Hepatitis C and Transplantation

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Liver Transplantation
Vanderbilt Transplant Center
Overview

• What is hepatitis C and its significance?
• Timeline of hepatitis C (HCV) and approved treatment options
• History of HCV in transplant
• Current treatment guidelines and resources
• New considerations for HCV in transplant
  – HCV-positive donors to HCV-naïve recipients
What is HCV and why is it important?

- Blood borne virus that affects the liver
- 75-85% develop chronic HCV
- Asymptomatic

Initial Infection

Chronic

- Liver fibrosis → cirrhosis
- Asymptomatic

Complications

- Liver Failure
- Liver Cancer
- Transplant
- Death

Timeline (years)

0 10 20 30
1989

- Hepatitis C is identified
Timeline of Hepatitis C

1991

• The FDA approves interferon alfa-2B (Intron A), the first of the interferon drugs
  – Sustained viral response (SVR) around 11%

1993

• Genotype diversity—variations in treatment efficacy
Timeline of Hepatitis C

1998
• FDA approves the use of ribavirin in conjunction with interferon

2001
• FDA approves pegylated interferon—the addition of polyethylene glycol
  – When used as combination therapy with ribavirin—improved SVR to ~35% for GT1 and ~80% for GT2/3
FDA approves the first direct-acting anti-virals (DAAs) used in combination with peg-IFN-α and ribavirin

- “Triple therapy”
- Telaprevir (Incevik) and boceprevir (Victrelis) (NS3/4A protease inhibitors)
- Dosed three times daily
- Interacted with immunosuppression
  - Post-transplant patient required labs every few days for the duration of therapy
  - Telaprevir taken with high fat meal—increased absorption
  - Boceprevir required a 4-week lead in with interferon
  - Further improved SVR >70% among GT1 patients
Recommendation to test all “baby boomers” born between 1945-1965 and all those with “high risk” behaviors.
Timeline of Hepatitis C

2013

• The FDA approves the first potentially interferon-free treatment regimen
  – Sofosbuvir (Sovaldi®) (polymerase inhibitor) and simeprevir (Olysio®) (protease inhibitor)
  – Used in conjunction with ribavirin +/- peg-IFN
  – Sofosbuvir was approved for GT 1-4
  – Simeprevir approved for GT1
  – Were not initially approved to be used together
Timeline of Treatment Efficacy

- **Standard Interferon 1991**: 6%
- **Ribavirin 1998**: 16%
- **PegIFN 2001**: 42%
- **PegIFN RBV**: 55%
- **PegIFN RBV/PI**: >70%
- **IFN-Free DAA 12 wk**: >90%

**Polymerase Inhibitors 2013**
2014

• The first monotherapy is approved for treatment of HCV
  – Combination once-daily oral medication
  – ledipasvir/sofosbuvir (Harvoni ®)
    • Increased barrier to resistance
    • Still most commonly prescribed regimen
• FDA approves ombitasvir, paritaprevir, and ritonavir with dasabuvir tablets (Viekira Pak ™)
  – Complicated dosing—two ombitasvir, paritaprevir, ritonavir tablets once daily (in the morning) and one dasabuvir tablet twice daily (morning and evening)
  – Requires adjustments in IS
Timeline of Hepatitis C

2015

- The first year we see a decrease in the number of patients listed and transplanted for the primary indication of HCV (22.7%)—see an increase in NASH and alcohol-related
- Concern over the high cost of treatment

<table>
<thead>
<tr>
<th>Regimen and Duration of Therapy^</th>
<th>Cost of Regimen*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elbasvir-Grazoprevir for 12 weeks</td>
<td>$54,600</td>
</tr>
<tr>
<td>Elbasvir-Grazoprevir for 16 weeks</td>
<td>$72,800</td>
</tr>
<tr>
<td>Ledipasvir-Sofosbuvir for 12 weeks</td>
<td>$94,500</td>
</tr>
<tr>
<td>Ombitasvir-Paritaprevir-Ritonavir + Dasabuvir + Ribavirin for 12 weeks</td>
<td>$83,819</td>
</tr>
<tr>
<td>Sofosbuvir + Simeprevir for 12 weeks</td>
<td>$150,000</td>
</tr>
<tr>
<td>Sofosbuvir-Velpatasvir for 12 weeks</td>
<td>$74,760</td>
</tr>
<tr>
<td>Sofosbuvir + Daclatasvir x 12 weeks</td>
<td>$147,000</td>
</tr>
</tbody>
</table>

^Regimen and Duration of therapy for Initial treatment of patients with Genotype 1a without cirrhosis
*Cost of regimen estimated based on Wholesale Acquisition Cost (WAC)
From Cure to Controversy

With 16-week cure rates approaching 95% in certain disease genotypes and limited side effects noted in several pivotal phase 3 studies, a once-daily tablet of sofosbuvir quickly established itself as an unprecedented breakthrough. The positive news was compounded when an uncommonly productive drug-development pipeline produced other FDA-approved HCV agents in quick succession, most notably Gilead's ledipasvir/sofosbuvir combination (Harvoni®) and AbbVie's ombitasvir/paritaprevir/ritonavir/dasabuvir tablet combination (Viekira Pak™).

