication). As a result, there is insufficient evidence about possible differences in treatment efficacy and side effects by race.

About the Study
The Abi Race clinical trial enrolled 100 men with metastatic castration-resistant prostate cancer (mCRPC) of whom 50 self-identified as white and 50 self-identified as black. The men received a standard treatment regimen for this disease – abiraterone acetate and prednisone (Deltasone) – until the cancer worsened or unacceptable side effects arose.

Cancer worsening was assessed through imaging scans (radiographic progression-free survival, rPFS) and by measuring PSA level in the blood (PSA PFS). This pilot study was aimed at demonstrating feasibility and describing responses and side effects by race. The researchers also conducted exploratory research on genetic ancestry, as well as on differences in genomic markers, metabolism, and hormone levels by race.

Key Findings
The time to radiographic disease progression was similar between the two cohorts, but when the researchers looked at PSA, a marker of cancer response and progression, they found differences by race. Abiraterone was more effective at both lowering PSA and delaying PSA progression in black men than in white men.

The median PSA PFS was 16.8 months in black men and 11.5 months in white men. After treatment with abiraterone, a greater percentage of black men than white men had a PSA decline of:

- 90% or more (48% vs. 38%)
- 50% or more (76% vs. 66%)
- 30% or more (86% vs. 76%)

In addition, more white patients than black patients (8 vs. 4) had no PSA decline. PSA is a prognostic marker in prostate cancer – people who have a decline in PSA level upon treatment live longer and have a better quality of life than those who do not have a decline in PSA, said Dr. George.

Based on imaging scans, black men did not have worse outcomes than white men -- the median rPFS was the same for black men and white men (16.8 months).

Most side effects were similar by race, but fatigue occurred more often in white patients than black patients (40% vs. 26%). In addition, twice as many black men than white men experienced low potassium level (36% vs. 18%), a complication directly related to the effect of abiraterone on adrenal hormones, which can be life-threatening if not corrected.

**Next Steps**

This study shows that prospective research of cancer outcomes by race is feasible, laying the groundwork for future studies. Another 100-patient study exploring outcomes of treatment with abiraterone in combination with apalutamide (Erleada) is underway. The researchers are also co-leading an initiative to study all treatments of men with advanced prostate cancer through a global registry of 5,000 patients called IRONMAN.

Although this study was small, the differences in PSA response observed in this study suggest that the biology driving advanced prostate cancer may be different in black men and white men, noted Dr. George. Research shows that hormone levels and hormone metabolism tend
to be different in black men and white men, and these differences may be contributing to variances in PSA response. The researchers plan to conduct a molecular analysis of blood and tissue samples collected in this study to gain more insight into the factors that might be driving differences in outcomes.

This study received funding from Janssen.

**Study at a Glance**

<table>
<thead>
<tr>
<th><strong>Disease</strong></th>
<th>Advanced prostate cancer</th>
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<tbody>
<tr>
<td><strong>Trial Type</strong></td>
<td>Prospective clinical trial</td>
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<td><strong>Patients on Trial</strong></td>
<td>100</td>
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<td><strong>Intervention Tested</strong></td>
<td>Abiraterone acetate plus prednisone in black men and white men</td>
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<td><strong>Primary Finding</strong></td>
<td>No difference in radiologic progression-free survival between black men and white men</td>
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<tr>
<td><strong>Secondary Finding(s)</strong></td>
<td>Better PSA cancer response to treatment in black men than in white men</td>
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