



eViralHepatitis Review Special Edition

eViralHepatitis Review Special Edition is supported by an educational grant from Bristol-Myers Squibb

Program Information

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Length of Activity

- 1.0 hour Physicians
- 1.0 contact hour Nurses

Launch Date

February 19, 2015

Expiration Date

February 18, 2017

TO ACCESS THE POST-TEST

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eViralHepatitis Review SPECIAL EDITION ISSUE 2

INDIVIDUALIZING THERAPY IN PATIENT SUBPOPULATIONS INFECTED WITH HCV WHO ARE COINFECTED WITH HIV, HAVE DECOMPENSATED CIRRHOSIS, OR HAVE UNDERGONE LIVER TRANSPLANTATION



In this Issue...

This eViralHepatitis Review Special Edition continues our focus on patients with hard-to-treat HCV, discussing individualized therapy in patients who have HIV coinfection, or decompensated cirrhosis, or have undergone liver transplantation. In this issue, eViralHepatitis Review Program Director Dr. Raymond Chung:

- Reviews the current clinical trial data presented at the 2014 American Association for the Study of Liver Diseases (AASLD)
- Interviews Dr. Susanna Naggie from Duke University about HCV-HIV coinfection
- Interviews Dr. Paul Kwo from Indiana University about HCV management in two patient groups: those with decompensated cirrhosis and those who have undergone liver transplantation
- Discusses strategies to treat this hard-to-treat patient population with eViralHepatitis Review Program Director Dr. Mark Sulkowski (also available through an audio link embedded in the body of this newsletter)

LEARNING OBJECTIVES

After participating in this activity, the participant will demonstrate the ability to:

- Identify strategies to increase HCV cure rates in patients who are HIV coinfecting by using oral direct-acting antiviral regimens.
- Identify strategies to increase HCV cure rates in patients with decompensated cirrhosis by using oral direct-acting antiviral regimens.
- Identify strategies to increase HCV cure rates in patients who have undergone liver transplantation by using oral direct-acting antiviral regimens.

OTHER VALUABLE RESOURCES

- AASLD
- Hepatitis B Foundation
- Hepatitis C Association
- iCasesCME
- Hepatitis Foundation

The Johns Hopkins University School of Medicine takes responsibility for the content, quality, and scientific integrity of this CME activity.

IMPORTANT CME/CE INFORMATION

▼ Program Begins Below

ACCREDITATION STATEMENTS

Physicians

This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education through the joint providership of the Johns Hopkins University School of Medicine and the Institute for Johns Hopkins Nursing. The Johns Hopkins University School of Medicine is accredited by the ACCME to provide continuing medical education for physicians.

Nurses

The Institute for Johns Hopkins Nursing is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

CREDIT DESIGNATIONS

Physicians

The Johns Hopkins University School of Medicine designates this enduring material for a maximum of 1.0 AMA PRA Category 1 Credit(s)[™]. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Nurses

This 1 contact hour educational activity is provided by the Institute for Johns Hopkins Nursing. Each activity carries a maximum of 1 contact hour or a total of 2 contact hours for the two activities in this program.

SUCCESSFUL COMPLETION

To successfully complete this activity, participants must read the content, and then link to the [Johns Hopkins University School of Medicine's website](#) or the [Institute for Johns Hopkins Nursing's website](#) to complete the post-test and evaluation. A passing grade of 70% or higher on the post-test/evaluation is required to receive CE credit.

There are no fees or prerequisites for this activity.

LAUNCH DATE

February 19, 2015; activities expire 2 years from the date of publication.

The estimated time to complete this activity is one hour.

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INTENDED AUDIENCE

The target audience (clinicians) for this initiative includes hepatologists, gastroenterologists, infectious disease physicians, primary care physicians (PCPs), and other clinicians involved in the care of patients with hepatitis C.

