Hep C Patient Cases: Interactive Discussion
5/4/2017
NM Annual HIV & HCV Update Conference

Meet the Panel

- Moderator: Michelle Iandiorio, MD; NMAETC
- Panel:
  - Edward Gardner, MD; Denver Health
  - Karla Thornton, MD, MPH; UNM Division of Infectious Diseases; Associate Medical Director of Project ECHO®
  - Paulina Deming, PharmD, PhC; UNM College of Pharmacy, Assistant Director Project ECHO® HCV TeleECHO Clinics
Learning Objectives

1. Discuss the management of HIV-HCV coinfected patients
2. Discuss the significance and limitations of HCV antibody test results.
3. Recognize the potential for drug-drug interactions between HCV agents, antiretrovirals (ARVs), and other common medications.
4. Discuss the significance of infection with HCV genotype 3 and approach to treatment.

Abbreviations Used

- SVR: sustained virologic response
- IFN: interferon
- RBV: ribavirin
- Peg: pegylated
- BOC: boceprevir
- TPV: telaprevir
- SMV: simeprevir
- SOF: sofosbuvir
- DCV: daclatasvir
- EBR/GZR: elbasvir/grazoprevir
- LDV/SOF: ledipasvir/sofosbuvir
- SOF/VEL: sofosbuvir/velpatasvir
Case 1

55 yo male with HIV/HCV both diagnosed in 2004

- Risk Factor IDU/MSM, last IDU 6 months ago
- HIV-RNA < 20 cps/ml
- CD4 = 767 cells/ul (31%)
- HCV Genotype 1a  HCV-RNA = 4,506,410

- Other PMH:
  - Chronic renal insufficiency with creatinine 1.6
  - HBV immune
  - HAV non-immune (vaccinated in 2005 and 2013)

Case 1

- ALL: sulfa
- Meds:
  - HIV: 3rd regimen, current regimen for 4 years
  - History of M184V, bumped creatinine on TDF
  - Current Regimen:
    darunavir/ritonavir qday + nevirapine
  - Oxycodone/APAP
  - Quetiapine
  - Pitavastatin vs. Placebo
Case 1

- PE
  - Thin
  - No track marks
  - No cutaneous signs of cirrhosis
  - No hepatomegaly or splenomegaly

- Labs
  - AST = 52
  - ALT = 58
  - Alk Phos = 129
  - Alb = 3.6
  - T.B. = 0.4
  - Creatinine = 1.56
  - WBC = 6.5
  - HgB = 15.2
  - PLT = 251
  - INR 1.06
  - FIB-4 = 1.50

Case 1

- Imaging
  - CT 2016: liver and spleen normal in appearance

- Pathology
  - Liver biopsy 2013: chronic hepatitis with minimal activity, Stage 2 Fibrosis
Question for the Audience
(ARS Question)

- Because of potential drug interactions is it ok to hold the HIV treatments for 12 weeks?
  A. Yes
  B. No
  C. I don’t know

Questions for the Panel

- When HIV is stable is it OK to hold antiretroviral therapy to avoid drug interactions?
- Which regimen is most likely to be compatible with most HIV treatments?
Don’t Hold HIV Treatments to Avoid Drug Interactions with HCV Therapy

- The SMART Study demonstrated that stopping HIV therapy increased the risk of AIDS and non-AIDS events in persons living with HIV infection.
- HIV immunosuppression is associated with more rapid progression of fibrosis during HCV infection.

Regimens Not Recommended for Patients with HIV/HCV Coinfection
- Antiretroviral treatment interruption to allow HCV therapy is Not Recommended.
  Rating: Class III, Level A

