Hypofractionated vs. Standard Fractionated Proton Beam Therapy for Low Risk Prostate Cancer: Interim Results of a Randomized Trial – PCG GU 002

Carlos Vargas, Mayo Clinic, Phoenix, AZ
William F Hartsell, CDH Proton Center, Warrenville, IL
Megan Dunn, Proton Collaborative Group, Warrenville, IL
Gary Larson Proton Center Oklahoma City, OK

Purpose: After prostate cancer treatment, most AE and QOL changes can be initially identified within the first 2 years. The purpose of this interim analysis is to determine if there are differences in terms of Quality of Life (QOL), International Prostate Symptom Score (IPSS), or adverse events (AE) among prostate cancer patients treated on a randomized prospective trial with either standard fractionation or hypofractionation.

Methods and Materials: Eighty-two patients were randomized to 38 Gy RBE in 5 treatments (n=49) vs. 79.2 Gy RBE in 44 treatments (n=33). All patients had low risk prostate cancer, and were treated with proton therapy using fiducial markers and daily image guidance.

Results: Median follow up for both groups was 18 months with 33 patients reaching follow-up of two years or more. Patient characteristics for both groups were similar with most patients being T1c (84%), all having a Gleason score of 6, and a PSA <10 (median 5.6). Baseline median IPSS was 5 for the 38 Gy RBE arm (range 0-13) and for the 79.2 Gy RBE arm (range 0-17). There was no difference between the two groups with regards to Expanded Prostate Index Composite (EPIC) urinary, bowel or sexual function scores at 3, 6, 9, 12, 18, or 24 months. The only significant difference was the IPSS score at 12 months, 5 for 44 fractions vs 8 for the 5-fraction arm (p=0.039), but there was no difference in the IPSS scores at the other time points. No grade 3 or higher AEs were seen in either arm.

Conclusions: Patients treated with proton therapy in this randomized trial tolerated treatment well with excellent QOL scores, persistent low IPSS, and no grade 3 or higher adverse events were reported on either arm. There is no apparent clinical difference in outcomes with hypofractionated proton beam therapy compared to standard fractionation for the treatment of low risk prostate cancer.