Proton Collaborative Group (PCG) Phase I Study of Hypofractionated Proton Therapy for Stage II-III Non-Small Cell Lung Cancer

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BACKGROUND AND PURPOSE

We investigated whether proton therapy would allow safe dose intensification with concurrent chemotherapy for patients with stage II/III non-small cell lung cancer (NSCLC).

PATIENT AND DISEASE METHODS

• 18 patients from 4 different Proton Collaborative Group institutions were enrolled and treated on an IRB-approved prospective phase I study.
• Patients received concurrent chemotherapy with hypofractionated proton therapy to a planned total dose of 60 GyRBE, but with an increasing dose per fraction in a 5x5 step-wise fashion.
  • Arm 1 delivered 2.5 Gy/fraction (n=5);
  • Arm 2 was 3 Gy/fraction (n=5);
  • Arm 3 was 3.53 Gy/fraction (n=7);
  • Arm 4 was 4 Gy/fraction (n=1).
• Dose arms were considered safe provided 0/5 or 1/7 patients developed a radiation-related SAE within 90 days.
• Patients received consolidative chemotherapy or immunotherapy after completing concurrent therapy.

RESULTS

• Median age, 71 (range 50-86) years
• Median follow-up of surviving patients, 30 (range 16-65) months
  • 1 yr OS= 90%; 2 yr OS= 73% (Figure)
• No radiation-related SAEs within the first 90 days on Arm 1 or 2
• 1 patient developed an SAE on Arm 3 (among the first 5 enrolled), leading to another 2 patients enrolled (n=7) with another SAE.
• 2 SAEs in the first 90 days were both unrelated to radiation:
  • Patient 1: Hospitalized with C. diff colitis and influenza
  • Patient 2: 2-day hospitalization for pneumonia out-of-field

CONCLUSIONS

1. Hypofractionated proton therapy with concurrent chemotherapy to a dose of 60 GyRBE in 2.5-3.53 Gy/fraction is well tolerated.
2. A phase II study of hypofractionated proton therapy with concurrent chemotherapy for patients with stage II/III NSCLC is warranted.

Figure: Kaplan-Meier Survival Analysis

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