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Cabazitaxel Versus Docetaxel As First-Line Therapy for Patients With Metastatic Castration-Resistant Prostate Cancer: A Randomized Phase III Trial—FIRSTANA

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The Who, What, and How of Cabazitaxel Treatment in Metastatic Castration-Resistant Prostate Cancer
Tian Zhang et al., J Clin Oncol

Phase III Study Comparing a

Purpose

In patients with metastatic castration-resistant prostate cancer (mCRPC), overall survival (OS) is significantly improved with cabazitaxel versus mitoxantrone after prior docetaxel treatment. FIRSTANA (ClinicalTrials.gov identifier: NCT01308567) assessed whether cabazitaxel 20 mg/m^2 (C20) or 25 mg/m^2 (C25) is superior to docetaxel 75 mg/m^2 (D75) in terms of OS in patients with chemotherapy-naïve mCRPC.

Patients and Methods

Patients with mCRPC and Eastern Cooperative Oncology Group performance status of 0 to 2 were randomly assigned 1:1:1 to receive C20, C25, or D75 intravenously every 3 weeks plus daily prednisone. The primary end point was OS. Secondary end points included safety; progression-free survival (PFS); tumor, prostate-specific antigen, and pain response; pharmacokinetics; and health-related quality of life.

Results

Between May 2011 and April 2013, 1,168 patients were randomly assigned. Baseline characteristics were similar across cohorts. Median OS was 24.5 months with C20, 25.2 months with C25, and 24.3 months with D75. Hazard ratio for C20 versus D75 was 1.01 (95% CI, 0.85 to 1.20; $P = .997$), and hazard ratio for C25 versus D75 was 0.97 (95% CI, 0.82 to 1.16; $P = .757$). Median PFS was 4.4 months with C20, 5.1 months with C25, and 5.3 months with D75, with no significant differences between treatment arms. Radiographic tumor responses were numerically higher for C25 (41.6%) versus D75 (30.9%; nominal $P = .037$, without multiplicity test adjustment). Rates of grade 3 or 4 treatment-emergent adverse events were 41.2%, 60.1%, and 46.0% for C20, C25, and D75, respectively. Febrile neutropenia, diarrhea, and hematuria were more frequent with C25; peripheral neuropathy, peripheral edema, alopecia, and nail disorders were more frequent with D75.

Conclusion

C20 and C25 did not demonstrate superiority for OS versus D75 in patients with chemotherapy-naïve mCRPC. Tumor response was numerically higher with C25 versus D75; pain PFS was numerically improved with D75 versus C25. Cabazitaxel and docetaxel demonstrated different toxicity profiles, with overall less toxicity with C20.

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