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This prospective study expands upon prior studies to further evaluate SBRT efficacy and QOL for a large patient population that includes low-, intermediate-, and high-risk prostate cancer patients.

Alan Katz, MD, JD, Josephine Kang, MD, PhD; Long Island Radiation Therapy; Flushing Radiation Oncology

Objectives: Stereotactic body radiation therapy (SBRT) takes advantage of the low alpha-beta (α/β) ratio in the prostate to deliver a large radiation dose in few fractions. Initial studies on small groups of low-risk patients support the potential of SBRT for clinical efficacy while limiting treatment-related morbidity and maintaining quality of life (QOL). This prospective study expands upon prior studies to further evaluate SBRT efficacy and QOL for a large patient population that includes low-, intermediate-, and high-risk prostate cancer patients.

Methods: A total of 515 patients with organ-confined prostate cancer (471 T1c and 44 T2a, all N0M0) received CyberKnife SBRT. The mean age was 69 years, and the mean PSA was 6.48 ng/mL; 343 patients were low-risk (PSA = 10 ng/mL and Gleason < 7), 134 were intermediate-risk (PSA 10–20 ng/mL or Gleason = 7), and 38 were high-risk (PSA > 20 ng/mL or Gleason > 7). Androgen deprivation therapy was administered to 70 patients for up to 1 year. A total of 158 patients received 35 Gy delivered in five daily fractions. These patients were either low-risk or low–intermediate-risk. The remaining patients, from all risk groups, received a total dose of 36.25 Gy in five daily fractions. The dose was prescribed to a planning target volume (PTV), created by a 5-mm expansion of the prostate gross tumor volume (GTV), with a 3-mm posterior expansion. The proximal seminal vesicles were included for intermediate- and high-risk patients. The PTV was covered by the 83% to 87% isodose line; real-time intrafractional motion tracking was used. Biochemical failure was assessed using the Phoenix criterion.

Results: At a median follow-up of 63 months (range: 9–84 mo), 49 patients died of other unrelated causes and 39 were lost to follow-up. The median PSA at 60 months was 0.11 ng/mL. Biochemical failures occurred for 10 low-risk patients (2 locally), 10 intermediate-risk patients (2 locally), and 10 high-risk patients (2 locally). The actuarial 6-year freedom from biochemical failure was 97%, 90.8%, and 71.8% for the low-, intermediate-, and high-risk groups, respectively (P < .001). For low- and low–intermediate-risk patients, there was no difference in terms of median nadir or biochemical control between doses of 35 and 36.25 Gy. Late Radiation Therapy Oncology Group (RTOG) toxicity was mild, with 4% grade 2 rectal, 7.8% grade 2 urinary, and 1.4% grade 3 urinary (all with 36.25 Gy). Late grade 2 urinary toxicity for 35 Gy was 5.1% versus 9.9% for 36.25 Gy (P = .01). Mean Expanded Prostate Cancer Index Composite (EPIC) urinary and bowel QOL declined at 1 month posttreatment and returned to baseline by 2 years, where it remains. Mean EPIC sexual QOL declined by 25% at 72 months. Seventy-three percent of the patients who were potent at baseline remain potent.

Conclusions: CyberKnife SBRT produces excellent biochemical control rates at up to 7 years, with mild toxicity and minimal impact on QOL. Median PSA levels compare favorably with other radiation modalities and strongly suggest durability of response. Further follow-up is needed to determine if these results are durable in the long term. These results also strongly suggest that 35 Gy is as effective as 36.25 Gy for low- and low–intermediate-risk patients with less urinary toxicity.

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