Improved outcomes in elderly patients with metastatic castration-resistant prostate cancer treated with the androgen receptor inhibitor enzalutamide: results from the phase III AFFIRM trial.

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Abstract

BACKGROUND: The randomized, double-blind phase III AFFIRM trial demonstrated that enzalutamide, an oral androgen receptor inhibitor, significantly prolonged overall survival (OS) [median 18.4 versus 13.6 months (hazard ratio, HR) 0.63 (95% confidence interval, CI, 0.53-0.75); P < 0.001] compared with placebo in patients with metastatic castration-resistant prostate cancer who received prior docetaxel chemotherapy.

PATIENTS AND METHODS: A post hoc analysis was carried out to assess the efficacy and safety of enzalutamide on outcomes in younger (<75 years) and elderly (≥75 years) patients in the AFFIRM population. Statistics are presented by age group (<75 years, ≥75 years) for efficacy outcomes of OS, radiographic progression-free survival (rPFS), time to prostate-specific antigen (PSA) progression, PSA response, and safety.

RESULTS: OS was significantly improved with enzalutamide over placebo in patients <75 years [median not yet reached versus 13.6 months; HR 0.63 (95% CI 0.52-0.78), P < 0.001] and in patients ≥75 years [median 18.2 versus 13.3 months; HR 0.61 (95% CI 0.43-0.86), P = 0.004], respectively. rPFS was similarly improved in both the younger [HR 0.45 (95% CI 0.38-0.53), P < 0.001] and elderly patient cohorts [HR 0.27 (95% CI 0.20-0.37), P < 0.001] relative to placebo, as were time to PSA progression and PSA response. Adverse events (AEs) were similar between the two enzalutamide age groups, with the exception of an increase in patients ≥75 years in the rates of all grade peripheral edema (22.1% versus 12.5%), fatigue (39.7% versus 31.6%), and diarrhea (26.6% versus 19.6%). The overall grade ≥3 AE rates were low with no major difference in frequency or severity between age groups or treatment arms. Five patients were reported with seizure events; three patients <75 years and two patients ≥75 years.

CONCLUSIONS: Enzalutamide significantly improves outcomes in both younger (<75 years) and elderly patients (≥75 years), with comparable safety and tolerability.

KEYWORDS: AFFIRM trial, elderly patients, enzalutamide, metastatic castration-resistant prostate cancer

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