Yet just as quickly, the story changed when the wholesale acquisition price tags for these 12-week treatments were revealed: $83,319 for Viekira Pak, $84,000 for Sovaldi, and $94,500 for Harvoni. These prices rise further when one factors in other agents that could be delivered alongside them and the general cost of care. That the issue could be boiled down to a media-friendly "$1000-a-day pill" headline only heightened the controversy, which eventually led to a December Senate hearing on the issue.
Cost-Effectiveness and Budget Impact of Hepatitis C Virus Treatment With Sofosbuvir and Ledipasvir in the United States

Jagpreet Chhatwal, PhD; Fasiha Kanwal, MD, MSHS; Mark S. Roberts, MD, MPP; and Michael A. Dunn, MD

Figure 1. Total spending on sofosbuvir-ledipasvir to treat all HCV-infected patients in the United States in the next 5 y.

HCV = hepatitis C virus.
Timeline of Hepatitis C

2016

- FDA approves dasabuvir, ombitasvir, paritaprevir, and ritonavir extended-release (Viekira XR™)
  - Simpler dosing
  - GT1 only, +/- ribavirin
- FDA approves elbasvir/grazoprevir (Zepatier ®)
  - GT 1 and 4
  - Approved for renal impairment
- FDA approves first pangenotypic regimen
  - Sofosbuvir/velpatasvir (Epclusa ®)
  - Velpatasvir is a NS5A inhibitor, pangenotypic
Timeline of Hepatitis C

2017

• FDA approves first “salvage therapy” – a DAA combination for those who have failed other DAA treatments
  – Sofosbuvir/valpatasvir/voxilaprevir (Vosevi ™)
  – Voxilaprevir is a NS3/4A inhibitor, pan-genotypic
  – POLARIS 1 and 4 trials tested a 12 week regimen among people with GT1-6, previously treated with DAAs, including those who took another NS5A inhibitor, and failed: 97% SVR12
  – POLARIS 2 and 3 trials tested an 8 week regimen among people with GT1-6 (including those with cirrhosis), treatment naïve: 95-96% SVR12
Timeline of Hepatitis C

2017

• FDA approves shorter, pan-genotypic treatment
  – Glecaprevir/pibrentasvir (Mavyret ™)
  – Pan-genotypic 8 week therapy for treatment naïve patients
  – Safe to use with some HIV antiretroviral regimens without required dose adjustments

• Seeing some manufacturers bow out
  – Crowded market
  – Highly effective therapies, even for specific historically “difficult to treat” sub-populations
Hepatitis C in Liver Transplant
Hepatitis C in Liver Transplant

• Have been doing liver transplants in the setting of hepatitis C for decades
• HCV remains the leading cause of liver transplant, although declining
• Virus will recur after transplant
• Liver injury associated with HCV is often accelerated in the setting of IS
• Rare but severe complication of fibrosing cholestatic hepatitis
Post-transplant Survival Pre-DAAs

Forman et al. Gastroenterology 2002
### Table 1: Treatment of recurrent post liver transplant hepatitis C with interferon-free regimes

