Initial Toxicity Results of a Pilot Trial Evaluating Stereotactic Body Radiotherapy with Integrated Boost for Clinically Localized Prostate Cancer

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Abstract

Objectives: To determine the technical feasibility of stereotactic body radiotherapy (SBRT) with an integrated boost (SIB) for clinically localized prostate cancer and to prospectively assess the early toxicity associated with this therapy.

Methods: This prospective pilot trial enrolled men with histologically proven prostate adenocarcinoma classified as low or intermediate risk (T1c-T2c, Gleason=7, PSA<20 ng/mL, no evidence of lymphadenopathy). Two clinical target volumes (CTVs) were defined: CTV1 consisted of the entire prostate and CTV2 consisted of intra-prostate lesions seen on MRI but was limited to less than 50% of the total prostate volume. Planning target volume (PTV) expansions were 5mm in all directions except posteriorly where the expansion was 3mm. PTV1 was prescribed 36.25 Gy in 5 fractions with a simultaneous integrated boost prescribed to PTV2 for a total dose of 40 Gy in 5 fractions. The primary endpoint was development of urinary retention requiring catheter placement within 3 months of SBRT.

Results: A total of 26 men were enrolled. In each case a dominant nodule was able to be defined and all enrollees were successfully treated with SBRT with a SIB. Of the 18 men who have been followed for longer than 3 months, 2 (11%) developed acute urinary retention that required temporary placement of a urinary catheter. The maximal dose to the urethra in each case was 38.6 Gy and 36.6 Gy, respectively. In both cases the catheter was able to be removed within 5 days and did not have to be reinserted. Other grade 2 urinary toxicities were observed in 10 (55%) subjects, typically due to increased urinary frequency, and grade 2 rectal toxicity was observed in 3 (16%) subjects, typically due to diarrhea. No patient developed a grade 3 complication of any type.

Conclusions: Planning and delivery of 5 fraction prostate SBRT with a SIB to MRI-defined dominant tumor nodules is feasible. Though clinical follow-up is ongoing, these early results suggest that acute urinary retention is not excessive. Other grade 2 urinary and rectal adverse effects appear consistent with those observed following SBRT without a SIB.