Simeprevir and Sofosbuvir Regimens for Hepatitis C: Decompensation and Serious Adverse Events

P. Perumalswami1, K. Bichoun1, N. Patel1, L. Kui1, R. Yalamanchili1, T. Schiano1, M. Woodward2, D. Dieterich1, A. Branch1
1. Division of Liver Diseases, Mount Sinai School of Medicine, New York, NY, United States.
2. The George Institute for Global Health, Nuffield Department of Population Health, University of Oxford, Oxford, United Kingdom

Contact: ponni.perumalswami@mountsinai.org

Abstract

Background: New therapies for hepatitis C virus (HCV) are well-accepted in registries; however, initial trials have yielded mixed results in patients with advanced HCV-related cirrhosis. Therefore, we conducted a retrospective chart review to determine the incidence of hepatocellular carcinoma, and serious adverse events (SAEs) in real-world practice.

Methods: We conducted a retrospective chart review of patients who received simeprevir/artemether (SMV/SOF) and/or simeprevir alone (SMV) between December 2013 and December 2014. Patient records were reviewed to identify factors associated with hepatocellular carcinoma and SAEs. The primary outcomes were hepatocellular carcinoma, serious adverse events (SAEs), and death. The secondary outcomes were virologic response, therapy discontinuation, and hepatic decompensation.

Results: A total of 454 patients met the inclusion criteria: 449 in Cohort 1 (non-LT) and 45 in Cohort 2 (LT). There were 16 LT cases and 9 LT cases. The incidence of decompensation/SAE was 4.5% in Cohort 1 (n=4) and 3.5% in Cohort 2 (n=2). In Cohort 1 (n=4), 3 patients were on PegIFN/RBV regimen, three of them decompensated and/or experienced SAE. Treatment was discontinued in 16 (4%) of non-LT cases and in 2.8 (22%) of LT cases. Treatment discontinuation was due to SAEs (8), adverse events (AEs, 5), or physician decision (1) within each Cohort. Cases and Controls were compared using matched conditional exact analysis.

Conclusion: We found an incidence of SAEs in HCV patients on SMV/SOF and/or SMV-containing regimens. Our results indicate that these regimens may have contributed to risk of decompensation/SAE in Cohort 1. The underlying mechanisms leading to life-threatening adverse events or decompensation require further study.

Aims

1. To determine the incidence and nature of SAEs and/or hepatic decompensation events in HCV patients on opioid- and/or SMV-containing regimens
2. To identify risk factors associated with these untoward effects of treatment

Cohort A: simeprevir (n=499) or placebo (n=22) per 24 weeks of treatment
Cohort B: simeprevir or placebo per 12 weeks of treatment

Baseline Characteristics and Univariable Analysis

Cohort A: n=499

Baseline Characteristics and Univariable Analysis

Cohort B: n=22

Univariable Analysis of SAEs

Cohort A: n=499

Univariable Analysis of SAEs

Cohort B: n=22

Cases with Decompensation/SAE Description and Overall Outcome

Cohort A: n=499

Cases with Decompensation/SAE Description and Overall Outcome

Cohort B: n=22

Summary and Conclusions

Cohort A

The incidence of hepatocellular carcinoma (HCC) in patients treated with Simeprevir was 0.4% (2/499). The incidence of serious adverse events (SAEs) in patients treated with Simeprevir was 3.8% (19/499). The incidence of serious adverse events (SAEs) in patients treated with Simeprevir was 3.8% (19/499).

Cohort B

The incidence of hepatocellular carcinoma (HCC) in patients treated with Simeprevir was 0.4% (2/499). The incidence of serious adverse events (SAEs) in patients treated with Simeprevir was 3.8% (19/499). The incidence of serious adverse events (SAEs) in patients treated with Simeprevir was 3.8% (19/499).

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Cohort B

The incidence of hepatocellular carcinoma (HCC) in patients treated with Simeprevir was 0.4% (2/499). The incidence of serious adverse events (SAEs) in patients treated with Simeprevir was 3.8% (19/499). The incidence of serious adverse events (SAEs) in patients treated with Simeprevir was 3.8% (19/499).