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Stereotactic Intensity Modulated Radiotherapy after Radical Prostatectomy (SCIMITAR): Two Year Quality of Life and Toxicity Outcomes of a Multicenter Phase II Trial

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Abstract
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Abstract

Objectives:

Postoperative radiotherapy for men with biochemical recurrence or adverse pathologic features after radical prostatectomy (RP) remains underutilized. Postoperative stereotactic body radiotherapy (SBRT) may improve utilization and poses potential radiobiological advantages. The purpose of this study was to evaluate two year toxicity and patient-reported quality of life (QOL) outcomes of post-RP SBRT.

Methods:

SCIMITAR (NCT03541850) was a phase II, dual center, single arm trial that enrolled men post-RP who had a prostate-specific antigen (PSA) >0.03 ng/mL or adverse pathologic features. Patients were treated with 30-34 Gy in five fractions to the prostate bed with or without nodal radiation, boost to gross disease, or hormonal therapy. Late (≥3 months) genitourinary (GU) and gastrointestinal (GI) toxicities were graded according to Common Terminology Criteria for Adverse Events (CTCAE), version 4.03. Patient-reported QOL outcomes were measured using Expanded Prostate Cancer Index Composite (EPIC) and International Prostate Symptom Score (IPSS). We evaluated the proportion of men whose QOL scores for each domain had decrements greater than twice the threshold for minimal clinically important change (>2x MCIC) at any point during the first two years. We compared the longitudinal QOL profiles of men receiving SBRT on the SCIMITAR trial with a cohort of 200 men receiving conventionally fractionated postoperative intensity modulated radiotherapy. We adjusted for baseline QOL scores. In the case of sexual function, we also adjusted for administration of hormonal therapy.

Results:

Between February 2018 and March 2021, 100 patients enrolled in SCIMITAR at two institutions. Median follow-up was 43 months (interquartile range: 37-53 months). Grade 2 late GU and GI toxicity rates were 25% and 3%, respectively. Grade 3 late GU and GI toxicity rates were 4% and 3%, respectively. The percentage of patients who had decrements in QOL scores >2x MCIC was 24% for bowel function, 18% for sexual function, 29% for urinary incontinence, 11% for urinary irritation, and 5% for IPSS. When compared to a cohort of 200 men who received conventionally fractionated postoperative radiotherapy, the adjusted odds ratio for patients on SCIMITAR experiencing higher rates of >2x MCIC was 1.2 (95% confidence interval [CI]: 0.5-2.8; P=0.6) for bowel function scores, 0.8 (95% CI: 0.3-2.3; P=0.7) for sexual function scores, 1.0 (95% CI: 0.5-2.2; P>0.9) for urinary incontinence scores, 0.7 (95% CI: 0.3-1.8; P=0.4) for urinary irritation scores, and 1.9 (95% CI: 0.3-14.4; P=0.5) for IPSS.

Conclusion(s):

SBRT was well-tolerated in the post-RP setting with no measurably different decline in urinary, bowel, or sexual QOL through 2 years in comparison to conventionally fractionated treatment. Randomized studies and longer follow-up will better define the toxicity and efficacy profile of SBRT in this context.