- Daclatasvir with Sofosbuvir can be utilized with most HIV Treatments.
- Many drug interactions with HCV and HIV therapies.
- Sofosbuvir has the least interactions.
- Daclatasvir interactions can commonly be managed by dose adjustments of the daclatasvir.
- Ledipasvir also has few interactions except for cautions on renal side effects of TDF when used together.
| Drug              | Sofosbuvir | Ledipasvir | Velpatasvir | Simeprevir | Daclatasvir | Elbasvir/ grazoprevir | Paritaprevir, ritonavir, ombitasvir plus dasabuvir (PODC) | Paritaprevir, ritonavir, ombitasvir (POD) |
|-------------------|------------|------------|-------------|------------|-------------|------------------------|---------------------------------------------------------------------------------|
| Ritonavir-boosted atazanavir | No data    | Ledipasvir ↑ atazanavir ↑  | Velpatasvir ↑ atazanavir ↑  | No data    | Daclatasvir ↓  | Elbasvir ↓; grazoprevir ↓ atazanavir ↓  | Paritaprevir ↑ atazanavir ↑  | Paritaprevir ↑ atazanavir ↓  |
| Ritonavir-boosted darunavir | Sofosbuvir ↑ darunavir     | Ledipasvir ↑ darunavir     | Velpatasvir ↑ darunavir     | Simeprevir ↑ darunavir ↑  | Daclatasvir ↓ darunavir ↓  | Elbasvir ↓; grazoprevir ↓ darunavir ↓  | Paritaprevir ↑ darunavir     | Paritaprevir ↑ darunavir     |
| Ritonavir-boosted lopinavir | No data                          | No data                          | Velpatasvir ↑ lopinavir ↑  | No data    | Daclatasvir ↓ lopinavir ↓  | Elbasvir ↓; grazoprevir ↓ lopinavir ↓  | Paritaprevir ↑ lopinavir ↓  | Paritaprevir ↑ lopinavir ↓  |
| Ritonavir-boosted tipranavir | No data                          | No data                          | No data                          | No data    | No data                          | No data                          | No data                          | No data                          |
| Efavirenz         | Sofosbuvir ↑ efavirenz ↑     | Ledipasvir ↑ efavirenz ↑     | Velpatasvir ↑ efavirenz ↑     | Simeprevir ↑ efavirenz ↑  | Daclatasvir ↑ efavirenz ↑  | Elbasvir ↑; grazoprevir ↑ efavirenz ↑  | No data                          | No data                          |
| Rilpivirine       | Sofosbuvir ↑ rilpivirine ↑     | Ledipasvir ↑ rilpivirine ↑     | Velpatasvir ↑ rilpivirine ↑     | Simeprevir ↑ rilpivirine ↑  | No data                          | Elbasvir ↑; grazoprevir ↑ rilpivirine ↑  | Paritaprevir ↑ rilpivirine ↑     | No data                          |
| Etravirine        | No data                          | No data                          | No data                          | No data    | No data                          | No data                          | No data                          | No data                          |

| Drug              | Sofosbuvir | Ledipasvir | Velpatasvir | Simeprevir | Daclatasvir | Elbasvir/ grazoprevir | Paritaprevir, ritonavir, ombitasvir plus dasabuvir (PODC) | Paritaprevir, ritonavir, ombitasvir (POD) |
|-------------------|------------|------------|-------------|------------|-------------|------------------------|---------------------------------------------------------------------------------|
| Raltegravir       | Sofosbuvir ↑ raltegravir ↑     | Ledipasvir ↑ raltegravir ↑     | Velpatasvir ↑ raltegravir ↑     | Simeprevir ↑ raltegravir ↑  | No data                          | Elbasvir ↑; grazoprevir ↑ raltegravir ↑  | ProD ↑; raltegravir ↑  | ProD ↑; raltegravir ↑  |
| Cobicistat-boosted elvitegravir | Sofosbuvir ↑ cobicistat ↑     | Ledipasvir ↑ cobicistat ↑     | Velpatasvir ↑ cobicistat ↑     | No data                          | Daclatasvir ↑ cobicistat ↑     | Elbasvir ↑; grazoprevir ↑ cobicistat ↑  | No data                          | No data                          |
| Dolutegravir      | No data                          | Ledipasvir ↑ dolutegravir ↑     | Velpatasvir ↑ dolutegravir ↑     | No data                          | Daclatasvir ↑ dolutegravir ↑     | Elbasvir ↑; grazoprevir ↑ dolutegravir ↑  | Paritaprevir ↓ dolutegravir ↓     | No data                          |
| Maraviroc         | No data                          | No data                          | No data                          | No data    | No data                          | No data                          | No data                          | No data                          |
| Tenofovir         | No data                          | No data                          | No data                          | No data    | No data                          | No data                          | No data                          | No data                          |
| Disoproxil        | Sofosbuvir ↑ tenofovir ↑     | Ledipasvir ↑ tenofovir ↑     | Velpatasvir ↑ tenofovir ↑     | Simeprevir ↑ tenofovir ↑  | Daclatasvir ↑ tenofovir ↑  | Elbasvir ↑; grazoprevir ↑ tenofovir ↑  | ProD ↑; tenofovir ↑  | ProD ↑; tenofovir ↑  |
| Tenofovir         | Sofosbuvir ↑ tenofovir ↑     | Ledipasvir ↑ tenofovir ↑     | Velpatasvir ↑ tenofovir ↑     | No data                          | No data                          | No data                          | No data                          | No data                          |
Case 1

