# Hepatitis C virus (HCV) treatment Interruptions in patients prescribed ledipasvir/sofosbuvir at three ambulatory care clinics

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Background

Hepatitis C affects 3.5 million Americans and is a significant source of morbidity and mortality. Ledipasvir/sofobuvir (LDV/SOF) has rates of sustained virologic response at 12 weeks (SVR12) above 90% and adherence rates around 95% in clinical trials; side effects are less severe and occur less frequently than the previous standard of care and treatment regimens are shorter. Costs, prior authorizations and required follow-up labs can create multiple challenges to completing therapy uninterrupted in real-life settings. Barriers to successful completion of therapy have been reported in various steps along the care cascade. Currently, there is limited knowledge of the causes of treatment interruptions or the clinical and economic consequences of those interruptions.

Objectives

The primary objective of this study was to describe the patients who experienced treatment interruptions while on LDV/SOF and the characteristics of those interruptions. The secondary objective was to describe SVR12 in patients treated with LDV/SOF who experienced treatment interruptions.

Methods

Patients in this retrospective, single cohort study were included if they were age 18-89, have HCV genotype 1, were treated with LDV/SOF at one of three ambulatory care clinics and had at least one prescription for LDV/SOF filled at one of three pharmacies associated with the University of Maryland Medical Center between October 15, 2014 and October 15, 2015. Sociodemographic (age, gender, race, payer source, clinic location, pharmacy), clinical (HCV genotype, HCV treatment history, METAVIR, baseline viral load (VL), intended treatment duration, comorbidities), and interruption (length, reason, provider response) variables were collected using the electronic medical record.

Results

A total of 11 treatment interruptions were identified through pharmacy claims data and provider recall. Overall, the primary cause of interruptions varied widely with 3 (27.3%) caused by a perceived adverse drug reaction and 2 (18.2%) each caused by VL not being drawn on time, prescription insurance coverage change, medication not brought to hospital during admission, and “other”. Provider response to interruptions was diverse with LDV/SOF being discontinued in 6 (54.5%) subjects and the others being resumed or re-started with full treatment course. The rate of checking VL at 12 weeks was poor but 10 (91.9%) subjects had VL drawn at some point post-baseline. Of those patients, 8 (80%) achieved undetectable VL, though it is unknown whether this response is sustained.

## Conclusion

This study successfully described patient characteristics, treatment interruptions, and virologic responses in patients on LDV/SOF experiencing treatment interruptions and is of interest to clinicians, patients, payers, and drug manufacturers. Barriers to successful completion of therapy exist but the clinical and economic impact of treatment interruptions remains unknown. Further work is needed to determine the barriers to successful completion of therapy and the implications of treatment interruptions.