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SCIMITAR Study FAQs

Question	Answer
Key Takeaways	The goal of SCIMITAR in the context of our clinical roadmap is to determine the feasibility of post-op SBRT and look for a signal of MRIdian clinical benefit. SBRT for post-op prostate is only used within the context of a clinical trial, is considered experimental and is not currently reimbursed. SCIMITAR initial safety data suggests post-op SBRT is safe and they will continue to measure efficacy. The primary aim of the study is efficacy of a 4-year recurrence rate of 50% after SBRT compared to historical control of 70% recurrence. In the secondary analysis, UCLA saw a signal that MRIdian patients had a reduced overall GI toxicity profile, which they directly attribute to further margin reduction (3mm vs 5mm). The results from this study provide a compelling signal of clinical benefit of MRIdian and will be validated with efficacy data. Additionally, this data will be further confirmed with the SHORTER RCT of 20fx vs 5fx.
Overview of Study	Available on ClinicalTrials.gov; Identifier: NCT03541850 • Phase 2 single arm, single center trial • Prespecified secondary analysis of technology comparison • 100 patients (69 CT; 31 MRIdian) • 5 fraction SBRT (30-34Gy/5 fractions) • Margins: CT (5mm) and MRIdian (3mm) • No patients had fiducials or spacers regardless of radiation technology
What are the MRIdian prostate related clinical studies and why do they matter to patients?	ViewRay's clinical strategy in prostate cancer is to bring forward level 1 evidence proving that MRIdian can safely reduce the course of treatment for patients. Additionally, we need to generate the evidence to position MRIdian as the frontline radiation therapy for intact prostate and extend SMART as an adjuvant therapy to a new patient population in the post-operative setting. **MIRAGE RCT (Randomized Controlled Trial)** is intended to evaluate the superiority in reduction of acute grade ≥2 GU toxicity for MRI-guided SBRT over standard CT-guided SBRT in intact prostate cancer patients. (Enrollment complete) **SCIMITAR** is a Phase 2 study intended to evaluate the feasibility of salvage SBRT for post-op prostate. (Enrollment complete) **SHORTER RCT** is intended to evaluate the non-inferiority of 5fx vs 20fx salvage RT treatment for post-prostatectomy patients. (Enrolling patients) **FORT RCT** is intended to evaluate the non-inferiority of 2fx vs 5fx treatment for intact prostate cancer patients. (Open for enrollment)
What is the aim of the study?	Safety: Physician and patient reported toxicity Efficacy: Long term biochemical recurrence-free survival Exploratory: compare toxicity profile between CT and MRI-guided linac

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What are the clinical outcomes reported in this acute data set?	**Zero patients treated with MRIdian experienced a grade 3 GU or GI toxicity.** **Compared to CT guided, MRIdian had a 30.5% reduction in any grade acute GI toxicity (p=0.0056) and a 32% reduction in any grade cumulative GI toxicity up to 6 months (p=0.0021).** The low incidence of acute and late GU and GI toxicities were confirmed by patient reported outcome data.
What is the current paradigm of care for post-prostatectomy radiation therapy?	Estimates of 30-50% of men will experience recurrence within 10 years of prostatectomy. Treatment entails 7-8 weeks of radiation therapy and large margins (7-10mm).
Why aren't physicians treating these patients with SBRT today?	SBRT is currently only delivered under clinical trial due to safety concerns and lack of efficacy data.
How is RT reimbursed in the post-prostatectomy setting?	IMRT is reimbursed, SBRT is not.
Was adaptive planning used for the MRIdian patients?	Yes, but less than 3% of cases were adapted.
Why did UCLA run this study?	UCLA believes that safely increasing radiation dose in treating post-operative recurrent patient has the potential to increase efficacy and reduce logistical barriers underlying current lack of utilization of RT in the post-operative setting. SBRT in this setting is currently not approved outside of a clinical trial and UCLA opened this trial to begin to generate data required to change the treatment paradigm to SBRT.
What is the impact of this data to care patterns?	SCIMITAR paves the way for future studies such as SHORTER. Physicians tell us that the field is still 5+ years away from SBRT moving to standard practice, but that the data pipeline in place is poised to move the standard of care towards shorter and shorter treatments. Within the context of the SCIMITAR and SHORTER trials, both Cornell and UCLA have built strong referral networks with surgeons to enroll these patients on clinical trials and anecdotally report that surgeons are willing to refer patients for SBRT under a clinical trial. The lead investigators tell us that SHORTER, if positive, has the potential to provide data necessary to drive coverage/reimbursement decisions and allow SBRT outside of a clinical trial.
What are possible acute grade ≥2 GI toxicities?	Acute grade ≥2 GI toxicity can include adverse events ranging from diarrhea, discharge, or rectal/abdominal pain to abdominal distention or obstruction.
Does Dr. Kishan have any conflicts of interest?	Conflicts of Interest: Amar Kishan, M.D. discloses research funding from the Department of Defense, the National Institutes of Health, the Jonsson Comprehensive Cancer Foundation, the Prostate Cancer Foundation, and the American Society for Radiation Oncology. He also discloses research support, not related to this study, from ViewRay, Inc. AUK discloses consulting fees from ViewRay, Inc. and Varian Medical Systems, Inc. Dr. Kishan also discloses low-value stock held in ViewRay Inc.

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