Prospective Evaluation of CyberKnife Stereotactic Body Radiotherapy for Low- and Intermediate-Risk Prostate Cancer: Emulating HDR Brachytherapy Dose Distribution

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Objectives: The goal of this multi-institutional study is to document the efficacy and acute and late toxicity of HDR-like CyberKnife Stereotactic Body Radiotherapy (SBRT) for prostate cancer in both low- and intermediate-risk cohorts. Interim, 24-month results are reported.

Methods: Between 11/07 and 9/10, 126 patients with localized, biopsy-proven prostate cancer (clinical stage T1bN0M0 to T2bN0M0) were treated as part of an industry-sponsored study*. None received hormone therapy. The planning target volume (PTV) included a 2-mm margin expansion around the prostate in favorable patients, which was unilaterally or bilaterally increased to 5 mm as dictated by patient-specific DRE and pathology findings, plus proximal SV coverage, for intermediate-risk patients (Gleason 7 and PSA < 10 ng/ml or Gleason=7, PSA between 10-20 ng/ml). The CTV to PTV expansion against the rectal wall was reduced to zero for both risk groups. The PTV received 38 Gy in 4 fractions, and the extraurethral PTV Dmax had to measure at least 150% of the prescription dose, to satisfy the "emulating HDR" protocol dosimetry requirement. Toxicities were assessed using CTCAE v 3.0 criteria. Quality of life was assessed using the Expanded Prostate Cancer Index Composite Short Form (EPIC-26) and the Sexual Health Inventory for Men (SHIM) questionnaire. The presence of erectile function was defined as a response of >= 3 to question #2 of the SHIM. Biochemical failures were assessed using both ASTRO and Phoenix definitions.

Results: At a median follow-up of 16 months (range, 3 - 33 months) there have been no biochemical failures. The median pre-treatment PSA of 5.08 ng/ml (range 0.40 – 19.33 ng/ml) decreased to 1.20, 0.90, 0.67 and 0.60 ng/ml at 6, 12, 18, and 24 months, respectively. Grade 1-2 acute urinary and rectal toxicities were 47% and 28%, respectively. No Grade 3+ acute toxicities occurred. For patients with a minimum of 12-months follow-up, Grade 1-2 late urinary and rectal toxicities were 36% and 9.3%, respectively. There were no Grade 3+ late rectal toxicities. One Grade 3 late urinary retention toxicity occurred; no other Grade 3 or higher toxicities occurred. The mean EPIC bowel domain score showed a mild decrease at 1 month, with subsequent improvement and stability to 24 months. The mean urinary EPIC domains decreased at one month and subsequently increased. Of those patients that were potent prior to treatment, 66% remained potent at 12 months follow-up.

Conclusions: In a multi-institutional setting, HDR-like CyberKnife SBRT for low- and intermediate-risk, localized prostate cancer has resulted in minimal toxicity, with a favorable and progressively improving PSA response out to 24 months.

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