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Abstract

Radiotherapy May Improve Progression Free Survival in Patients with Hepatocellular Carcinoma Treated with Nivolumab

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Objectives: Hepatocellular carcinoma (HCC) is a leading cause of cancer death worldwide, and outcomes for patients with locally advanced to metastatic disease are often particularly poor. In recent years, immunotherapy has become more widely used for these patients since the accelerated FDA approval of nivolumab as a second line agent. Little is known, however, regarding outcomes for patients who receive a combination of local therapy in addition to immunotherapy. In this study, we demonstrate a trend of improvement in progression free survival in patients who were treated with nivolumab and also received radiation therapy and/or other local therapy.

Methods: We conducted a retrospective review of patients with HCC who were treated with nivolumab between 2016-2019. We recorded all other local and systemic therapies administered. Adverse events were scored using CTCAE v. 4.0. Median durations of progression-free survival (PFS) and overall survival (OS) after initiation of immunotherapy were estimated using the Kaplan-Meier method. Clinical characteristics, including performance status, alpha-fetoprotein (AFP) level at time of diagnosis, ALBI score prior to start of immunotherapy, and presence of tumor thrombus, were collected.

Results: Fifty-three patients met eligibility criteria for this analysis. Thirty-four patients (64%) had ECOG performance status (PS) 0-1, 16 (30%) had PS 2, and 3 (6%) had PS 3. Six patients (11%) were ALBI Grade 1, 37 (70%) were ALBI Grade 2, and 10 (19%) were ALBI Grade 3. Thirty-two patients (60%) had tumor thrombus. Forty-one patients (77%) received local therapy, with eighteen patients (34%) receiving radiation therapy, 23 (43%) receiving at least one transarterial chemoembolization (TACE), 12 (23%) receiving Y-90, 11 (21%) undergoing surgical resection, and 3 (6%) receiving radiofrequency ablation (RFA). Almost all radiation therapy was performed using stereotactic body radiation therapy (SBRT) technique. Five patients experienced Grade 1 radiation related toxicities including nausea, vomiting, esophagitis, and fatigue. There were no Grade 2 or higher acute toxicities, and no documented late radiation related toxicities. With a median follow-up of 6.8 months after start of immunotherapy (range: 0.2 to 22.6 months), 32 patients (60%) developed documented disease progression and 22 (42%)

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were known to have died. The median PFS is 2.36 months. There was some improvement in PFS for those who received radiation therapy and/or other local therapy within 3 months of immunotherapy versus those who did not (HR 0.68, p=0.30). There was no difference in OS between the two groups (HR 1.07, p=0.88) and the median OS for all patients in the cohort was 6.9 months (range: 1.5 to 11.6 months).

Conclusions: The addition of radiation therapy, and/or other local therapy, resulted in a trend toward improvement in progression free survival in this population of patients with hepatocellular carcinoma who were treated with nivolumab. Further clinical study exploring combination radiation therapy and immunotherapy is warranted to more clearly elucidate the potential survival benefits in this otherwise aggressive malignancy.