

The Proton Collaborative Group's Research Portfolio

Minesh Mehta, MD 1, Megan Dunn PhD 2, Bradford Hoppe, MD 3, George Laramore PhD, MD 4, Andrew Chang, MD 5, Carlos Vargas, MD 6, William Hartsell, MD 7

1 University of Maryland, 2 Proton Collaborative Group, 3 University of Florida, 4 University of Washington, 5 Scripps Proton Therapy Center, 6 Mayo Clinic, 7 CDH Proton Center

The Proton Collaborative Group's (PCG) "Evaluation Tracking Project: the Prospective Chart Review of Patients Treated with Proton Therapy" (REG001-09) protocol allows for the collection and analysis of data to evaluate the diseases, treatment processes, and outcomes for patients with various tumors treated with proton beam therapy (PBT). This multi-institutional prospective, web-based, HIPPA-compliant registry trial, which includes both patient-reported QOL measures, and provider-scored toxicities, is currently being run at seven centers and includes information on over 4,400 patients representing a wide array of disease sites. The registry has been enrolling patients continuously since July, 2009 at an average rate of 66 subjects per month.

We present key trends in this database according to enrollment by disease site. In the start-up phase, prostate cancer dominated enrollment, accounting for 91% of enrolled patients in year 1; this dropped to 67, 64, 58, 53 and 48% in years 2-6, which reflects the maturity of PBT in terms of its application for non-prostate indications. The total number of prostate cancer patients enrolled increased from 40 to 2030 during this 6 year time frame, showing that the number of prostate cancer patients treated with proton therapy is not necessarily declining substantially, but that usage for non-prostate indications is rapidly increasing.

In terms of non-prostate indications, the most common categories are adult CNS tumors, head-and neck cancer, pediatric CNS tumors, sarcomas, lung cancer, breast cancer, "other", lymphoma, colorectal cancer, cancer of the esophagus, hepatobiliary malignancies, ocular tumors, and pancreatic cancer, accounting for 10, 8, 7, 6, 6, 4, 3, 2, 1, 1, 1, 1, and 0.6 % of cases, respectively, in the most current complete year of reporting. These categories clearly represent "growth areas" for proton therapy, with greater maturity of PBT delivery techniques.

Follow-up data are prospectively collected using standardized, web-based "live in-clinic" submissions, allowing for the generation of a robust database designed for data analysis to create testable hypotheses. Eight proton centers contribute to PCG as member institutions and physicians from 18 different sites participate in the collaborative group with PCG providing the research and QA infrastructure for this project. PCG offers member institutions access to the registry as well as five treatment trials: three focused on hypofractionation schema for prostate and lung patients, and two evaluating outcomes for breast patients.

To date, 65 independent requests for use of these data have been approved by the publications committee. Resulting research has been presented at ARS, ASTRO, AAPM, PTCOG, NASBS, ONS, ASCO, SIOP, ISPNO and AAMD and published in 6 different journals.

In 2014, ASTRO called for PBT-treated patients to be enrolled on prospective multi-institutional registry trials, in order to generate superior evidence for this modality. The PCG represents the largest and most mature entity in this category.