The effectiveness and safety of cabazitaxel (CBZ) in patients with metastatic castration-resistant prostate cancer (mCRPC) in routine clinical practice: Results of a prospective observational study (CAPRISTANA)

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Background
- Cabazitaxel (CBZ) is an approved treatment for patients with metastatic castration-resistant prostate cancer (mCRPC) who have been previously treated with docetaxel (DOC).
- CBZ was approved following the Phase II TROPIC study, where 25 mg/m² CBZ improved overall survival (OS) by 2.5 months compared to placebo (PBO).
- The Phase III PROSELICA study demonstrated the non-inferiority of 20 mg/m² CBZ compared to 25 mg/m² DOC.

Methods

Study population and study design
- The observational study included patients with mCRPC treated with CBZ under routine clinical practice conditions.

Results

Patient characteristics
- A total of 189 patients were treated with CBZ in 54 centers across six countries between April 2012 and June 2016.
- Patients had a median age of 69 years; 93.7% had an Eastern Cooperative Oncology Group performance status (ECOG PS) of 0–1, and 65.6% had a Charlson Comorbidity Index of 0.

Efficacy
- Patients received a median of six cycles of CBZ (range 1–10) at a median cumulative dose of 140.52 mg/m².
- Overall survival (OS) at 1 and 2 years was 46.6% and 34.4%, respectively.

Safety
- Treatment-emergent adverse events (TEAEs) of any grade possibly related to CBZ were reported in 65.6% of patients, the most frequent of which was neutropenia (22.2%).
- Grade 3 TEAEs occurred in 13.8% of patients, the most frequent of which was neutropenia (9.0%).

Conclusions
- This international, observational study documented use of CBZ in patients with mCRPC previously treated with a DOC-containing regimen.
- Patients had similar baseline characteristics to those in the TROPIC and PROSELICA studies.

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References
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