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eViralHepatitis Review
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HIGHLIGHTS FROM THE EUROPEAN ASSOCIATION FOR THE STUDY OF THE LIVER (EASL) MEETING APRIL 2016

In this Issue...

Hepatitis C virus researchers and specialists from around the world came to Barcelona, Spain this April to attend the International Liver Congress. They shared important findings from new studies that investigated novel all oral, direct-acting drug combinations for the treatment of HCV infections in patients with genotypes 1-6. Here we look at selected studies that focused on drug efficacy in treatment-naïve and treatment-experienced patients, including those with GT3 infection and HCV-HIV coinfection, and salvage therapies for patients harboring resistance-associated variants (RAV).

LEARNING OBJECTIVES

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

- Describe effects of HCV resistance-associated variants on treatment outcomes.
- Discuss treating HCV/HIV coinfections using direct-acting antivirals.
- Discuss curing HCV in patients who failed previous treatments, including DAAs.
- Discuss individualized salvage therapy based on RAV analysis.
- Identify new DAA combinations to cure GT3 in infected patients.

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CME Info
Accreditation
Credit Designations
Intended Audience
Learning Objectives
Planners Disclosures
Disclaimer Statement

Length of Activity
1.0 hour Physicians
1.0 contact hour Nurses

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May 26, 2016

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Raymond T. Chung has indicated that he has received research/grant support from AbbVie, Bristol-Myers Squibb, Gilead Sciences, Inc., Merck & Co.

Stephanie Petrou Binder, MD has indicated that she has no financial interests or relationships with a commercial entity whose products or services are relevant to the content of this presentation.

Unlabeled/Unapproved Uses

The authors have indicated that there will be references to the unlabeled/unapproved uses of ABT-493, ABT-530, SOF/VEL fixed-dose combination therapy for HCV infection, GS-9857, FDC SOFNEL, FDC LDV/SOF, LDV/SOF, SIM/SOF.

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Dr. Michael R. Charlton has disclosed that he has received research support from AbbVie, Gilead, Janssen, and Merck He has served as a consultant/advisor for AbbVie, Gilead, and Merck.

Dr. David L. Wyles has disclosed that he has received research/grant support from, and served as a consultant/advisor for, AbbVie, Bristol-Myers Squibb, Gilead, and Merck & Co.

SOFOSBUVIR/VELPATASVIR PLUS GS-9857

High Efficacy of Sofosbuvir/Velpatasvir plus GS-9857 for 12 Weeks in Treatment-experienced Genotype 1-6 HCV-Infected Patients, Including those Previously Treated with Direct-acting Antivirals. Presented at the Congress of the European Association for the Study of the Liver EASL; April 13-17, 2016, Barcelona, Spain

A new triple drug combination of sofosbuvir (SOF), velpatasvir (VEL), and GS-9857 shows promise in persons with hepatitis C virus (HCV) infections whose previous treatments failed, even after failed direct-acting antiviral (DAA)-containing regimens. The data come from two phase II studies that showed a sustained virologic response (SVR) 12 weeks after treatment in 99% of patients with HCV genotypes 1, 2, 3, 4, and 6.

The once daily, all oral, open-label, fixed-dose combination (FDC) of 400 mg SOF, 100 mg VEL, and 100 mg GS-9857 was administered for 12 weeks to 128 patients in the US and New Zealand who had experienced virologic failure to previous treatments, such as regimens including multiple classes of DAAs, including NS5A-inhibitors, with or without pegylated-interferon or ribavirin (RBV).

DAA-containing regimens are highly effective in HCV-infected patients. However, there are few retreatment options for patients unsuccessfully treated with DAA-containing regimens, particularly following NS5A inhibitor therapy. Meanwhile, the number of DAA-experienced individuals continues to rise.

Of 128 study participants, 21% were DAA-naïve, 28% had been treated with one DAA class and 51% with two or more DAA classes. Twenty-seven percent of the study participants were NS5A-experienced.

Nearly half of the patients had HCV GT1 (49%), followed by GT2 (16%), GT3 (27%s), GT4 (5%), and GT6 (2%). They were mostly male (75%) and 82% white, and half had compensated cirrhosis.

Overall, 99% of the study participants achieved SVR12. All patients (100%) with GT1, GT2, GT4, and GT6, and 97% with GT3 reached SVR12. Of the patients who did not achieve SVR12, one had cirrhosis, one patient had no NS5A experience, and one had experience with one DAA class.