<table>
<thead>
<tr>
<th>Trial</th>
<th>Regime</th>
<th>Fibrosis grade</th>
<th>Treatment duration (weeks)</th>
<th>Patients (n)</th>
<th>SVR12 (n, %)</th>
<th>Study type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Charlton&lt;sup&gt;52&lt;/sup&gt;</td>
<td>Sofosbuvir + ribavirin</td>
<td>2–4</td>
<td>24</td>
<td>40</td>
<td>28 (70)</td>
<td>Case series</td>
</tr>
<tr>
<td>CORAL-1&lt;sup&gt;51&lt;/sup&gt;</td>
<td>Paritaprevir/r + ombitasvir + dasabuvir + ribavirin</td>
<td>≤2</td>
<td>12</td>
<td>34</td>
<td>33 (97)</td>
<td>Prospective</td>
</tr>
<tr>
<td>Forns&lt;sup&gt;53&lt;/sup&gt;</td>
<td>Sofosbuvir + ribavirin</td>
<td>FCH, 4</td>
<td>24–48</td>
<td>92</td>
<td>54 (59)</td>
<td>Case series</td>
</tr>
<tr>
<td>SOF/LDV Phase 3&lt;sup&gt;56&lt;/sup&gt;</td>
<td>Sofosbuvir + ledipasvir</td>
<td>0–3</td>
<td>12</td>
<td>55</td>
<td>53 (96)</td>
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<td>50 (88)</td>
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<td>Sofosbuvir + ledipasvir</td>
<td>4</td>
<td>24</td>
<td>46</td>
<td>41 (89)</td>
<td>Prospective</td>
</tr>
<tr>
<td>Mayo Clinic&lt;sup&gt;55&lt;/sup&gt;</td>
<td>Sofosbuvir + simeprevir ± ribavirir</td>
<td>24% 3–4</td>
<td>12</td>
<td>66</td>
<td>60 (91)</td>
<td>Case series</td>
</tr>
<tr>
<td>HCV-TARGET&lt;sup&gt;53&lt;/sup&gt;</td>
<td>Sofosbuvir + ledipasvir</td>
<td>Any</td>
<td>Physicians choice</td>
<td>68</td>
<td>61 (90)</td>
<td>Case series</td>
</tr>
<tr>
<td>University of Massachusetts&lt;sup&gt;84&lt;/sup&gt;</td>
<td>Sofosbuvir + ledipasvir</td>
<td>17.5% with 4</td>
<td>12&lt;sup&gt;8&lt;/sup&gt;</td>
<td>22</td>
<td>22 (100)</td>
<td>Case series</td>
</tr>
<tr>
<td>Emory University&lt;sup&gt;85&lt;/sup&gt;</td>
<td>Sofosbuvir + simeprevir ± ribavirin</td>
<td>22% with 4</td>
<td>12</td>
<td>37</td>
<td>34 (92)</td>
<td>Case series</td>
</tr>
<tr>
<td>Daclatasvir NPP&lt;sup&gt;88&lt;/sup&gt;</td>
<td>Sofosbuvir + daclatasvir</td>
<td>4</td>
<td>24</td>
<td>12</td>
<td>9 (75)</td>
<td>Case series</td>
</tr>
<tr>
<td>CUPILT&lt;sup&gt;37&lt;/sup&gt;</td>
<td>Sofosbuvir + daclatasvir ± ribavirin</td>
<td>FCH</td>
<td>12</td>
<td>15</td>
<td>15 (100)</td>
<td>Case series</td>
</tr>
<tr>
<td>AIF-SOFOLT&lt;sup&gt;88&lt;/sup&gt;</td>
<td>Various sofosbuvir-based</td>
<td>FCH, 4</td>
<td>24</td>
<td>39</td>
<td>31 (79)</td>
<td>Case series</td>
</tr>
<tr>
<td>Lahey Clinic&lt;sup&gt;59&lt;/sup&gt;</td>
<td>Sofosbuvir + simeprevir</td>
<td>6% with 4</td>
<td>12</td>
<td>16</td>
<td>13 (81)</td>
<td>Case series</td>
</tr>
<tr>
<td>University of Louisville&lt;sup&gt;50&lt;/sup&gt;</td>
<td>Sofosbuvir + simeprevir ± ribavirin</td>
<td>&lt;4</td>
<td>12</td>
<td>18</td>
<td>16 (89)</td>
<td>Case series</td>
</tr>
</tbody>
</table>

*Unless otherwise stated. †Patients who completed treatment and follow-up. ‡Addition of ribavirin possible at the discretion of treating physician.

Abbreviations: FCH, fibrosing cholestatic hepatitis; SVR12, sustained virologic response at 12 weeks.
Current Considerations in Transplant Patients

- Pre-transplant considerations
  - Can limit organ offers
  - Can delay transplantation
- Post-transplant considerations
  - Post-liver transplant patients are more susceptible to renal insufficiency, which can alter drug metabolism and susceptibility to toxicity (i.e. ribavirin)
  - Current regimens do not require adjustments in IS
  - Low urgency to treat
  - Can convert genotype if received HCV-positive donor
  - Changes in risk-adjustment metrics reflective of highly effective treatment options
Current Treatment Guidelines and Resources
Current Treatment Recommendations

- HCVguidelines.org
- Joint guidelines from AASLD and IDSA
- EASL HCV Advisor APP
### Current Recommendations: Decompensated Cirrhosis

