Title

One Year Radiographic Response Following Prostrate SBRT: An Exploratory Analysis of a Phase III Randomized Trial

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catheterization was performed (Grade 2). Most of the acute GU toxicity tended to improve at 1 month after IGPT, and almost improved at 3 months. Mean score deteriorations beyond the minimum clinically important difference threshold (1/2 SD) were observed only at 1 month in the following scales: summary (-6.0), bother (-7.0), and irritative/obstructive (-6.3).

Conclusion: Hypofractionated IGPT with 12 fractions for prostate cancer is well tolerated in acute GU toxicities. Longer follow-up is necessary to evaluate the efficacy and late toxicities. Further investigation of hypofractionated IGPT with 12 fractions for prostate cancer is warranted. Since April 2021, an additional 1000 cases of prospective registration study have been conducted.

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2868

Dosimetric Implications of Prostate Bed Deformability: An Analysis of the SCIMITAR Clinical Trial

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Purpose/Objective(s): The post-operative prostate bed is a dynamic target volume due to the deformable nature of the bladder and rectum. These changes can lead to incorrect dosing of the prostate bed and organs at risk (OARs). Our objective was to quantify the dosimetric impact of prostate bed and OAR deformation.

Materials/Methods: SCIMITAR (NCT03541850) is a prospective phase II clinical trial evaluating stereotactic body radiotherapy (SBRT) in the post-prostatectomy setting. This analysis included a subset of patients who received 5 fractions of 6−6.8 Gy to the prostate bed under CT-based image guidance. The clinical target volume (CTV) and OARs were contoured on fractional CBCT images. Changes in volume, shape (via the dice similarity coefficient [DSC]), and dosimetry were quantified. Student's t-test was used to analyze the differences between planning and daily treatment outcomes.

Results: A total of 29 patients (145 fractional images) were analyzed. We found the CTV volume remained stable (median change 1.1%; IQR: -15.1% − 16.1%), whereas the CTV shape was deformable (DSC of 0.76 [IQR: 0.71 − 0.79]). The bladder and rectum exhibited changes with median volume change of 5.7% (IQR: -24.3% − 51.0%) and 5.5% (IQR: -8.7% - 21.9%), respectively and median DSC of 0.77 (IQR: 0.68 − 0.84) and 0.74 (IQR: 0.69 − 0.80) respectively. The CTV received less radiation dose than planned (volume receiving 95%: 93.2% actual vs 99.6% planned, $p < 0.01$). 39% (56/145) of total fractions and 52% (15/29) of patients met criteria for CTV under-coverage (volume receiving 95% of the prescription dose < 93%). The rectum received higher dose than planned on several parameters (e.g., V27.5 Gy increased from 15.4% to 21.0% [$p = 0.009$] and V32.5 Gy increased from 6.0% to 10.9% [$p = 0.006$]) (Table 1).

Conclusion: We found underdosing of the prostate CTV and overdosing of the rectum in patients receiving CT-guided postoperative SBRT. While future work will correlate these dosimetric consequences with toxicity, these data suggest that approaches such as adaptive radiotherapy may be beneficial.

Abstract 2868 − Table 1: Dosimetry outcomes for key parameters for CTV and PTV of the prostate, bladder, rectum, and rectal wall. ** = $p < 0.01$

		Predicted Plan	Actual Plan
Dosimetry Parameter	**Adaptive Criterion**	**Mean**	**Mean**
CTV mean dose (Gy)		33.4	**32.6****
CTV V95 (%)	> 93%	99.6	**93.2****
PTV mean dose (Gy)		33.2	**31.3****
PTV V95 (%)	> 90%	97.9	**80.3****
Bladder dose (Gy)		35.5	36.0
Bladder Dmax (Gy)	< 36.8 Gy	35.9	36.4
Bladder V32.5 (%)	< 35%	20.0	16.9
Rectum dose (Gy)		35.0	35.7
Rectum Dmax (Gy)	< 36.7 Gy	35.6	36.2
Rectum V27.5 (%)	< 45%	15.4	**21.0****
Rectum 32.5 (%)	< 30%	6.0	**11.0****
Rectal wall V24 (%)	< 50%	25.3	27.8

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2869

One Year Radiographic Response Following Prostrate SBRT: An Exploratory Analysis of a Phase III Randomized Trial

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Purpose/Objective(s): Radiographic MRI response following prostate radiotherapy, particularly stereotactic body radiotherapy (SBRT), remains poorly understood. Our objective was to describe radiographic changes to the prostate gland and prostate tumor following SBRT of men treated on a prospective, randomized trial.

Materials/Methods: MIRAGE (NCT 04384770) is a single center, randomized phase III trial of patients receiving either CT or MRI guided SBRT for localized prostate cancer. Patients underwent pre-treatment and annual post-treatment MRIs, in addition to routine PSA surveillance. Outcomes reported include percent gland shrinkage, percent PSA response at one year, and presence of residual tumor based on radiographic interpretation.

Patient characteristics were compared via two-sample t-test or Fischer's exact test. Both univariate and multivariable logistical analysis were employed to identify potential clinical predictors of residual tumor on 1-year follow up MRI.