FACULTY DISCLOSURE

As a provider approved by the Accreditation Council for Continuing Medical Education (ACCME), it is the policy of the Johns Hopkins University School of Medicine Office of Continuing Medical Education (OCME) to require signed disclosure of the existence of financial relationships with industry from any individual in a position to control the content of a CME activity sponsored by OCME. Members of the Planning Committee are required to disclose all relationships regardless of their relevance to the content of the activity. Faculty are required to disclose only those relationships that are relevant to their specific presentation. The following relationship has been reported for this activity:

Mark S. Sulkowski, MD, served as a consultant/scientific advisor for AbbVie, Inc., Achillion Pharmaceuticals, Bristol-Myers Squibb, Gilead, Janssen, and Merck. He has received grant/research funding from AbbVie, Inc., Bristol-Myers Squibb, Gilead, Janssen, and Merck. Dr. Sulkowski has served as a DSMB member for Gilead, and has served on a steering committee for Pfizer, Inc.

Raymond T. Chung, MD, discloses that he has served as a principal investigator for AbbVie, Bristol-Myers Squibb, Gilead, and Mass Biologics.

No other planners have indicated that they have any financial interest or relationships with a commercial entity whose products or services are relevant to the content of their presentations.

[Guest Author Disclosures](#)

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STATEMENT OF RESPONSIBILITY

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STATEMENT OF NEED

- Many clinicians are unaware of promising new oral treatment options for subpopulations of patients with difficult-to-treat HCV (eg, patients who have cirrhosis, patients with genotype 3 who have failed standard PEG-IFN/RBV, patients who are post-transplant, and patients who are coinfecting with HIV) and how to match developing treatment regimens to appropriate patients.
- Clinicians treating patients with HCV are unaware of the efficacy/safety data of many new investigational agents targeting the HCV life cycle (eg, NS3/4A PIs, NS5A, RNA-dependent RNA polymerase NS5B inhibitors, and cyclophilins).

LEARNING OBJECTIVES

- Distinguish among the various classes and targets of current and investigational HCV agents.
- Evaluate emerging data on current and investigational HCV agents and their impact on different hard-to-treat patient populations.
- Identify appropriate treatment decisions based on both individual patient factors and emerging data on current and investigational HCV agents.

For CME Questions, please contact the CME Office (410) 955-2959 or e-mail cmenet@jhmi.edu. For CME Certificates, please call (410) 502-9634.

Johns Hopkins University School of Medicine Office of Continuing Medical Education Turner 20/720 Rutland Avenue Baltimore, Maryland 21205-2195 Reviewed & Approved by: General Counsel, Johns Hopkins Medicine (4/1/03) (Updated 4/09 and 3/14)

HARDWARE & SOFTWARE REQUIREMENTS

To access activities, users will need:

- A computer with an internet connection
- An HTML5 compliant web browser or Internet Explorer 8 (and higher)

IN THIS ISSUE

- [Commentary & Review](#)
- [Interview with Dr. Susanna Naggie](#)
- [Interview with Dr. Paul Kwo](#)
- [Case Discussions with Dr. Mark Sulkowski](#)

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Dr. Naggie has indicated that she has served as a consultant for AbbVie, Achillion Pharmaceuticals, Bristol-Myers Squibb, Gilead Sciences, Infectious Diseases Society of America, and Merck. She has received research grant funding from AbbVie, Inc., Achillion Pharmaceuticals, Bristol-Myers Squibb, Gilead Sciences, Janssen Pharmaceuticals, and Vertex Pharmaceuticals. Dr. Naggie has participated in educational activities for International Antiviral Society-USA and Merck.

Dr. Kwo has indicated he has served as a consultant for AbbVie, Bristol-Myers Squibb, CVS, Gilead, Janssen, and Merck. He has received grant/research funding from AbbVie, Bristol-Myers Squibb, Gilead, Janssen, Lunatus, and Merck.

Dr. Sulkowski has indicated that he has served as a consultant/scientific advisor for AbbVie, Inc., Achillion Pharmaceuticals, Bristol-Myers Squibb, Gilead, Janssen, and Merck. He has received grant/research funding from AbbVie, Inc., Bristol-Myers Squibb, Gilead, Janssen, and Merck. Dr. Sulkowski has served as a DSMB member for Gilead, and has served on a steering committee for Pfizer, Inc.

Unlabeled/Unapproved Uses

Dr. Chung, Dr. Naggie, Dr. Kwo, and Dr. Sulkowski have indicated that there will be references to daclatasvir, ledipasvir, ombitasvir, dasabuvir, paritaprevir,

ABT-450/r, asunaprevir – alone or in combination, with or without ribavirin – that are not on-label for treating HCV, or HCV/HIV coinfection.