#### Recommended for All Patients with HCV Infection Who Have Decompensated Cirrhosis

<table>
<thead>
<tr>
<th>RECOMMENDED</th>
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<tr>
<td>Patients with HCV infection who have decompensated cirrhosis (moderate or severe hepatic impairment; Child Turcotte Pugh [CTP] class B or C) should be referred to a medical practitioner with expertise in that condition (ideally in a liver transplant center).</td>
<td>I, C</td>
</tr>
</tbody>
</table>

#### Recommended Regimens by evidence level and alphabetically for:

**Patients with Genotype 1, 4, 5, or 6, Who Have Decompensated Cirrhosis (Moderate or Severe Hepatic Impairment; CTP Class B or C)**, Who May or May Not Be Candidates for Liver Transplantation, Including Those with Hepatocellular Carcinoma

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<td>Daily fixed-dose combination of ledipasvir (90 mg)/sofosbuvir (400 mg) with low initial dose of ribavirin (600 mg, increased as tolerated); for patients with genotype 1, 4, 5, or 6</td>
<td>12 weeks</td>
<td>I, A*</td>
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<tr>
<td>Daily fixed-dose combination of sofosbuvir (400 mg)/velpatasvir (100 mg) with weight-based ribavirin; for patients with genotype 1, 4, 5, or 6</td>
<td>12 weeks</td>
<td>I, A*</td>
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<td>Daily daclatasvir (60 mg*) plus sofosbuvir (400 mg) with low initial dose of ribavirin (600 mg, increased as tolerated); for patients with genotype 1 or 4</td>
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**Current Recommendations:**

** Decompensated Cirrhosis**

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### Current Recommendations: Post LT

#### Genotype 1 or 4

**Recommended Regimens by evidence level and alphabetically for:**

**Treatment-naive and -Experienced Patients, with HCV Genotype 1 or 4 Infection in the Allograft, Including Those with Compensated Cirrhosis**

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**Recommended Regimens by evidence level and alphabetically for:**

**Treatment-naive Patients, with HCV Genotype 1 or 4 Infection in the Allograft, and with Compensated Liver Disease, Who Are Ribavirin Ineligible**

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### Current Recommendations: Post LT

#### Genotype 2

**Recommended Regimens by evidence level and alphabetically for:**

**Treatment-naive and -Experienced Patients, with HCV Genotype 2 Infection in the Allograft, Including Those with Compensated Cirrhosis**

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<td>II, A</td>
</tr>
<tr>
<td>Daily sofosbuvir (400 mg) and weight-based ribavirin</td>
<td>24 weeks</td>
<td>II, C</td>
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**Recommended Regimen for:**

**Treatment-naive and -Experienced Patients, with HCV Genotype 2 Infection in the Allograft, Including Those with Compensated Cirrhosis, Who Are Ribavirin Ineligible**

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## Current Recommendations: Post LT

### Genotype 3

**Recommended Regimen for:**
**Treatment-naive and -Experienced Patients, with HCV Genotype 3 Infection in the Allograft, Including Those with Compensated Cirrhosis**

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**Recommended Regimen for:**
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Current Recommendations: Post LT

Additional Considerations

- Ribavirin-free regimens are highly effective, new research suggesting ribavirin does not influence SVR rates in post-transplant patients

Safety and Efficacy of Current Direct-Acting Antiviral Regimens in Kidney and Liver Transplant Recipients With Hepatitis C: Results From the HCV-TARGET Study


Data outside of clinical trials with direct-acting antiviral regimens with or without ribavirin as treatment of chronic hepatitis C virus in solid organ transplant recipients are limited. Liver transplant (LT), kidney transplant (KT), and dual liver kidney (DLK) transplant recipients from the Hepatitis C Therapeutic Registry and Research Network database, a multicenter, longitudinal clinical care treatment cohort, treated with direct-acting antiviral regimens between January 1, 2014, and February 15, 2016, were included to assess safety and efficacy. Included were 443 posttransplant patients (KT = 60, LT = 347, DLK = 36); 42% had cirrhosis, and 54% had failed prior antiviral therapy. Most had genotype (GT) 1 (87% with 52% GT1a, 27% GT1b, and 8% GT1 no subtype) and were treated with sofosbuvir (SOF)/ledipasvir ± ribavirin (85%) followed by SOF + daclatasvir ± ribavirin (9%) and ombitasvir/paritaprevir/ritonavir + dasabuvir ± ribavirin (6%). Rates of sustained virologic response (SVR) at 12 weeks were available on 412 patients, and 395 patients (95.9%) achieved SVR at 12 weeks: 96.6%, 94.5%, and 90.9% among LT, KT, and DLK transplant recipients, respectively. Ribavirin did not influence SVR rates and was more often used in those with higher BMI, higher estimated glomerular filtration rate and lower creatinine. Female gender, baseline albumin ≥3.5 g/dL,
Current Recommendations: Renal Impairment