Baseline resistance-associated variants (RAVs) were detected in 60% of patients, of which 20% were NS5A RAVs, 15% were NS3 RAVs, 2% were NS5B RAVs, and 23% had resistance to multiple classes. One GT3 patient with cirrhosis and NS5A RAV, Y93H, detected at baseline relapsed at post-treatment week 8.

Adverse events (AE) reported in over 5% of individuals were headache, fatigue, diarrhea, and nausea, although most AEs were mild or moderate in severity. No clinically significant laboratory abnormalities were observed.

Therapy with the drug combination SOF/VEL plus GS-9857 was safe and well tolerated, offering a promising alternative for patients who have failed previous treatments, who have had limited retreatment options so far. This triple drug combination is being further evaluated in phase III trials as a single-tablet regimen for salvage in DAA-experienced patients.

SUMMARY: The triple drug combination of SOF, VEL, and GS-9857 was highly effective in HCV patients whose previous treatments failed, including multiple DAA-containing regimens.

Click here to hear *e*ViralHepatitis Review Program Director Dr. Raymond T. Chung discuss Sofosbubvir/Velpatasvir Plus GS-9857 with study author Dr. Eric Lawitz

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HIGH SVR RATES WITH ABT-493 + ABT-530

High SVR Rates with ABT-493 + ABT-530 Co-Administered for 8 Weeks in Non-Cirrhotic Patients with HCV Genotype 3 Infection. Presented at the Congress of the European Association for the Study of the Liver EASL; April 13-17, 2016, Barcelona, Spain

A new drug combination of two direct-acting antivirals (DAAs), ABT-493 and ABT-530, demonstrated 97% sustained virologic response (SVR) in genotype (GT) 3 patients after just eight weeks of treatment, with no patients experiencing virologic failure, according to outcomes of part 2 of the phase II SURVEYOR-II study.

Hepatitis C virus (HCV) GT3 accounts for roughly 30% of all cases of HCV worldwide and is considered the most difficult to cure of all HCV genotypes, often requiring a longer course of treatment. The current EASL recommendations for treatment-naïve GT3-infected patients without cirrhosis include 12-week regimens of sofosbuvir (SOF), pegIFN/RBV, and daclatasvir (DCV) in various combinations.

The open-label SURVEYOR-II study treated 29 treatment-naïve, HCV GT3-infected patients without cirrhosis with once daily ABT-493 300 mg plus ABT-530 120 mg for eight weeks.

The earlier 12-week dose-ranging part 1 SURVEYOR-II study revealed this regimen to be well tolerated in GT3 patients, achieving SVR in 97% of the 29 study patients without any experiencing virologic failure. Part 2 was carried out to determine the efficacy of an eight-week treatment course.

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The part 2 study patients were 52% male, 90% white; 86% had GT3a and 62% non-CC IL28B and had a median HCV RNA log10 IU/mL of 6.3 (range: 5.0–7.5); 24% of the study patients had HCV RNA of over 6M IU/mL at baseline. Persons with HIV coinfection were excluded.

SVR4 was achieved by 97% (28/29) of patients. There were no virologic failures, with 100% mITT SVR12. High efficacy was achieved regardless of baseline viral load or the presence of baseline NS3 and/or NS5A variants.

No patients discontinued due to AEs or experienced any serious AEs. The majority of AEs were mild, with headache and fatigue reported by over 10% of patients. One patient discontinued the study after treatment week six due to intolerance to blood draws, although HCV RNA was undetectable at that visit.

ABT-493 is an NS3/4A protease inhibitor and ABT-530 is an NS5A inhibitor. They both have potent, pangenotypic antiviral action and maintain activity against common variants that confer resistance to first-generation agents of their classes. These next-generation DAAs have demonstrated in vitro a higher barrier to resistance and additive synergistic antiviral activity.

The combination of these next-generation antivirals coadministered for eight weeks in treatment naïve, noncirrhotic patients with HCV GT3 infection was well tolerated and achieved high SVR rates. These encouraging data warrant confirmation in a larger cohort of GT3-infected patients.

SUMMARY: The DAAs, ABT-493 and ABT-530, demonstrated a high SVR rate in GT 3 patients after only eight weeks of treatment.

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SOLAR-1 & 2

Resistance Analysis for Ledipasvir/Sofosbuvir containing regimens in patients infected with chronic HCV who have advanced liver disease or are post Liver Transplant (SOLAR-1 & 2 STUDIES). Presented at the Congress of the European Association for the Study of the Liver EASL; April 13-17, 2016, Barcelona, Spain

Chronic HCV infection in patients who suffer from advanced liver disease and recurrent infections following liver transplantation has been among the most difficult to cure, with very little therapeutic recourse. Data from the SOLAR 1 and 2 studies, however, reveal highly beneficial effects using the therapeutic combination of ledipasvir (LDV)/sofosbuvir (SOF) and ribavirin (RBV) in this patient group.

