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Rectal Radiation Dose and Clinical Outcomes in Prostate Cancer Patients

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Abstract
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Abstract

Objective: SpaceOAR hydrogel is a rectal spacer designed to limit rectal radiation dose for prostate cancer patients. The purpose of this study was to evaluate the effect of SpaceOAR hydrogel on rectal radiation dose and clinical outcomes in prostate cancer patients receiving stereotactic body radiation therapy (SBRT).

Methods: Data was retrospectively collected for patients undergoing prostate SBRT with and without SpaceOAR from February 2017 to January 2020. All patients were treated with 40Gy in 5 fractions. Baseline patient characteristics including prostate size, rectal diameter, BMI, age, pre-treatment PSA, Gleason Score, T-stage, ADT usage were compared between patients with and without SpaceOAR using Welch's and student's t-tests. Univariate log rank test was used to compare biochemical recurrence-free survival (BFS) according to the Phoenix definition. Multivariate multiple regressions were performed for rectal dose-volume histogram (DVH) parameters (V40Gy, V36Gy, V32Gy, V20Gy), and for prostate clinical target volume (CTV) and planning target volume (PTV) V100% coverage. Sexual health inventory for men (SHIM) score, International Prostate Symptom Score (IPSS), and CTCAE v5.0 graded toxicity were recorded and compared using Welch's and student's t-tests.

Results: 92 prostate cancer patients underwent SBRT, of which 51 patients received hydrogel. For the whole cohort, the median follow-up was 12.5 months (range 3.1 - 36.1 months) and the median age was 72 (range 46 - 85). A total of 20, 65, and 7 patients were high-, intermediate-, and low-risk, respectively. Baseline characteristics did not differ ($p>0.536$). Rectum DVH parameters (mean difference) were significantly lower in hydrogel patients ($p<0.005$) after controlling for baseline variables: V40Gy (-1.27%), V36Gy (-2.64%), V32Gy (-3.53%), and V20Gy (-5.17%). PTV and CTV V100% did not differ ($p>0.589$). No patients experienced biochemical recurrence. There were no patients in either group that experienced Gr ⩾3 GU and GI toxicity. Average changes in patient reported IPSS GU and SHIM sexual function quality of life outcomes were not statistically different between patients with and without hydrogel at 6 months (IPSS $p=0.11$, SHIM $p=0.72$) and 12 months (IPSS $p=0.62$, SHIM $p=0.52$).

Conclusion: SpaceOAR hydrogel placement prior to SBRT in prostate cancer patients is a safe intervention that results in lower rectal volumetric radiation dosing.