[Program Directors' Disclosures](#)

COMMENTARY & REVIEW

We have recently witnessed a breathtaking introduction of new antiviral agents for treating hepatitis C virus that have already revolutionized our approach to this patient population. In our previous Special Edition, we considered several difficult-to-treat groups of patients with HCV, including those with genotype 3 infection, those with compensated cirrhosis, and those with prior treatment experience. In this issue, we consider the outcome of DAA-based treatment for several additional patient groups that have historically been viewed as harder to treat, but in the current era may no longer be so. These include persons with HIV coinfection, those with decompensated cirrhosis, and those who have undergone liver transplantation.

1) Patients coinfecting with HIV

Patients with HCV/HIV coinfection are at risk for accelerated liver disease progression, and it is thus imperative to treat the HCV infection. Successful HCV eradication in this subgroup is associated with a reduction in all-cause and liver-related mortality.¹ The previous standard therapy of PEG-IFN (pegylated interferon) and RBV (ribavirin) was associated with disappointingly low sustained virologic response (SVR) rates (about 30%) for genotype 1 (GT1).² The first generation protease inhibitors, telaprevir and boceprevir, when combined with PEG and RBV, improved treatment efficacy to the extent that SVR rates approached those seen with patients who were negative for HIV.³ However, the treatment toxicities and drug-drug interactions associated with these regimens posed significant challenges for their use in the population with coinfection.

Sofosbuvir (SOF) metabolism is independent of cytochrome P450 (it is phosphorylated by host kinases and eliminated by the kidney); thus it has few drug-drug interactions with contemporary HAART regimens. The PHOTON-1 and PHOTON-2 studies evaluated SOF with RBV for variable durations in patients with HCV/HIV coinfection who were both treatment-naïve and treatment-experienced. This combination produced SVR rates exceeding 80% across GT1 to GT3, including in patients with advanced fibrosis,^{4,5} again putting SOF with RBV on par with results observed for the same regimen in HCV monoinfection. The recently approved SOF/LDV FDC (sofosbuvir/ ledipasvir fixed-dose combination), which produces remarkably high SVR rates among those with HCV monoinfection, is currently being evaluated in the phase III ION-4 study of those with HCV/HIV coinfection.

A recent phase II study of 50 treatment-naïve patients with genotype 1 HCV/HIV coinfection who were on a wide range of ART regimens, with the exception of boosted HIV PIs, evaluated the use of SOF/LDV FDC. The study, called ERADICATE, disclosed 98% SVR12 rates with this regimen.⁶ This regimen was well tolerated with no premature discontinuations due to AEs. There was also no loss of HIV control. Although SOF/LDV FDC can raise tenofovir levels, no significant tenofovir nephrotoxicity was observed. It will be of great interest to define the safety of coadministration of SOF/LDV FDC and ART regimens containing boosted PIs, which themselves could further increase tenofovir levels. In the meantime, persons with limited GFR should have alternative, non-TDF centered ART regimens considered during antiviral therapy for HCV. Until further data are available to clarify their use, boosted HIV PIs should be avoided in persons on TDF-based ART who are being considered for sofosbuvir/ledipasvir therapy.

Another NS5A inhibitor, daclatasvir, does not appear to have clinically relevant interactions with tenofovir or other commonly used antiretroviral agents, although this agent has not yet



been tested in HCV-HIV coinfection. A phase III trial, ALLY-2, combining daclatasvir with sofosbuvir, has conducted to address this population.

High rates of response may also be accomplished with other DAA combinations. A study assessing the use of paritaprevir boosted with ritonavir, ombitasvir, dasabuvir, and weight-based RBV for 12 or 24 weeks (TURQUOISE-1) in 63 treatment-naïve and -experienced patients with genotype 1 coinfecting with HCV/HIV also produced a promising SVR rate (91-94%).⁷ Those subjects were on raltegravir or boosted atazanavir-based ART regimens. No clinically significant drug-drug interactions were observed on these regimens, but other antiretrovirals are expected to present concerns with respect to drug interactions. Overall, all oral IFN-free regimens with comparable SVR and good tolerability and safety profile are viable options in patients with HCV/HIV coinfection.