The SOLAR 1 and 2 studies were phase II, open label, randomized, prospective trials that used a fixed-dose combination of LDV/ SOF and RBV for 12 or 24 weeks in treatment-naïve (TN) and treatment-experienced (TE) patients with HCV genotypes (GT)-1 or 4 to evaluate the effect of baseline HCV NS5A and NS5B resistance-associated variants (RAVs) on treatment outcomes. SOLAR 1 was conducted in the US while SOLAR 2 was conducted in Australia, Canada, Europe, and New Zealand.

The studies included patients with decompensated cirrhosis and moderate to severe hepatic impairment, or subjects who had undergone liver transplantation.

The results showed that the presence of baseline RAVs did not affect the treatment outcome at either 12 or 24 weeks. While the 24-week results for patients with decompensated cirrhosis showed no sign of worsened treatment outcomes, a lower SVR rate of 83% was observed among the limited number of patients with decompensated cirrhosis and baseline NS5A RAVs who received 12 weeks of LDV/SOF + RBV treatment. (n = 10/12)

To evaluate the effect of baseline RAVs on treatment outcome and characterize the viral resistance in cases of virologic failure, the study investigators performed deep sequencing with a 1% assay cutoff for NS5A and NS5B at baseline for all patients and at the time of

virologic failure for those who experienced relapse. Of 625 patients, 622 had analyses for NS5A and 619 for NS5B.

At 24 months, SVR was achieved in 95% of GT1 HCV-infected patients with NS5A RAVs, and in 97% of those without NS5A RAVs. Eighty-eight percent of GT4 HCV-infected patients with NS5A RAVs achieved SVR24, as did 100% of the patients with GT4 but no RAVs.

NS5B RAVs at baseline were uncommon, occurring in 4.8% (28/586) of the GT1 patients and in 3.2% (1/31) of the GT 4 patients. Of these 29 patients, only one GT1 patient with CPT C cirrhosis who had L159F at baseline and was treated for 24 weeks with LDV/SOF + RBV did not achieve SVR12.

NS5A RAVs at positions 24, 28, 30, 31, 58, and 93 were enriched or emerged in 20/22 (91%) of GT1 and one third of GT4 infected patients with virologic failure. The NS5B NI RAV E237G emerged in three GT1a patients and in one GT4d patient at the time of relapse (4/23, 17%).

LDV/SOF with RBV demonstrated high SVR rates in patients with chronic HCV GT 1 or 4 infections with decompensated cirrhosis or who were post-liver transplantation.

SUMMARY: Chronic HCV GT 1-4 infected patients with decompensated cirrhosis or who are post-liver transplantation achieve high SVR rates following treatment with LDV/SOF plus RBV.

Click here to hear eViralHepatitis Review Program Director Dr. Raymond T. Chung discuss SOLAR-1 & 2 with study author Dr. Michael R. Charlton

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HCV TARGET INTERMIN ANALYSIS

Prevalence and impact of baseline resistance-associated variants on the efficacy of Ledipasvir/Sofobuvir or Simeprevir/Sofosbuvir against GT1 HCV infection: HCV Target Interim Analysis. Presented at the Congress of the European Association for the Study of the Liver EASL; April 13-17, 2016, Barcelona, Spain

Antiviral combination regimens are a proven, potent therapeutic means of eradicating hepatitis C virus (HCV), but they may only offer their full curative advantages in the absence of viral resistance. The identification of baseline (BL) resistance-associated variants (RAV) and their impact on sustained virologic response (SVR) may help shed light on drug efficacy in individual HCV patients, as a new study showed.

The observations of an HCV TARGET interim analysis suggested that the prevalence of BL RAVs was generally comparable between treatment-naïve (TN) and treatment-experienced (TE) genotype (GT)-1 patients and between cirrhotic and noncirrhotic patients

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receiving drug combinations of either ledipasvir (LDV)/sofosbuvir (SOF) with and without ribavirin (RBV) or simeprevir (SMV)/SOF with and without RBV.

Before therapy was initiated, serum was collected in a subset of GT1 patients who were enrolled in HCV TARGET, a multicenter, prospective, observational cohort study. Therapy was administered according to the local standards of care at both academic and community medical facilities in Europe and North America.

