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Multi-institutional Proton Beam Therapy Outcomes for HCC from the PCG REG001-09 Registry Study

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Objectives

External beam radiation therapy (EBRT) for hepatocellular carcinoma (HCC) is commonly delivered with x-rays, although protons offer a unique dosimetric advantage that for some patients may translate into meaningful clinical benefit. Most published outcomes of PBT for HCC come from Asian institutions, while there is a scarcity of data from Western countries. The primary study objective was to describe treatment efficacy and safety outcomes.

Methods

We identified patients with non-metastatic HCC patients treated with definitive PBT at various institutions in the United States and enrolled on the Proton Collaborative Group REG001-09 prospective registry study (NCT01255748).

Results

88 patients were treated from 2013-2021 across 9 institutions. Median age was 68 years (range, 40-91) most with ECOG performance status 0-1 (77.3%). Median tumor size was 5.0 cm (range, 1.2-19 cm). Baseline Child-Pugh (CP) class was A, B, C, or unknown in 43 (48.9%), 15 (17.0%), 2 (2.3%), and 28 (31.8%), respectively. The median prescribed dose was 59.3 Gy (range, 37.5-90 Gy) in a median 15 fractions (range, 5-36 fractions). Median follow-up from PBT was 13.5 months. Estimated 2-year freedom from local failure (FFLF), freedom from intrahepatic failure (FFIF), freedom from distant failure (FFDF), progression free survival (PFS), and overall survival (OS) from PBT were 93.4%, 63.3%, 85.7%, 35.0%, and 54.6%, respectively. On multivariate analysis, worse OS was associated with age >median (HR 2.33, 95% CI: 1.11-4.91; p=0.026) while improved OS was associated with BED10 >median (HR 0.40, 95% CI: 0.17-0.90; p=0.028). No grade 3 toxicity was observed.

Conclusions

To our knowledge, this is the largest evaluation of prospectively assessed outcomes after definitive PBT for HCC in the United States. PBT delivered with ablative doses predominantly with moderate hypofractionation achieved excellent FFLF with no grade 3 toxicity. These data support the use of dose-escalated PBT especially for larger HCC.