- HIV regimen switched: dolutegravir replaces nevirapine, darunavir/ritonavir continues
- One month later HIV-RNA remains undetectable
- The patient initiated ledipasvir/sofosbuvir
- Well tolerated; transaminases normalized
- HIV-RNA remained undetectable twice while on HCV Tx
- SVR12 is achieved for HCV

9 months later the patient has an ALT of 87 on routine labs
- He reports a relapse of injection drug use
Question for the Audience
(ARS Question 2)

- How do you check for re-infection after successful treatment of HCV?
  A. HCV Antibody Test
  B. HCV-RNA test
  C. HCV Genotype
  D. I don’t know

Question for the Panel

- How common is HCV re-infection after successful HCV treatment and what are the risk factors?

- When is HCV-RNA the preferred test for HCV evaluation?
How big of an issue is re-infection?

- 2/63 subjects in Turquoise I by SVR12
- Both SVR4
- No resistance mutations on relapse


HCV RNA is the preferred initial test for evaluation of possible active HCV …

- After spontaneous clearance of HCV infection
- After successful treatment of HCV infection
- When acute HCV is suspected and patient is HCV antibody negative
- HCV antibody negative patients with unexplained liver disease and high risk for HCV
- HCV antibody negative patients with unexplained liver disease who are immunocompromised
Recommended Testing Sequence for Identifying Current Hepatitis C Virus (HCV) Infection

Nonreactive
- No HCV antibody detected
  - STOP

Reactive
- HCV RNA
  - Not Detected
  - Additional testing as appropriate
  - Link to care
  - Detected
  - No current HCV infection
  - Current HCV infection

Treat HIV/HCV Coinfected Patients The Same As Monoinfected Patients

Recommended Regimens for HIV/HCV-coinfected Individuals
Listed in order of level of evidence, then within group alphabetically.

- HIV/HCV-coinfected persons should be treated and retreated the same as persons without HIV infection, after recognizing and managing interactions with antiretroviral medications (see Initial Treatment of HCV Infection and Retreatment of Persons in Whom Prior Therapy Has Failed).
  Rating: Class I, Level B

- Daily daclatasvir (refer above for dose) plus sofosbuvir (400 mg), with or without RBV (refer to Initial Treatment of HCV Infection and Retreatment of Persons in Whom Prior Therapy Has Failed sections for duration) is a Recommended regimen when antiretroviral regimen changes cannot be made to accommodate alternative HCV direct-acting antivirals.
  Rating: Class I, Level B

Case 2

- 16 yo otherwise healthy male patient
- No history of cirrhosis or any complications of liver disease
- Diagnosed with HCV genotype 1b at age 2
- Family History: mother HCV positive

- WBC 7.8
- H/H 14.1/42
- Platelet 290
- Creatinine 0.8
- INR 0.98
- TP 8 Alb 4.3
- AST 38 ALT 64
- AlkP 80
- Total Bili 0.6
- APRI 0.3

- Hep A total Ab reactive
- Hep B surface Ab non-reactive
- Hep B total core Ab reactive
- Hep B surface antigen non-reactive
- HCV 9,522,329 IU/mL
- Genotype 1b
Question for the Audience

(ARS Question)

- What therapy would you recommend for this patient?
  A. Daclatasvir + Sofosbuvir
  B. Elbasvir/Grazoprevir
  C. Ledipasvir/Sofosbuvir
  D. Treatment not indicated for this patient
  E. Treatment not FDA approved for this patient given his age

Questions for the Panel

- What treatment options are available for this patient?
- What is the significance of his hepatitis B serology results?
- Does he need the hepatitis B vaccine?
Approval for Pediatric Use

April 2017:

Ledipasvir/Sofosbuvir
Approved for pediatric patients
aged 12 and older or weighing at least 35 kg
with HCV genotypes 1, 4, 5, or 6

