Prostate

Ten-Year Update of a Randomised, Prospective Trial of Conventional Fractionated Versus Moderate Hypofractionated Radiation Therapy for Localised Prostate Cancer.

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PURPOSE

The previously published single institution randomised prospective trial failed to show superiority in the five-year biochemical and/or clinical disease failure (BCDF) rate with moderate hypofractionated intensity-modulated radiation therapy (H-IMRT) versus conventionally fractionated IMRT (C-IMRT). We now present 10-year disease outcomes using updated risk groups and definitions of biochemical failure.

METHODS

Men with protocol-defined intermediate- and high-risk prostate adenocarcinoma were randomly assigned to receive C-IMRT (76 Gy in 38 fractions) or H-IMRT (70.2 Gy in 26 fractions). Men with high-risk disease were all prescribed 24 months of androgen deprivation therapy (ADT) and had lymph node irradiation. Men with intermediate risk were prescribed four months of ADT at the discretion of the treating physician. The primary endpoint was cumulative incidence of BCDF. We compared disease outcomes and overall mortality by treatment arm, with sensitivity analyses for National Comprehensive Cancer Network (NCCN) risk group adjustment.

RESULTS

Overall, 303 assessable men were randomly assigned to C-IMRT or H-IMRT. The median follow-up was 122.9 months. Per updated NCCN risk classification, there were 28 patients (9.2%) with low-risk, 189 (62.4%) with intermediate-risk, and 86 (28.4%) with high-risk prostate cancer. The arms were equally balanced for clinicopathologic factors, except that there were more black patients in the C-IMRT arm (17.8% v 7.3%; P = .02). There was no difference in ADT use (P = 0.56). The 10-year cumulative incidence of BCDF was 25.9% in the C-IMRT arm and was 30.6% in the H-IMRT arm (hazard ratio, 1.31; 95% CI, 0.82 to 2.11). The two arms also had similar cumulative 10-year rates of biochemical failure, prostate cancer-specific mortality, and overall mortality; however, the 10-year cumulative incidence of distant metastases was higher in the H-IMRT arm (rate difference, 7.8%; 95% CI, 0.7% to 15.1%).

CONCLUSION

H-IMRT failed to demonstrate superiority compared with C-IMRT in long-term disease outcomes.