

SCART, A Multi-Center Phase I Trial of Stereotactic Central Ablative Radiation Therapy for Bulky Tumor

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Published 02/11/2022

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Categories: Radiation Oncology

Keywords: sfmt, lattice, scart

How to cite this abstract

Yan W, Lu Q, Qi W, et al. (February 11, 2022) SCART, A Multi-Center Phase I Trial of Stereotactic Central Ablative Radiation Therapy for Bulky Tumor. Cureus 14(2): a780

Abstract

Objective: Patients with bulky tumors have worse prognosis and often receive only palliative treatments. SFRT (Spatially fractionated radiation therapy) is important in its concept of covering whole or partial tumor with inhomogeneous radiation dose and gives the field more creativity and complimentary applications to supplement standard school of radiation therapy. SFRT, such as GRID therapy, has been shown to offer benefits in the bulky tumor settings. However, the optimal dose and fractionation of SFRT is yet to be explored. Therefore, a prospective, multi-center, dose-escalation trial was initiated. We are proposing a new treatment methodology (called Stereotactic Centralized Ablative Radiation Therapy, SCART) for bulky or metastatic tumor, which is based on the principles of SFRT, by using SBRT methods to deliver an ablative radiation dose to central portion of target while keeping the dose to surrounding normal tissue to relatively low level. We aim to establish the maximum tolerated dose of SCART in clinical practice.

Methods: We conducted a prospective multi center phase-1 dose-escalation study. Patients with unresectable solid "bulky" nonhematological malignancies with limited treatment options were enrolled and received SCART with a prescription to the central spot in the tumor with peripheral dose to the tumor edge at 20% isodose line of prescription dose. Six dose-levels were proposed, with starting dose level 1 of 15 Gy to primary central spot PTV in one fraction, level 2 of 15Gy X2, level 3 of 15Gy X3, level 4 of 18GyX3, Level 5 of 21GyX3, Level 6 of 24GyX3, while keep the whole tumor GTV's border dose at 5Gy each fraction. Primary endpoint was maximum tolerated dose (MTD), defined as the highest dose where zero of three or one of six patients experienced grade 3 dose-limiting toxicity (DLT), scored according to the Common Toxicity Criteria for Adverse Events v. 4.03, up to 6 months after SABR.

Results: Thirty patients received SCART. Radiotherapy was well tolerated with all treatment completed as scheduled. Dose was escalated two levels up from starting dose without encountering any DLT, currently at 18GyX3. No grade3 toxicity was observed in any of the enrolled patients. Patients who have long term follow up data available showed that 5/13 achieved PR, 3/13 achieved CR and 5/13 were SD, no PD was observed in patients treated.

Conclusion: SCART was feasible and effective with remarkably low toxicity rates and high local control rates. Current safe dose level was 18GyX3, MTD for SCART is yet to be established with ongoing trial.