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Case Report
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Harvoni-Induced Deterioration of Renal and Liver Function

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Introduction

Harvoni is now the most commonly used ant-HCV treatment in USA. The most common side effects are fatigue and headache. Rarely, it can cause nausea, diarrhea and insomnia. We describe a case of cirrhosis of liver secondary to HCV and alcohol. The patient received Harvoni but 4 weeks after receiving Harvoni he became extremely fatigued and developed acute renal failure with elevated transaminases.

Case Report

A 65 year old African American male was initially evaluated for his ascites. He was found to have cirrhosis of liver secondary to HCV genotype 1b and alcohol. He had also hypertension, cardiomyopathy, congestive heart failure, pulmonary hypertension and chronic kidney disease (CKD). He used to drink alcohol heavily in the past but stopped drinking alcohol few months prior to his presentation. He had never been treated for hepatitis C. He was a smoker. His medications included furosemide, spironolactone, aspirin, carvedilol, lisinopril, vitamin D3, multivitamin tablet and triamcinolone acetonide 0.1% external ointment. His physical examination was normal except mild abdominal distension with positive shifting dullness suggestive of ascites.

His lab studies showed

Before receiving Harvoni: WBC 5,000/cmm, Hb 10.1 gm/dl, platelet 233,000/cmm, BUN 28 mg/dl, creatinine 1.79 mg/dl, estimated GFR was 45 ml/min/m^2, INR 1.0, serum Albumin 3.9 gm/dl, AST 19 IU/L, ALT 39 IU/L, alkaline phosphatase 56 IU/L, total bilirubin 0.5 mg/dl. Serum HCV RNA : 4180000 units/ml. MELD score : 12, mainly due to high serum creatinine due to CKD. Child-Pugh class: B

4 weeks after receiving Harvoni

The patient became weak and tired. He was admitted to the hospital. WBC: 9,400/cmm, Hb 9.5 gm/dl, platelet 86,000/cmm, BUN 85 mg/dl, creatinine 5.1 mg/dl, INR 2.52, serum Albumin 3.4 gm/dl, AST 956 IU/L, ALT 859 IU/L, alkaline phosphatase 112 IU/L, total bilirubin 2.1 mg/dl, HCV RNA – undetectable. Harvoni was discontinued and the patient received hemodialysis.

10 days after discontinuing Harvoni

WBC 6,000/cmm, Hb 8.5 gm/dl, platelet 101,000/cmm, BUN 25 mg/dl, creatinine 3.4 mg/dl, INR 1.20,

Serum Albumin 3.9 mg/dl, AST 59, ALT 100, alkaline phosphatase 60, total bilirubin 0.6 mg/dl. The patient became more stable and was able to go home.

Discussion

Harvoni is a tablet in which there is combination of two direct acting anti-viral agents (DAA): 90 mg of Ledipasvir (NS5A inhibitor) and 400 mg of Sofosbuvir (NS5B Nucleotide Polymerase Inhibitor). It was approved by the FDA (Food and Drug Administration, USA) in October, 2014 for the treatment naïve and treatment-experienced patients suffering from chronic hepatitis C genotype 1 with or without cirrhosis. It is effective against HCV genotypes 1, 4, 5 and 6.Most of the patients tolerate this medication very well. In one study, Harvoni was given to patients with advanced liver disease: 4% of patients had to discontinue the medication because of adverse side effects and 3% of patients died [1]. Harvoni-induced acute renal failure has been reported in few case reports [2]. Biopsy proven acute interstitial nephritis was found in one case [3]. As Sofosbuvir is excreted via the kidneys, its metabolites remain in the circulation for long time in patients with CKD. The inactive nucleotide metabolite of sofosbuvir, PSI-6206 is increased in mild, moderate and severe renal impairment [4]. Their effects on renal and hepatic impairment are not known. Hepatotoxicity is probably due to rapid viral clearance from the liver rather than toxicity due to the drug or its metabolites. Harvoni-induced hepatotoxicity was documented when Harvoni was given in patients with

decompensated cirrhosis of liver [5].Our patient had multiple comorbidities including CKD and compensated cirrhosis of liver but developed acute renal failure and hepatotoxicity few weeks after receiving Harvoni. Clinicians should closely monitor this category of patients when treating hepatitis C with Harvoni.

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