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Titel des Beitrags:
Randomized, placebo-controlled, phase III trial of sunitinib plus prednisone versus prednisone alone in progressive, metastatic, castration-resistant prostate cancer.

Abstract:
We evaluated angiogenesis-targeted sunitinib therapy in a randomized, double-blind trial of metastatic castration-resistant prostate cancer (mCRPC). Men with progressive mCRPC after docetaxel-based chemotherapy were randomly assigned 2:1 to receive sunitinib 37.5 mg/d continuously or placebo. Patients also received oral prednisone 5 mg twice daily. The primary end point was overall survival (OS); secondary end points included progression-free survival (PFS). Two interim analyses were planned. Overall, 873 patients were randomly assigned to receive sunitinib (n = 584) or placebo (n = 289). The independent data monitoring committee stopped the study for futility after the second interim analysis. After a median overall follow-up of 8.7 months, median OS was 13.1 months and 11.8 months for sunitinib and placebo, respectively (hazard ratio [HR], 0.914; 95% CI, 0.762 to 1.097; stratified log-rank test, P = .168). PFS was significantly improved in the sunitinib arm (median 5.6 v 4.1 months; HR, 0.725; 95% CI, 0.591 to
0.890; stratified log-rank test, P< .001). Toxicity and rates of discontinuations because of adverse events (AEs; 27% v 7%) were greater with sunitinib than placebo. The most common treatment-related grade 3/4 AEs were fatigue (9% v 1%), asthenia (8% v 2%), and hand-foot syndrome (7% v 0%). Frequent treatment-emergent grade 3/4 hematologic abnormalities were lymphopenia (20% v 11%), anemia (9% v 8%), and neutropenia (6% v< 1%). The addition of sunitinib to prednisone did not improve OS compared with placebo in docetaxel-refractory mCRPC. The role of antiangiogenic therapy in mCRPC remains investigational.