Ledipasvir/Sofosbuvir in Adolescents

- 100 adolescents aged 12-17yo
  - Treatment naïve or experienced
  - 37 male, mean weight 61 kg (range 33-126)
  - 81 with HCV GT 1a
  - 1 with cirrhosis
- Pharmacokinetic study done with 10 patients
to confirm dosing
  - Prior data suggested no dose adjustment needed
Safety and Adverse Event Outcomes

**Overall Safety**
- 72 patients reported any adverse event
- None serious
- No treatment discontinuations

**Adverse Events in >10%**
- 27 headache
- 14 diarrhea
- 13 fatigue
- 12 nausea
- 10 each with cough, oropharyngeal pain, and vomiting
Questions for the Panel

- What treatment options are available for this patient?

- What is the significance of his hepatitis B serology results?

- Does he need the hepatitis B vaccine?

FDA Warning for HBV Reactivation

- Test all patients for evidence of current of prior hepatitis B virus (HBV) infection prior to treatment with any DAA

- HBV reactivation reported in patients undergoing or after completing HCV treatment with DAAs
Case 3

64 yo male with chronic hepatitis C

- HCV
  - Dx: 2004
  - Risk: IDU, received clotting factors before 1987
- PMH
  - HTN
  - Rheumatoid Arthritis
  - Chronic Pain
- Allergies: NKDA
- Medications
  - Omeprazole
  - Meloxicam
  - Lisinopril
  - Amlodipine

Clinical Exam:
  - Unremarkable
  - BMI 30.7
Case 3

- WBC 3.8
- H/H 12.8/44
- Platelet 199,000
- Creatinine 0.72
- TP 7.7 Alb 4
- AST 175 ALT 196
- AlkP 64 TB 0.3
- INR 1.0
- HIV Screen NR
- HCV Genotype 3
- HCV RNA: 8,310,000
- Abdominal U/S: consistent with fatty infiltration
- FIB4: 4.02
- APRI 2.2
- Fibroscan 5.8 kPa

Question for Audience

(ARS Questions)

- What is the recommended treatment for this patient?
  A. Sofosbuvir + Daclatasvir x 24 weeks
  B. Sofosbuvir/Velpatasvir x 12 weeks
  C. Sofosbuvir/Velpatasvir + Ribavirin x 12 weeks
  D. Depends if he is cirrhotic or not and results of NS5A RAS testing
Question for the Audience
(ARS Question)

- What is this patient’s level of liver disease?
  A. No evidence of cirrhosis
  B. Cirrhosis
  C. Unclear, needs a liver biopsy

Questions for the Panel

- What is this patient’s level of liver disease?
- Is biopsy necessary to stage liver disease?
- What are the limitations of minimally invasive techniques in assessing liver disease?
- What is the impact of genotype 3 infection on liver disease?
- What is the role of NS5A RAS testing in genotype 3?
Impact of Infection with Genotype 3 on Liver Disease Progression

- Independent risk of GT3 for accelerated fibrosis
- US Veterans Study
  - 110,484 patients with chronic HCV
  - 8,337 with GT3
    - Mean age 50.2 years was lower than GT1 or GT2
  - Among US veterans, compared to patients with GT1, patients with GT3 had:
    - 31% increased risk of developing cirrhosis
    - 80% increased risk of HCC

Hepatology 2014;60:98-105

Cumulative Incidence of Cirrhosis, by Genotype
Cumulative Incidence of HCC, by Genotype

Alaska Tribal Health Consortium Outcomes

- 1081 patients with chronic HCV followed for mean 10.3 years
- Patients recruited from 1995-2012
- 156 patients with HCV GT3
- Evaluated risk factors for developing complications of chronic liver disease
Recommendation for HCV Treatment: Genotype 3, treatment naive

- Without Cirrhosis
  - Daclatasvir plus Sofosbuvir x 12 weeks
  - Sofosbuvir/Velpatasvir x 12 weeks

- With Compensated Cirrhosis
  - Sofosbuvir/Velpatasvir x 12 weeks*
  - Daclatasvir plus Sofosbuvir x 24 weeks*

* RAS testing for Y93H is recommended for cirrhosis and ribavirin should be included if present
Effect of Baseline RASs on SVR with Sofosbuvir/Velpatasvir in HCV GT3