HCV TARGET investigators performed HCV resistance testing on serum samples collected before May 12, 2015 using Monogram Biosciences assays. The population sequence was derived from Illumina MiSeq data, with a 10% variant reporting threshold. LDV, SOF, and SMV susceptibility was interpreted using Monogram's rule-based algorithm.

In all, the study included 494 patients tested for BL resistance. Of these, 194 patients received LDV/SOF, 33 received LDV/SOF with RBV, 187 received SMV/SOF, 58 received therapy with SMV/SOF and RBV, and 22 patients were excluded for various reasons.

The study patients were 63% male, 13% black, 76% GT1a, 52% cirrhotic, 18% with liver transplants, and 54% who had received HCV therapy.

The study revealed that the overall prevalence of NS3, NS5A, and NS5B RAVs determined at 10% threshold was 45%, 13%, and 8%, respectively. Ten percent of the patients harbored RAVs in two or more drug classes, in particular NS3 and NS5A.

The prevalence of RAVs varied according to gene targets and amino acid position and was comparable between patients with and without cirrhosis, TN or TE patients, or liver transplant status.

To date, HCV TARGET has the SVR12 data for 472/494 patients. In those treated with LDV/SOF, baseline LDV RAVs at 28, 30, 31, 58, and 93 were associated with 1%-7% differences in SVR12 rates across subgroups including those with cirrhosis, TEs, and liver transplants, but without statistical significance.

Y93 RAVs were rare (5%) and associated with a 75% SVR12 in patients treated with LDV/SOF harboring this RAV, which was a statistically significant reduction (P = .046).

SMV/SOF-treated individuals had baseline SMV RAVs at 80, 122, 155, 168, and 170, which were associated with 0%-9% differences across subgroups, without statistical significance.

SUMMARY: The prevalence of BL RAVs in GT1 patients treated with SOF/SMV or SOF/LDV with or without RBV was comparable between experienced, naive, cirrhotic, noncirrhotic and liver transplant patients.

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RETREATMENT OF PATIENTS WHO FAILED DAA-COMBINATION THERAPIES

Retreatment of patients who failed DAA-Combination Therapies: Real-World Experience from a large Hepatitis C Resistance Database. Presented at the Congress of the European Association for the Study of the Liver EASL; April 13-17, 2016, Barcelona, Spain

Curing hepatitis C virus (HCV) infections may simply be a matter of finding the right drug combination for the right patient. New study data challenge direct-acting antiviral (DAA) regimen failure in HCV patients by demonstrating high, sustained virologic response (SVR) rates in previous treatment failures through the evaluation of resistance profiles and retreatment strategies.

The study evaluated 310 patients who had experienced virologic failure after eight to 24 weeks of treatment with interferon-free DAA combination regimens from a European

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resistance database that included over 3500 HCV-infected patients. Treatment failure was observed in each of the DAA treatment regimens studied.

DAAs are the treatment of choice for HCV infection, achieving SVR in over 90% of patients; however 1%-7% of patients do experience virologic failure. Real-world expectations are for these numbers to rise owing to the emergence and persistence of RAVs, potentially complicating retreatment.

The majority of failed-DAA regimen study patients were genotype (GT)1 (63%) or GT3 (22%). The resistance analysis detected RAVs in 90% of GT1 and 39% of GT3 treatment failures, based on serum sample analysis by direct sequencing of the NS3, NS5A, and NS4B genes.

Retreatment demonstrated SVR rates of 90% in GT1 and 100% in GT3 individuals, with salvage therapy. The individualized retreatments were based on the RAV analysis and carried out for either 12 or 24 weeks.

GT1 patients had failed treatment largely with the combination of simeprevir (SMV)/sofosbuvir (SOF). Of those GT1 patients retreated for 12-weeks with ledipasvir (LDV)/SOF with or without ribavirin (RBV) 100% (8/8 patients) achieved interim SVR12, while 90% (9/10 patients) of those retreated with LDV/SOF with or without RBV for 24 weeks achieved interim SVR12. Furthermore, 3/4 GT1 patients retreated with ombitasvir (OBV)/paritaprevir (PTV)/ritonavir (RTV) and dasabuvir (DSV), with or without RBV for 12 weeks achieved interim SVR12.

Among patients with GT1, 59% had cirrhosis, and 69% had failed prior PEG/RBV ± protease inhibitor treatment. High-level RAVs were detected in one to three targets in 83% of patients. The absence of negative predictors such as cirrhosis, prior treatment, and RAVs was observed in three patients with SOF/LDV-failure.

