**10-Year Update of a Randomized Prospective Trial of Conventional Versus Hypofractionated Radiation Therapy for Localized Prostate Cancer**

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**Purpose/Objective(s):** We present 10-year disease outcomes of a randomized prospective trial of conventional versus hypofractionated radiation therapy for localized prostate cancer.

**Materials/Methods:** Between June 2002 and May 2006, men with low- to high-risk prostate cancer were randomized to receive conventionally fractionated intensity-modulated radiation therapy (C-IMRT, 76 Gy in 38 fractions at 2 Gy per fraction) or hypofractionated IMRT (H-IMRT, 70.2 Gy in 26 fractions at 2.7 Gy per fraction) at a single institution. The latter treatment is estimated to have an equivalent dose in 2 Gy fractions of 84.4 Gy assuming an α/β ratio of 1.5. High-risk patients were scheduled to receive 24 months of androgen deprivation therapy (ADT) and some intermediate-risk patients were offered up to 4 months of ADT. The primary end point was the cumulative incidence of biochemical and/or clinical disease failure (BCDF). Biochemical failure (BF) was defined as nadir + 2. In the univariate analyses, Kaplan-Meier estimation was obtained for overall survival (OS) and prostate cancer-specific mortality (PCSM) and cumulative incidence function was estimated for BF and metastatic rate with death as the competing risk. Cox proportional hazard model was done for multivariable analyses (MVA) with adjustment for age, race, ADT, and risk group.

**Results:** A total of 303 men were randomized to C-IMRT (n = 152) or H-IMRT (n = 151), with 77 men being lost to long-term follow up. Median follow up for the whole cohort was 130 months (range 7 – 181 months). There were 28 (9.2%), 189 (62.4%), and 86 (28.4%) NCCN favorable-, intermediate-, and high-risk patients, respectively. The arms were equally balanced for clinicopathologic factors, except there were more African-Americans in the C-IMRT arm (17.8% vs 7.3%; p = 0.02). ADT was taken by 46.7% and 45% of men in the C-IMRT and H-IMRT arm, respectively (p = 0.97). The median length of ADT treatment was 23.9 and 23.7 months in the C-IMRT and H-IMRT arm, respectively (p = 0.94). On MVA, 10-year BCDF was similar in both arms (25.9% in the C-IMRT arm and 30.6% in the H-IMRT arm; HR 1.42, 95% CI 0.91 – 2.46; Table 1). The two treatment groups also had similar rates of 10-year BF, PCSM, and OS. The H-IMRT arm did have a trend toward higher 10-year metastatic rate (5.3% vs 12.7%; HR 2.12, 95% CI 0.97 – 4.63; Table 1).

**Conclusion:** H-IMRT demonstrated no differences in disease outcomes when compared to C-IMRT. There was a trend of increased risk of developing metastases in the H-IMRT arm for which further follow up is underway.