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Urethra-Sparing Single-Dose Ablative Radiation Therapy for Unfavorable Localized Prostate Cancer with Real-Time Target Motion Management

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Abstract
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Abstract

Objectives:

Along with huge improvement in radiobiological knowledge and technical capabilities, in recent years extreme hypofractionation using Stereotactic Body Radiotherapy (SBRT) has also been explored with optimal results in terms of biochemical control and side effects for patients with localized prostate cancer (PCa). If single fraction sessions are routinely used for intracranial targets, their utilization for mobile extracranial lesions is still a source of debate and apprehension. The aim of this study is to report the implementation of urethra-sparing Linac-based Single-Dose Ablative Radiation Therapy (SDART) for unfavorable localized PCa with real-time intrafraction organ motion management (NCT04831983).

Methods:

From June 2021 to July 2023, all thirty expected patients with localized unfavorable intermediate or selected high-risk prostate tumors were enrolled to receive an ultra-high SDART of 24 Gy (BED 1.5 = 408 Gy). Patients were simulated with empty rectum and bladder filled by a Foley catheter. Fused CT and T2W 3D MRI image sets were used to delineate the target and the Organs at Risk (OARs). The PTV consisted of the CTV with a 2-mm isotropic margin. A high-dose avoidance zone (HDAZ) was created by a 3-mm expansion around the rectum, bladder, and urethra. Patients were planned with a 10MV FFF single arc from 140° to 220° optimized using target penalties to a minimum dose defined by the OARs dose constraints with a dose escalation to 24 Gy to the target volume away from the HDAZ. During the treatment delivery, CBCT matching ensured accurate patient setup alignment through prostate and urethra localization. An electromagnetic tracking device allowed for the monitoring of real-time 3D prostate motion. Treatment was interrupted and position was corrected when the signals exceeded a 2 mm threshold. Acute toxicity was evaluated with Common Terminology Criteria for Adverse Events version 5 (CTCAE_5.0) after 3 months from the treatment.

Results:

All planning objectives were achieved. Median CTV and PTV were 50.8 cc [16.3 – 75.7] and 72.0 cc [25.6 – 100.6], respectively. The average total monitor units per plan were 6910 ± 592. All the treatment plans were quality assured using a 2D silicon diode array and fulfilled a 2%/2mm gamma passing rate >95% objective. The mean delivery time lasted 4.3 ± 0.5 minutes [3.3 – 5.7]. The overall mean treatment time, from procedure inception to beam-off, was 15.9 ± 8.4 minutes [6.9 – 35.5]. Intrafraction tracking was successfully carried out in all sessions and beam interruptions due to target motion beyond limits were needed in 17 patients (57%), with 1.5 [1 – 2] interruptions per patient on average. The prostate was found within 2 mm from its initial position in 82% of the treatment time, i.e. in 77% of the time during the setup phase and in 93% during the delivery phase (beam on + interruptions). At 3-month follow-up, only one patient experienced gastrointestinal (GI) side effects (G1), while genitourinary (GU) toxicity was observed in eight patients (six G1 and two G2), mainly consisting of increased urgency and frequency.

Conclusion(s):

24 Gy single-dose ablative radiation therapy irradiation of the whole prostate was feasible and well tolerated. The volume of rectal mucosa receiving critical doses was limited by the use of an HDAZ in patients

with good bowel preparation, without using invasive devices such as hydrogel spacer or endorectal balloon. The accomplishment of urethra sparing with a 20% dose reduction to minimize GU toxicity is feasible through appropriate catheter-guided imaging procedures and online tracking during treatment delivery. Our preliminary findings offer encouraging perspectives and the long-term results of this study will certainly shed light on the efficacy and safety of 24 Gy SDART in the treatment of localized PCa.