Seven GT3 patients had failed treatment with SOF with RBV and all achieved SVR12 at 12 and 24 weeks following retreatment with daclatasvir (DCV) or LDV plus SOF with or without RBV as salvage therapy. Of GT3 patients, 65% had cirrhosis, 75% had failed PEG/ RBV, and 67% had RAVs.

This study comprises the largest real-world database of DAA treatment failures to date. It showed that treatment failure occurred in all available DAA regimens and that RAVs were detected in the majority of treatment failures.

Although physicians are generally cautious about initiating salvage treatments because of the lack of data on their individual patients, the study results demonstrate high SVR rates using salvage therapy.

SUMMARY: DAA regimen failure in HCV patients can be successfully managed with retreatment strategies using complementary DAA classes.

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PHASE 3 ASTRAL-5

Sofosbuvir/Velpatasvir fixed dose combination for 12 Weeks in Patients Co-Infected with HCV and HIV-1: The Phase 3 ASTRAL-5 Study. Presented at the Congress of the European Association for the Study of the Liver EASL; April 13-17, 2016, Barcelona, Spain

Patients coinfected with hepatitis C virus (HCV) and human immunodeficiency virus (HIV-1) experience accelerated progression of liver disease as well as higher rates of cirrhosis, end-stage liver disease, and hepatocellular cancer. Therapy calls for direct-acting antivirals (DAA) that are applicable for all HCV genotypes.

Combined sofosbuvir/velpatasvir (SOF/VEL) fixed-dose combination (FDC) therapy has already demonstrated high efficacy in genotypes 1-6 HCV-infected patients as shown by the prior phase III ASTRAL trials (1-4).

According to recent data emerging from the phase III ASTRAL-5 trial, a dual regimen of SOF/VEL was both safe and effective in the treatment of GT 1-4 chronic HCV-infected patients with human immunodeficiency virus (HIV) coinfections.

The multicenter phase III ASTRAL-5 trial examined safety and efficacy in 106 chronically HCV/HIV coinfected patients treated with a once-daily FDC tablet of SOF/VEL for 12 weeks. The patients in the prospective, single arm, open label investigation were both treatment-naïve and treatment-experienced, with or without cirrhosis. They were 86% male and 45% black; 77% had IL28B non-CC genotypes, 29% had prior treatment failure (primarily PegIFN/RBV), and 16% had compensated cirrhosis.

The daily FDC was 400 mg SOF and 100 mg VEL. Eligible patients were on stable antiretroviral (ARV) regimens with fully suppressed HIV RNA at the start of the study. ARV regimens included emtricitabine/tenofovir disoproxil fumarate or abacavir/lamivudine with raltegravir, cobicistat/ elvitegravir, rilpivirine, ritonavir-boosted atazanavir, darunavir, or lopinavir.

The safety evaluations included adverse events, standard laboratory parameter monitoring and frequent renal function monitoring, CD4 count, and HIV-1 RNA levels. The primary endpoint was sustained virologic response 12 weeks after treatment (SVR12).

The genotype distribution was 62% GT1a, 11% GT1b, 10% GT2, 11% GT3, and 5%s GT4. The median baseline CD4 count was 548 cells/μL (range: 183 cells/μL –1513 cells/μL) with a median estimated glomerular filtration rate of 97 mL/min (range 57 mL/min–198 mL/min). Boosted protease inhibitor (PI) regimens were the most commonly used.

The overall SVR12 rate was 95%, but response rates varied among genotypes. GT 2 and GT 4 had 100% response rates, GT1a had a 95% response rate, and GT 1b and GT 3 had 92% response rates. SVR12 was also achieved in all of the 12% of patients who had NS5A resistance-associated variants at baseline.

SVR12 rates were similar among patients with or without cirrhosis as well as in treatment-naive and treatment-experienced patients.

Fatigue was reported most frequently (19%), followed by headache (14%) and nausea (7%). HIV virologic rebound was absent in study participants and defined as HIV-1 RNA ≥ 400 copies/mL. No significant changes in lab abnormalities, including renal function, were observed.

The interferon-free, RBV-free, single tablet regimen of SOF/ VEL administered once daily for 12 weeks was well tolerated in HCV/ HIV coinfected patients, regardless of past treatment experience or presence of cirrhosis.

SUMMARY: A dual regimen of SOF/VEL was safe and effective in curing a very high proportion of GT 1-4 chronic HCV/ HIV coinfected patients.

Click here to hear *e*ViralHepaitits Review Program Director Dr. Raymond T. Chung discuss PHASE 3 ASTRAL-5 with study author Dr. David L. Wyles

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