

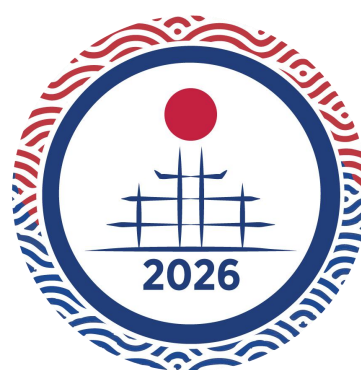


EP08.01: To Explore the Safety and Efficacy of Hypervision Proton Surgery for Early-Stage Lung Cancer (HyPROS)

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INTRODUCTION

This study adopted a dose escalation protocol (an improved "two-stage two-dose group" design) to explore the safety and efficacy of visual proton surgery (single large fractionated doses of 34GyE and 39GyE) in stage I peripheral lung cancer (T1aN0M0).

This study is a single-center, single-arm clinical trial. Based on the findings of the RTOG 0915 study¹, the 5-year primary tumor failure rate in the single-fraction group (34 Gy/f) was significantly higher than that in the multi-fraction group (48 Gy in 4 fractions). Therefore, in this study, the total dose at the center of the internal target volume was designed to be escalated sequentially. A dose-escalation scheme (an improved "two-stage, two-dose group" design) was adopted to explore the safety and efficacy of image-guided proton therapy (single high-dose fractions of 34 GyE and 39 GyE) for the treatment of early-stage peripheral lung cancer.

METHODS

The main inclusion criterias include: (1) Eligible participants were required to be ≥18 years of age with a Karnofsky Performance Status (KPS) score >80; (2) Patients had to have histologically or cytologically confirmed lung cancer. For patients in whom pathological confirmation could not be safely obtained due to tumor location, comorbidities, or high biopsy risk, the diagnosis was established by consensus of a multidisciplinary team (MDT) based on typical imaging features (contrast-enhanced chest CT and/or PET/CT) in conjunction with clinical presentation, consistent with accepted clinical diagnostic criteria; (3) T1 (≤3 cm) N0M0, tumors were required to be located more than 2 cm in all directions from the proximal bronchial tree (defined as the distal 2 cm of the trachea, the carina, and the named lobar bronchi up to their first bifurcation); (4) Adequate pulmonary function was required, defined as a forced expiratory volume in 1 second (FEV1) ≥1L or ≥40% of the predicted value (either criterion acceptable), and a diffusing capacity of the lung for carbon monoxide (DLCO) ≥40% of the predicted value; (5) Participants had to be able to tolerate PET-CT examination; (6) For women of childbearing potential, a negative urine or serum pregnancy test within 7 days prior to the initiation of study treatment was required; if the urine test was positive, a confirmatory serum pregnancy test was performed.

REFERENCES & ACKNOWLEDGEMENTS

All authors declare no conflict interests.

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2. Videtic GM, et al. Int J Radiat Oncol Biol Phys. 2019 Apr 1;103(5):1077-1084.

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RESULTS

Table1. The main dosimetric endpoints of OAR doses comparing HyPROS and photon based SBRT.

OAR	Radiation therapy	Dosimetric endpoint				
		Max Dose (cGyE)	Mean Dose (cGyE)	V5 (%)	V30 (%)	V40 (%)
Left lung	Proton	3899.7	192.2	10.8	0.8	0.0
	Photon	3816.0	283.7	16.0	1.3	0.0
Right lung	Proton	0.5	0.2	0.0	0.0	0.0
	Photon	623.3	44.2	0.2	0.0	0.0
Lungs	Proton	3899.7	83.4	4.7	0.3	0.0
	Photon	3816.0	148.0	7.1	0.6	0.0
Esophagus	Proton	8.2	0.2			
	Photon	628.1	53.6			
Heart	Proton	417.5	1.2			
	Photon	1408.0	58.0			
Ribs	Proton	2834.7	36.2			
	Photon	2785.2	84.5			
Spinal Cord	Proton	0.0	0.0			
	Photon	305.0	13.5			
Trachea	Proton	663.2	9.0			
	Photon	1105.5	198.8			

