**Long-term Patient Reported Outcomes From a Phase 3 Randomized Prospective Trial of Conventional Versus Hypofractionated IMRT Radiation Therapy for Localized Prostate Cancer**

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**Purpose/Objective(s):** To assess the long-term patient reported outcomes (PRO) from a phase 3 trial comparing conventional (CRT) versus hypo- fractionated (HRT) IMRT in patients with localized prostate cancer.

**Materials/Methods:** From 2002 and 2006, 303 men with low to high-risk prostate cancer were randomized to 76 Gy in 38 fractions at 2.0 Gy per fraction (CRT) versus 70.2 Gy in 26 fractions at 2.7 Gy per fraction (HRT). Patient reported outcomes were compared using the Expanded Prostate Cancer Index Composite (EPIC) and International Prostate Symptom Score (IPSS) questionnaires; PRO scores were reported as mean at each time point. Changes from baseline (defined as score <1 month prior to initiation of RT) were compared between treatment arms. Generalized estimating equation models were used to assess the effect of treatment over time.

**Results:** The median follow-up was 69 months (range, 7-136 months). There was no significant difference between the two cohorts in regards to clinical or treatment-related characteristics. There was an initial decrease in all EPIC domains in both treatment arms although this subsequently stabilized. There was no significant difference in mean score change for the EPIC bowel, sexual, hormonal, or urinary irritative/ obstructive domains between the two treatment groups. Patients in the HRT arm exhibited larger decrease in score on the EPIC urinary incontinence domain at three years versus the CRT arm (-7.2 versus -1.3, P =0.03) although this improved with further follow-up and was no longer significantly different after 5 years. There was no significant difference in overall IPSS score or quality of life score between the two treatment cohorts. There was a trend towards a worse IPSS score at 2 (P = 0.06) and 3 years (P = 0.06) in the HRT group, although this improved with further follow-up.

**Conclusion:** In this prospective randomized phase 3 study, PROs were not statistically different with long-term follow-up in patients receiving CRT or HRT for localized prostate cancer. Patients receiving HRT initially appeared to have worse urinary incontinence 3-4 years after treatment, although this subsequently resolved.