Radiation with or without Antiandrogen Therapy in Recurrent Prostate Cancer.


Abstract

Background Salvage radiation therapy is often necessary in men who have undergone radical prostatectomy and have evidence of prostate-cancer recurrence signaled by a persistently or recurrently elevated prostate-specific antigen (PSA) level. Whether antiandrogen therapy with radiation therapy will further improve cancer control and prolong overall survival is unknown.

Methods In a double-blind, placebo-controlled trial conducted from 1998 through 2003, we assigned 760 eligible patients who had undergone prostatectomy with a lymphadenectomy and had disease, as assessed on pathological testing, with a tumor stage of T2 (confined to the prostate but with a positive surgical margin) or T3 (with histologic extension beyond the prostatic capsule), no nodal involvement, and a detectable PSA level of 0.2 to 4.0 ng per milliliter to undergo radiation therapy and receive either antiandrogen therapy (24 months of bicalutamide at a dose of 150 mg daily) or daily placebo tablets during and after radiation therapy. The primary end point was the rate of overall survival. Results The median follow-up among the surviving patients was 13 years. The actuarial rate of overall survival at 12 years was 76.3% in the bicalutamide group, as compared with 71.3% in the placebo group (hazard ratio for death, 0.77; 95% confidence interval, 0.59 to 0.99; P=0.04). The 12-year incidence of death from prostate cancer, as assessed by means of central review, was 5.8% in the bicalutamide group, as compared with 13.4% in the placebo group (P<0.001). The cumulative incidence of metastatic prostate cancer at 12 years was 14.5% in the bicalutamide group, as compared with 23.0% in the placebo group (P=0.005). The incidence of late adverse events associated with radiation therapy was similar in the two groups. Gynecomastia was recorded in 69.7% of the patients in the bicalutamide group, as compared with 10.9% of those in the placebo group (P<0.001). Conclusions The addition of 24 months of antiandrogen therapy with daily bicalutamide to salvage radiation therapy resulted in significantly higher rates of long-term overall survival and lower incidences of metastatic prostate cancer and death from prostate cancer than radiation therapy plus placebo. (Funded by the National Cancer Institute and AstraZeneca; RTOG 9601 ClinicalTrials.gov number, NCT00002874 .).