2) Patients with decompensated cirrhosis

When patients with cirrhosis experience complications, including variceal hemorrhage, ascites, hepatic encephalopathy, coagulopathy, and jaundice, they enter an accelerated phase of the disease associated with limited hepatic reserve and a more ominous prognosis. Before the advent of DAA combinations, when the use of IFN-based regimens was the only option for managing HCV, treatment of decompensated cirrhosis was a contraindication because of IFN's high risk of hastening deterioration of hepatic function. The availability of all-oral, IFN-free combinations has now made treatment of HCV possible in decompensated cirrhotic HCV disease.

The SOLAR-1 study was a multicenter, randomized, controlled trial of 108 patients with HCV genotypes 1 and 4 who had decompensated cirrhosis. Study participants who were treatment-naïve or -experienced, with Child Turcotte Pugh (CTP) class B cirrhosis (score 7 to 9) or CTP class C cirrhosis (score 10 to 12), were randomly assigned to receive daily, fixed-dose, combination ledipasvir (90 mg) and sofosbuvir (400 mg) and RBV (initial dose of 600 mg, increased as tolerated) for 12 or 24 weeks.⁸

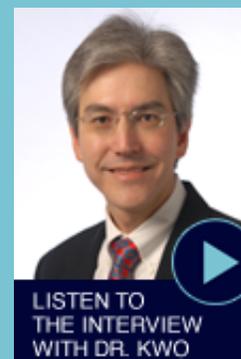
SVR was achieved in 87% of those in the 12-week treatment arm and 89% of those in the 24-week arm. Total bilirubin and serum albumin levels improved substantially at week 4 post-treatment compared with baseline in both treatment groups. Baseline CTP and MELD scores improved in over half of the treated patients, but some patients did experience worsening hepatic function. Five patients died, but none of the deaths was attributed to antiviral treatment. Most patients who started RBV at 600 mg/day did not escalate to higher doses. These findings support use of a 12-week course of ledipasvir/sofosbuvir and RBV for patients with decompensated cirrhosis who are infected with HCV genotype 1 or 4. This treatment may lead to objective improvements in hepatic function and reduce the likelihood of recurrent HCV infection after subsequent transplantation.

An alternative approach for persons who cannot tolerate ribavirin would be to extend therapy with sofosbuvir/ledipasvir to 24 weeks, given new data from a randomized trial in patients with compensated cirrhosis demonstrating the comparability of SOF/LDV + RBV for 12 weeks with SOF/LDV for 24 weeks.⁹

3) Patients who have undergone liver transplantation

HCV remains the leading indication for liver transplant (LT) in the United States. Historically, recurrence of viremia is universal, and allograft HCV infection has remained the major challenge for transplant centers worldwide. The natural history of allograft HCV disease is accelerated; 20%-30% will develop allograft cirrhosis within five years. In the era of PEG and RBV, SVR rates have been limited, in large measure due to the limited tolerability of the regimen and frequent need for PEG and RBV dose adjustments in patients post-LT. An additional complication is the risk of triggering IFN-induced plasma cell hepatitis in the allograft.

The newly FDA-approved DAA combination of SOF and LDV is well-tolerated post-transplant. In contrast to PIs, which are metabolized in the liver via cytochrome P450, SOF and LDV require no dose adjustment when used with calcineurin inhibitors (CNI).¹⁰ In a prospective multicenter study of 40 previously treated and treatment-naïve liver transplant recipients infected with GT1, 3 and 4, in which a combination of SOF and RBV was



administered for 24 weeks, 70% of patients achieved SVR. In this study, 40% of the patients had cirrhosis and 83% were treatment-experienced. Overall, this combination was well tolerated, with no important CNI toxicities.¹¹

More recent options for treating patients with HCV GT1 recurrence post-transplant include SOF/SMV (sofosbuvir/simeprevir) with or without RBV for 12-24 weeks. Retrospective analysis in a post-LT population revealed an SVR rate of 92%. Ongoing data have demonstrated a significant increase in SMV concentrations in patients receiving cyclosporine. Thus, cyclosporine should not be coadministered with SMV.

