Chemohormonal therapy in metastatic hormone-sensitive prostate cancer. Sweeney CJ, Chen YH, Carducci M, Liu G, Jarrard DF, Eisenberger M, Wong YN, Hahn N, Kohli M, Cooney MM, Dreicer R, Vogelzang NJ, Picus J, Shevrin D, Hussain M, Garcia JA, DiPaola RS. Department of Medicine; Department of Biostatistics and Computational Biology; Dana-Farber Cancer Institute, Boston; Harvard Medical School, Boston; Johns Hopkins University, Baltimore; University of Wisconsin Carbone Cancer Center; School of Medicine and Public Health; Madison; Fox Chase Cancer Center, Temple University Health System, Philadelphia; Indiana University Melvin and Bren Simon Cancer Center, Indianapolis; Mayo Clinic, Rochester, MN; University Hospitals Case Medical Center, Seidman Cancer Center; Cleveland Clinic Taussig Cancer Institute; Both in Cleveland; University of Virginia Cancer Center, Charlottesville; Comprehensive Cancer Centers of Nevada, Las Vegas; Siteman Cancer Center, Washington University School of Medicine, St. Louis; NorthShore University Health System, Evanston, IL; University of Michigan Comprehensive Cancer Center, Ann Arbor; Rutgers Cancer Institute of New Jersey, New Brunswick. N Engl J Med. 2015 Aug 20;373(8):737-46. [Epub 2015 Aug 5]. doi: 10.1056/NEJMoA1503747.

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Abstract

BACKGROUND: Androgen deprivation therapy (ADT) has been the backbone of treatment for metastatic prostate cancer since the 1940s. We assessed whether concomitant treatment with ADT plus docetaxel would result in longer overall survival than that with ADT alone.

METHODS: We assigned men with metastatic, hormone-sensitive prostate cancer to receive either ADT plus docetaxel (at a dose of 75mg per square meter of body-surface area every 3wk for 6 cycles) or ADT alone. The primary objective was to test the hypothesis that the median overall survival would be 33.3% longer among patients receiving docetaxel added to ADT early
during therapy than among patients receiving ADT alone.

RESULTS: A total of 790 patients (median age, 63y) underwent randomization. After a median follow-up of 28.9 months, the median overall survival was 13.6 months longer with ADT plus docetaxel (combination therapy) than with ADT alone (57.6 vs. 44.0mo; hazard ratio for death in the combination group, 0.61; 95% confidence interval [CI]: 0.47-0.80; P<0.001). The median time to biochemical, symptomatic, or radiographic progression was 20.2 months in the combination group, as compared with 11.7 months in the ADT-alone group (hazard ratio, 0.61; 95% CI: 0.51-0.72; P<0.001). The rate of a prostate-specific antigen level of less than 0.2ng/ml at 12 months was 27.7% in the combination group vs. 16.8% in the ADT-alone group (P<0.001). In the combination group, the rate of grade 3 or 4 febrile neutropenia was 6.2%, the rate of grade 3 or 4 infection with neutropenia was 2.3%, and the rate of grade 3 sensory neuropathy and of grade 3 motor neuropathy was 0.5%.

CONCLUSIONS: Six cycles of docetaxel at the beginning of ADT for metastatic prostate cancer resulted in significantly longer overall survival than that with ADT alone. (Funded by the National Cancer Institute and others; ClinicalTrials.gov number, NCT00309985.)