Results: This study cohort included 94 eligible patients with baseline characteristics in **Table 1.** Residual lesions were seen in 13 patients (14%), 5/27 (18.5%) treated without ADT and 8/67 (12%) with ADT. PSA ablation was deep, with a 79% median decrease without ADT and 98% median decrease with ADT. Patients receiving ADT showed more gland shrinkage (17% vs. 34% shrinkage, $p = 0.0001$), while radiographic non-responders and responders experienced similar gland shrinkage (median 21% vs 29% shrinkage, $p > 0.05$). No significant clinical predictors of residual tumor were identified on univariate and multivariate analysis. No patient had any clinical or biochemical evidence of failure.

Conclusion: A total of 14% of patients were found to have residual tumor detected on MRI one year after SBRT. These data highlight the protracted nature of radiographic tumor response to radiation therapy, even with ablative radiation techniques. The analysis is limited by the lack of biopsy data to quantify whether visualized residual tumor harbor active cancer.

Abstract 2869 – Table 1: Demographic and outcome data at 12-month follow-up stratified as responders and non-responders. Number in parentheses are interquartile ranges.

	Total Patients (N = 94)	Radiographic Responders (N = 81)	Radiographic Non-Responders (N = 13)	P-Value
Age	70.8 (66-76.5)	70 (67-77)	71 (65-74)	0.58
Risk Group (FIR/UIR) No Yes	60% 40%	61% 29%	54% 46%	0.76
ADT Used No Yes	28% 72%	27% 73%	39% 61%	0.51
GTV Boost No Yes	67% 33%	70% 30%	46% 54%	0.11
iPSA	9.5 (5.9-10.8)	8 (6-10.8)	6.1 (5-11.7)	0.61
T-Stage (High) No Yes	88% 12%	88% 12%	92% 8%	> 0.9
Gleason Score (High) No Yes	67% 33%	67% 33%	69% 31%	> 0.9
Initial Gland Volume (g)	46.5 (29.8-53.9)	38.7 (30-52.7)	41.9 (29.1-67)	0.56
Number of MRI Dominant Nodules 1 2 3	72% 22% 4%	71% 25% 4%	85% 8% 7%	0.25
Longest Lesion Diameter (cm)	1.86 (1.2-2.4)	1.6 (1.2-2.4)	1.5 (1.4-2.2)	0.92
Lesion Location Both TZ PZ	17% 68% 15%	15% 68% 17%	8% 85% 7%	0.72

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2870

MR-Guided HDR Brachytherapy Boost in Localized Prostate Cancer – Results of a Phase II Trial

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Purpose/Objective(s): Dose escalation in localized prostate cancer using brachytherapy combined with external beam radiation (EBRT) has demonstrated improved biochemical control compared to EBRT alone. However, ultrasound guided LDR brachytherapy might be associated with increased GU toxicity. We report the results of a prospective study of MR-guided HDR brachytherapy (MRgHDR) in combination with EBRT for localized prostate cancer.

Materials/Methods: Intermediate- (IR) and high-risk (HR) prostate cancer patients were eligible. Patients received either 15Gy single fraction or 10Gy x 2 fractions using MRgHDR technique, followed by EBRT (37.5 Gy, [prostate only] -IR or 45–46 Gy – [prostate + pelvic nodes] -HR). Toxicity (CTCAE v4) and HRQoL (EPIC) were recorded at 1, 3 and 6 months, then at 1, 2, 3, and 5 years. Androgen deprivation therapy (ADT) was used according to the appropriate disease risk category. Biochemical failure was defined according to Phoenix definition (nadir+2).

Results: From 2010-2018, 120 patients were enrolled, 53 (44%) had IR and 67 (56%) had HR disease. Median age was 69 years (range, 46-78), median PSA was 12.1 ng/ml (3.2-148). ADT was used in 84 (70%) of patients, of whom 51 (60%) patients received <1 year and 33 (40%) received >1 year of ADT. A single fraction of 15Gy was given to 94 patients (78%) and the remaining 26 patients (22%) received 10Gy x 2 fractions. EBRT dose was 37.5Gy in 52 (43%) patients while 67 (56%) received 45-46Gy. One patient received only the first fraction of 10Gy, declined the second fraction and subsequently received 60Gy EBRT to the prostate. The median follow up was 58 months (11-134). Overall, 5-year biochemical control was 90% while it was 95% and 86% for IR and HR, respectively. At 5 years 7% patient had nodal or distant relapse or both. While the 5-yr distant control rates were 95% and 91% in the IR, HR, respectively. Acute grade ≥2 GU and GI toxicity was 6.7% and 5% respectively. Acute toxicity trended back to baseline by 6 months in all patients except one. Late grade ≥ 2 GU and GI worst toxicity was seen in 10% and 4.2%, respectively. As with acute toxicity, late toxicity tended to improve over time. Only one patient experienced severe toxicity (Grade 3 GU - frequency) at 6 months but subsequently this resolved. HRQol will be reported separately.

Conclusion: MRgHDR brachytherapy boost in conjunction with EBRT provides comparable biochemical outcomes compared to the literature. Severe toxicity rates were minimal. Further follow-up will determine if these outcomes are sustained.

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2871

Prostate Cancer Screening Uptake in Transgender Females

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