Another approach has been treatment with SOF/LDV FDC with RBV for 12 weeks. In a recent prospective study, SOF/LDV FDC with RBV (initial dose 600 mg) was evaluated in 223 patients infected with GT1 and GT4 post-liver transplant. The median post-transplant period was 4.4 years. This study consisted of both treatment-naïve (17%) and treatment-experienced individuals (83%). Approximately 50% of patients had mild to moderate fibrosis (metavir F0-F3). The study included patients with both compensated and decompensated cirrhosis. The SVR4 in patients without cirrhosis was 96% and 94% in the 12 week and 24 week arms, respectively. The SVR 4 in patients with cirrhosis was 92% and 82% in the 12 week and 24 week arms, respectively. Overall, this combination was well tolerated; five deaths were reported in the cohort with cirrhosis. The deaths were not thought to be related to the study drugs; few were due to complications of cirrhosis.¹²

An additional treatment option for management of allograft GT1 infection will soon include a combination of ritonavir-boosted paritaprevir, ombitasvir, dasabuvir, and ribavirin. This combination was evaluated in the CORAL-1 study that consisted of 34 patients who had liver transplant with minimal or no fibrosis. The great majority of patients tolerated therapy (33/34 patients) for 24 weeks with a low rate of adverse events. Only one patient discontinued therapy at 18 weeks due to severe rash, memory impairment, and anxiety, all thought to be drug-related. The SVR12 in this cohort was 97%. Ribavirin-associated anemia was the most common adverse event, with nine patients requiring ribavirin dosage adjustment and five patients requiring erythropoietin administration. No blood transfusions were required. Because of the interactions of ritonavir-boosted paritaprevir with CNIs, major dose reductions of tacrolimus or cyclosporine are mandated prior to initiating a course of antiviral therapy, along with careful monitoring of CNI levels throughout the treatment course.¹³

Daclatasvir (DCV), a potent NS5a inhibitor, has been approved in Europe for the management of HCV. Combination of DCV with SOF has been used successfully in the US for management of particularly severe, life-threatening, fibrosing cholestatic HCV, with very encouraging results. Clinical trials of DCV and SOF are ongoing in patients with allograft HCV.

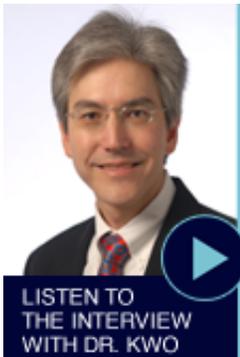
In summary, the management of HCV in populations once viewed as challenging to treat—including those with HIV coinfection and those who have hepatic decompensation or have undergone liver transplantation—has become much more successful with the introduction of combination DAA regimens. The combination of sofosbuvir with NS5a inhibitors, or the use of triple class therapy with a PI, NS5a, and NNI with or without RBV, has produced SVR rates that approach those seen in more conventional HCV populations: that is, in excess of 90%. Some drug drug interactions between DAAs and antiretroviral agents or calcineurin inhibitors require attention, but there is a wide latitude of options to successfully navigate these interactions. Remarkably, in a large portion of decompensated patients, improvements in hepatic dysfunction may be observed, suggesting that antiviral therapy could stabilize or improve the prognosis of some patients with end-stage liver disease.



[Click here to hear eViralHepatitis Review program director Dr. Raymond Chung discuss recent data on hard-to-treat patients with HCV with Dr. Susanna Naggie of Duke University Medical Center.](#)



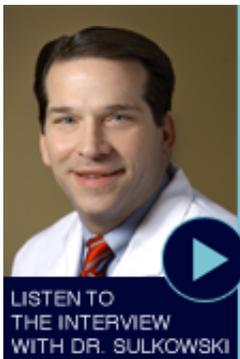
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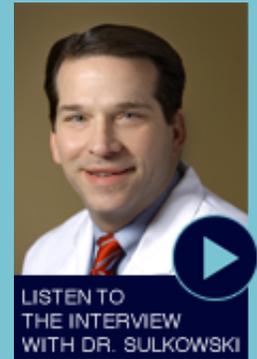
[Click here to hear eViralHepatitis Review program directors Dr. Raymond Chung and Dr. Mark Sulkowski discuss hard-to-treat HCV cases — HCV/HIV coinfection, cirrhosis, and post-liver transplant.](#)



[Click here to access the transcript version of the case discussions.](#)

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