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Is semi-weekly whole prostate gland stereotactic radiotherapy with focal boosting in the phase II hypo-FLAME 2.0 trial associated with acceptable acute toxicity?

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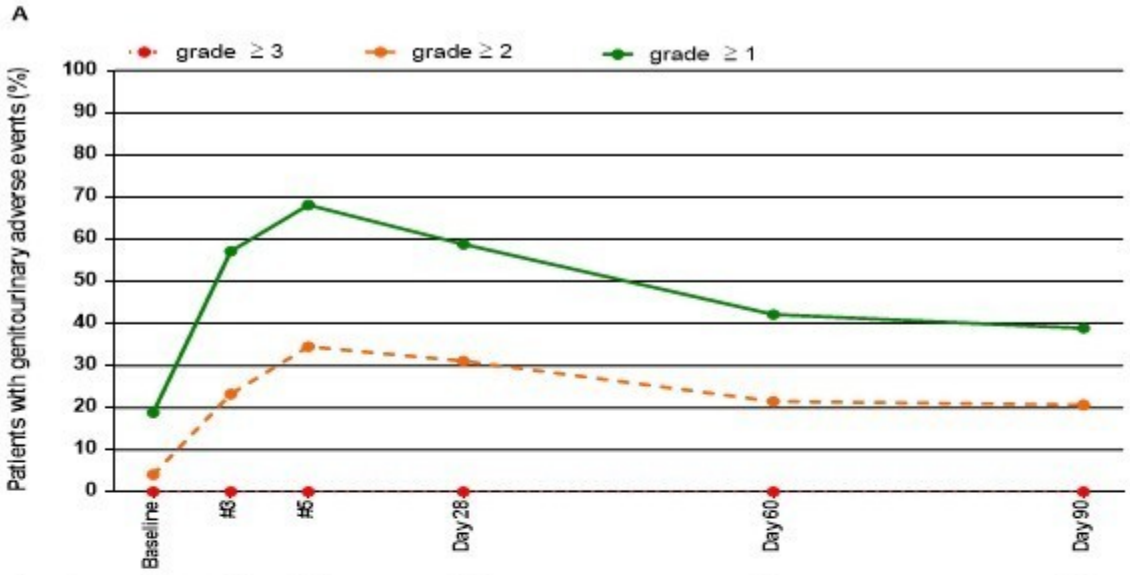
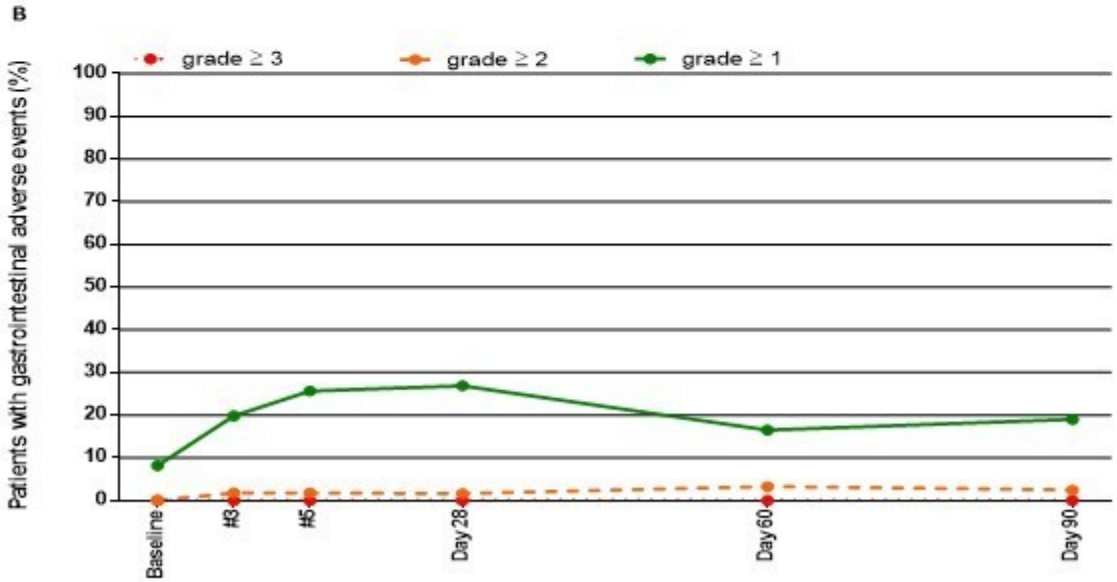
Introduction & Objectives: Recently, the phase II hypo-FLAME trial showed that whole prostate gland stereotactic body radiotherapy (SBRT) with simultaneous focal boosting up to 50 Gy to the macroscopic tumor(s) is associated with acceptable acute genitourinary (GU) and gastrointestinal (GI) toxicity in patients with intermediate- and high-risk prostate cancer (PCa). However, in recent studies a longer overall treatment time (OTT) was identified as a potential adverse factor for treatment outcome. Therefore, we investigated the feasibility and safety of reducing the OTT of whole prostate gland SBRT with focal boosting from 29 (hypo-FLAME schedule) to 15 days (hypo-FLAME 2.0 schedule).

Materials & Methods: In this prospective, multicenter phase II trial, patients with intermediate- and high-risk PCa were included. Treatment consisted of SBRT with a total dose of 35 Gy in 5 fractions to the whole prostate gland with an iso-toxic simultaneous integrated boost up to 50 Gy to intraprostatic lesion(s) visible on the multiparametric (mp)MRI in a semi-weekly schedule. Primary endpoint of the trial was treatment-related acute GU and GI toxicity, measured by CTCAE v5.0.

Results: One hundred twenty-four patients were enrolled in the trial between August 2020 and February 2022. The majority of patients (67%) were classified as high-risk PCa according to the EAU risk classification. Patients were followed for at least 3 months. The median near minimum dose delivered to the GTV was 41.58 Gy. No grade ≥ 3 GU or GI toxicity was observed. The 90-days cumulative incidence of grade 2 GU and GI toxicity rates were 47.5% and 7.4%, respectively. The prevalence of grade 2 GU toxicity reached a maximum at week 3 of 34.5% and declined to 20.7%, 90 days after start of treatment. Furthermore, the prevalence of grade 2 GI toxicity did not exceed 5% at any timepoint (Figure 1).



	Baseline	#3	#5	Day 28	Day 60	Day 90
Number of patients	122	112	113	119	121	121
G1 toxicity	18	38	38	33	25	22
G2 toxicity	5	26	39	37	26	25



	Baseline	#3	#5	Day 28	Day 60	Day 90
Number of patients	122	111	113	119	121	121
G1 toxicity	10	20	27	28	16	20
G2 toxicity	0	2	2	4	4	3

Figure 1 CTCAE v5.0 toxicity by timepoint. (A) Prevalence of genitourinary (GU) and (B) prevalence of gastrointestinal (GI) toxicity. Grade ≥ 1 = grade 1 or worse adverse event. Grade ≥ 2 = grade 2 or worse adverse event. Grade ≥ 3 = grade 3 or worse adverse event. #3/5 = At fraction 3 (week 2)/5 (week 3), respectively.

Conclusions: Semi-weekly SBRT combined with iso-toxic focal boosting is associated with acceptable acute GU and GI toxicity in intermediate- and high-risk PCa patients.