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**Minimal toxicity after proton beam therapy for prostate and pelvic nodal irradiation: results from the proton collaborative group REG001-09 trial**

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**Abstract**

**Background:**Proton beam therapy (PBT) reduces normal organ dose compared to intensity modulated radiation therapy (IMXT) for prostate cancer patients who receive pelvic radiation therapy. It is not known whether this dosimetric advantage results in less gastrointestinal (GI) and genitourinary (GU) toxicity than would be expected from IMXT.

**Material and methods:**We evaluated treatment parameters and toxicity outcomes for non-metastatic prostate cancer patients who received pelvic radiation therapy and enrolled on the PCG REG001-09 trial. Patients who received X-ray therapy and/or brachytherapy were excluded. Of 3210 total enrolled prostate cancer patients, 85 received prostate and pelvic radiation therapy exclusively with PBT. Most had clinically and radiographically negative lymph nodes although 6 had pelvic nodal disease and one also had para-aortic involvement. Pelvic radiation therapy was delivered using either 2 fields (opposed laterals) or 3 fields (opposed laterals and a posterior beam). Median pelvic dose was 46.9 GyE (range 39.7-56) in 25 fractions (range 24-30). Median boost dose to the prostate +/- seminal vesicles was 30 GyE (range 20-41.4) in 16 fractions (range 10-24).

**Results:**Median follow-up was 14.5 months (range 2.8-49.2). Acute grade 1, 2, and 3 GI toxicity rates were 16.4, 2.4, 0%, respectively. Acute grade 1, 2, and 3 GU toxicity rates were 60, 34.1, 0%, respectively.

**Conclusions:**Prostate cancer patients who receive pelvic radiation therapy using PBT experience significantly less acute GI toxicity than is expected using IMXT. Further investigation is warranted to confirm whether this favorable acute GI toxicity profile is related to small bowel sparing from PBT.