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Safety and efficacy of anti-PD1 therapy in patients with viral hepatitis: A case series

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Anti-PD1 monoclonal antibodies have demonstrated durable long-term survival benefit in patients with metastatic melanoma. Limited evidence exists regarding the safety and efficacy of anti-PD1 agents in patients with Hepatitis B and C (HBV/HCV) as these patients have traditionally been excluded from clinical trials due to a theoretical risk of immune reconstitution inflammatory syndrome. This study presents seven patients treated with anti-PD1 agents' nivolumab and pembrolizumab for either metastatic melanoma or metastatic non-small cell lung cancer in the setting of chronic or past HBV/HCV infection. Safety and efficacy of treatment was determined by analyzing response to treatment, viral load and ALT trends. Patient-1 demonstrated an ALT rise of CTCAE grade-2 severity which returned to normal range following treatment of his HCV infection with ledipasvir 90 mg/sofosbuvir 400 mg. Patients 2-5 demonstrated an ALT rise of CTCAE grade-1 severity. Of these five patients, two achieved partial response, two had cancer progression after ≤ 2 cycles of treatment and one experienced cancer progression after maintaining stable disease throughout twenty cycles of treatment. The remaining two patients experienced nil hepatic toxicity with stable disease maintained after >24 cycles of nivolumab. Our results indicate that patients with metastatic melanoma and NSCLC can be safely treated with anti-PD1 immunotherapy in the context of HBV/HCV infection. Only one patient demonstrated an ALT rise greater than CTCAE grade-1 severity which returned to baseline following HCV treatment. This study recommends that those with active viral hepatitis be closely monitored for signs of hepatotoxicity and treated with anti-viral therapy if indicated.

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