Prostate

Long-Term Results of a Phase 3 Randomized Prospective Trial of Erectile Tissue-Sparing Intensity-Modulated Radiation Therapy for Men With Clinically Localized Prostate Cancer

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Clinical Trial

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Abstract

PURPOSE

The objective of this study was to determine whether limiting the doses delivered to the penile bulb (PB) and corporal bodies with intensity modulated radiation therapy (IMRT) preserves erectile function compared with standard IMRT in men with prostate cancer.

METHODS AND MATERIALS

A total of 117 patients with low- to intermediate-risk, clinical T1a-T2c prostate adenocarcinoma were enrolled in a single-institution, prospective, single-blind, phase 3 randomized trial. All received definitive IMRT to 74 to 80 Gy in 37 to 40 fractions and standard IMRT (s-IMRT) or erectile tissue-sparing IMRT (ETS-IMRT), which placed additional planning constraints that limited the D90 to the penile bulb and corporal bodies to ≤15 Gy and ≤7 Gy, respectively. Erectile potency was assessed with components of the International Index of Erectile Function and phosphodiesterase type 5 inhibitor (PDE5) medication records.

RESULTS

Sixty-two patients received ETS-IMRT, and 54 received s-IMRT; 1 patient did not receive radiation therapy. Before treatment, all patients reported erectile potency. No patients received androgen deprivation therapy. In the intention-to-treat analysis, treatment arms did not differ in potency preservation at 24 months (37.1% ETS-IMRT vs 31.5% s-IMRT, P = .53). Of 85 evaluable patients with International Index of Erectile Function and PDE5 medication follow-up, erectile potency was seen in 47.9% of patients in the ETS-IMRT arm and 46.0% of patients in the s-IMRT arm (P = .86). PDE5 inhibitors were initiated in 41.7% of ETS-IMRT patients and 35.1% of s-IMRT patients (P = .54). Among all patients enrolled, there was no difference in freedom from biochemical failure between those treated with ETS-IMRT and s-IMRT (5-year 91.8% vs 90.7%, respectively, P = .77), with a median follow-up of 7.4 years. There were no differences in acute or late gastrointestinal or genitourinary toxicity. An unplanned per-protocol analysis demonstrated no differences in potency preservation or secondary endpoints between patients who exceeded erectile tissue-sparing constraints and those who met constraints, although power was limited by attrition and unplanned dosimetric crossover.

CONCLUSIONS

ETS-IMRT that strictly limits dose to the penile bulb and corporal bodies is safe and feasible. Use of this planning technique did not show an effect on potency preservation outcomes at 2 years, though power to detect a difference was limited.