• If eGFR <30mL/min, consult specialist—limited data
Current Recommendations: HIV/HCV Co-infection

- Same recommendations as HCV-monoinfected patients
- Consider drug-drug interactions and dose adjustments
- In collaboration with HIV practitioner
- Some approved regimens do not require dose adjustments
- Some regimens should NOT be used in patients that are NOT currently on antiretroviral therapy.
New Considerations for Hepatitis C in Transplantation
New Considerations for HCV in Transplant

• Highly effective treatments
• Mortality may be higher awaiting transplant than potential mortality of HCV
• Consideration for HCV-positive donors for HCV-naïve recipients
• HCV-positive donors tend to be young (average age of 37)
• Increase in HCV-positive donors due to opioid epidemic
Infected a patient with hepatitis C to save his life

Montefiore became the first New York health system to use livers with hep-C in transplants for uninfected patients who might otherwise die waiting for a match. Alvin Fisher was first in line

Robin D. Schatz

Published: July 23, 2017 - 12:01 am

Alvin Fisher was back at Montefiore Health System on March 23, hospitalized again for problems related to his failing liver. He expected to be discharged the next day, but early that morning a doctor delivered the news: After 14 months, the Bronx hospital had found the 21-year-old a new liver. A man in his early 30s had died in a fall, and a team from Montefiore was heading upstate to examine the organ.

Fisher contained his emotions. "I didn't get my hopes up too much, because they could say at the last minute it was too damaged for me to have," he said.

There was reason for Fisher to be circumspect. Until then he had been behind about 30 New Yorkers waiting for a liver, giving him just a 50-50
New Considerations for HCV in Transplant

Transplanting kidneys with Hepatitis C saves patients’ lives, cures disease

Text by Heather A. Davis

More than 97,000 people in the United States are currently awaiting kidney transplants—waits that can often take five or more years.

Two Perelman School of Medicine faculty members recently released findings from a clinical trial that could lead to about 1,000 more kidney transplants each year.

The research, led by David Goldberg and Peter Kostglass, medicine and epidemiology, shows that 10 patients transplanted from deceased donors infected with Hepatitis C can now be cured of the disease.

The trial was launched in June of 2016, and is testing if it’s possible to eradicate HCV from patients who could otherwise be denied the organs they need to survive. Researchers say this could open up access to more kidneys—and hopefully lessen the amount of time someone who needs one has to wait.

A Transplant and a Cure: Penn Team Eradicates Hepatitis C in 10 Patients Following Lifesaving Transplants from Infected Donors

Penn Study Results Point to Potential for Hundreds More Transplants Each Year

April 30, 2017

CHICAGO — Ten patients at Penn Medicine have been cured of the Hepatitis C virus (HCV) following lifesaving kidney transplants from deceased donors who were infected with the disease. The findings point to new strategies for increasing the supply of organs for the nation’s more than 97,000 patients who are awaiting kidney transplants—often for as many as five or more years.
Novel approach expanded transplant patient’s options

by Jessica Pasley | Thursday, Aug. 31, 2017, 8:38 AM

Savannah Parks’ dual organ transplant involved using hepatitis C-positive organs. (photo by Susan Urmy)
Additional Considerations

• HCV antibody positive versus HCV NAT positive

• HCV Ab+/HCV NAT-
  – Treated donors
  – Donors that spontaneously cleared virus
  – False positives
  – Theoretically, no risk of transmission to recipient
  – Still monitor these patients
Additional Considerations

- **HCV Ab+/HCV NAT+ donors**
  - Donors with active viremia
  - Assume recipient will develop active viremia
  - Potential to spontaneously clear, although rare in the setting of immunosuppression

- **HCV Ab-/HCV NAT+ donors**
  - False positive
  - Recent infection, assume active viremia
  - Still monitor these patients
Additional Considerations

• Education
  – Provide additional documented education on hepatitis C donors
  – Include complications, potential treatment options
  – Do not guarantee a cure

• Consent
  – Consider additional documented consent
  – Confirm additional education
Summary

- Dramatic changes in the world of HCV over the last five years
- Several, highly effective DAAs for the treatment of HCV, even in historically “difficult to treat” populations
- Declining indication for liver transplant
  - Improved outcomes for LT recipients transplanted for HCV
- Opportunities to increase donor pool
  - Opportunities for HCV-naïve recipients
Resources

- **CDC: Hepatitis C**
- **HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C**
Resources

- [SRTR Annual Data Report](#)