Patients Treated with Sofosbuvir/Velpatasvir
N=231

Presence of Y93 Mutation N=25

SVR 97%

SVR 84%

Recommendations for Pre-Treatment Resistance Testing in HCV

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<tr>
<th>Year</th>
<th>Therapy</th>
<th>Resistance Recommendation</th>
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<td>&lt;2013</td>
<td>PegIFN + RBV +/- BOC or TPV</td>
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<td>2013</td>
<td>PegIFN + RBV + SMV</td>
<td>Baseline for NS3 Q80k for SMV in genotype 1a</td>
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<td>2014</td>
<td>PrOD +/- RBV</td>
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<td>2016</td>
<td>EBR/GZR +/- RBV</td>
<td>Baseline NS5A resistance testing for genotype 1a</td>
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<td>2016</td>
<td>SOF/VEL +/- RBV</td>
<td>Baseline NS5A resistance for patients with genotype 3 and cirrhosis or prior treatment experience</td>
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</table>
Which of the Following Patients with HCV Genotype 3 Should Be Tested for NS5A RAS Prior to Starting HCV Treatment?

A. A non-cirrhotic, treatment naïve patient
B. A patient with decompensated cirrhosis
C. A non-cirrhotic patient who failed pegylated interferon/ribavirin
D. A non-cirrhotic patient who failed sofosbuvir and ribavirin
E. C and D only

Question for the Audience

Which Patients with Genotype 3 Need NS5A RAS Testing Prior to Start of HCV Treatment?

- Persons with genotype 3 who are treatment experienced
- Persons with genotype 3 AND cirrhosis

*Patients with genotype 3 and decompensated cirrhosis receive ribavirin even if no baseline resistance so do not need testing*
### Case 3

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### The Evolution of Highly Effective Treatment

![Graph showing the evolution of highly effective treatment](image)

- **Standard IFN** (1991)
- **RBV 1998**
- **PegIFN 2001**
- **2011**
- **BOC and TPV**
- **2013**
- **LDV/SOF >90** in 2014
- **DCV/SOF >90** in 2016
- **EBR/GZR >90** in 2018
- **SOF/VEL >90** in 2020
### Sofosbuvir/Velpatasvir

- Fixed-dose combination of sofosbuvir (NS5B inhibitor) and velpatasvir (NS5A inhibitor)
- Approved June 28, 2016 for chronic HCV genotypes 1, 2, 3, 4, 5, or 6
  - Treatment naïve
  - Treatment experienced (Peg-IFN/RBV with or without PI)

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**ASTRAL-1: SOF/VEL STR for 12 Weeks in GT 1, 2, 4, 5, 6 HCV-Infected Patients**

**SVR12 by Cirrhosis Status or Treatment History**

![Graph showing SVR12 by cirrhosis status or treatment history](image)
HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C

- [www.hcvguidelines.org](http://www.hcvguidelines.org)
- First published on January 29, 2014
- Updated several times since

Overview of AASLD/IDSA Recommendations for DAA Use in HCV Genotype 1 Treatment Naive

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<th>Therapy</th>
<th>GT1a Non-Cirrhotic</th>
<th>GT1a Compensated Cirrhosis</th>
<th>GT1b Compensated Cirrhosis</th>
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Note: Need for concomitant ribavirin and duration of therapy varies
[www.hcvguidelines.org](http://www.hcvguidelines.org)
### Overview of AASLD/IDSA Recommendations for DAA Use in Other HCV Genotypes

<table>
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<td>DCV+SOF</td>
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<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>(Alternative)</td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>EBR/GZR</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SOF/VEL</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

Note: Need for concomitant ribavirin and duration of therapy varies

[www.hcvguidelines.org](http://www.hcvguidelines.org)

### Resources

- **Present case on HCV TeleECHO Clinic**
  - Wednesdays 3-5pm MT
  - [hcvecho@salud.unm.edu](mailto:hcvecho@salud.unm.edu)

- **Present coinfected cases on HIV TeleECHO Clinic**
  - Tuesdays 12-1pm MT
  - [hivecho@salud.unm.edu](mailto:hivecho@salud.unm.edu)

- **Contact NMAETC for additional trainings**
  - [NMAETC@salud.unm.edu](mailto:NMAETC@salud.unm.edu)