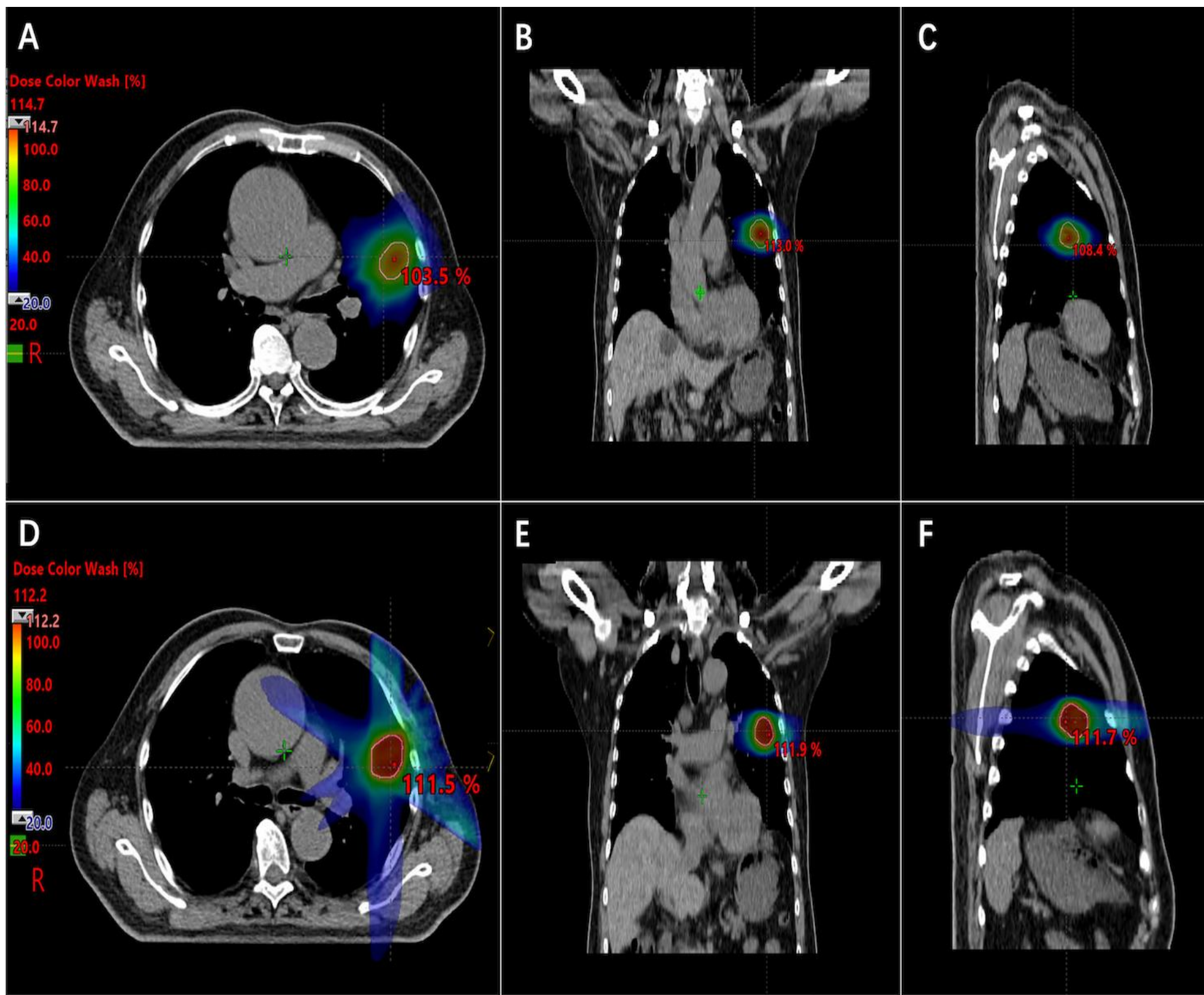


Figure1. Target volume delineation for a patient (peripheral non-small-cell lung cancer) who received single-fraction proton radiotherapy with a prescribed dose of 34 GyE with HyPROS and photon based SBRT. A, B, C, the target volume in the coronal, axial, and sagittal planes of HyPROS; D, E, F, the target volume in the coronal, axial, and sagittal planes of photon based SBRT.

DISCUSSION AND CONCLUSION

We have finished treatment of three patients with peripheral non-small cell lung cancer in the first stage. The proton surgery all demonstrated unique dosimetric advantages such as the ipsilateral lung, both lungs, heart, esophagus, spinal cord and trachea. These three patients are still under follow-up, and no adverse events have been observed to date.

The single-fraction proton surgery (34 GyE/f) maybe delivered safely in stage I peripheral lung cancer.