EXAMINING THE 3 Cs OF HEPATITIS C: CARE, CURE, CO$T

Update presented by
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Followed by
Round Table Discussion:
ANTHC Liver Disease & Hepatitis Program Staff and Audience

Question #1

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A. Too low

B. Too high

C. Just right

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A. Person with mild liver fibrosis
B. Person with moderate liver fibrosis
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D. All of the above

Question #3

Would you give hepatitis C treatment to a past substance abuser?

A. Yes

B. No

Question #4

Would you give hepatitis C treatment to a current substance abuser?

A. Yes

B. No

Disclosures

- This talk will include information about investigational drugs that have not yet been approved by the FDA and one off-label practice used in the treatment of hepatitis C.

- No commercial or financial interests to disclose

Objectives

- Understand treatment medications by genotype and appropriate prescribing
- Recognize hepatitis C treatments result in cure of hepatitis C in ≥ 90% of patients now and soon ≥ 95%
- Recognize that cure of hepatitis C leads to significant decrease in liver cancer, liver failure and liver-related death
- Identify issues related to hepatitis C treatment

Glossary of Liver Disease Terms Used

- ESLD – End stage liver disease
- HCC - Hepatocellular carcinoma
- LT – Liver transplant
- NASH – Non-alcoholic steatohepatitis
- Peg - Peginterferon alfa
- Rib - Ribavirin
- Sof - Sofosbuvir
- SVR - Sustained virologic response
- TN - Treatment-naïve (never treated before)
- TE - Treatment-experienced (previously treated and either failed treatment or relapsed after)

WHAT DRUGS ARE CURRENTLY FDA APPROVED?

Sofosbuvir: Current FDA Approved Indications

HCV and HCV/ HIV Co-Infection	Treatment	Duration
Genotypes 1, 4 Interferon Ineligible Alternative	Sofosbuvir + Peginterferon (Peg) + Ribavirin (Rib) Sof + Rib	12 weeks 24 weeks
Genotype 2	Sof + Rib	12 weeks
Genotype 3	Sof + Rib	24 weeks

Simeprevir:

FDA Approved Indication is with Peg/Rib for Genotype 1 only with compensated liver disease

Patient Population	Simeprevir, Peg and Rib	+ Treatment with Peg and Rib	Total Treatment Duration
Treatment naïve and prior relapser patients	First 12 weeks	Additional 12 weeks	24 weeks
Prior partial or null responder patients	First 12 weeks	Additional 36 weeks	48 weeks

SVR Rates of FDA-Approved Treatments

Treatment	Overall SVR	SVR in Advanced Fibrosis
Sofosbuvir-based Geno 1 Geno 2 Geno 3 Geno 4	 89% 93% 84% 96%	 80% 83-100% TN & TE 92% TN/60% TE --
Simeprevir (Geno 1 only) with Peg/Rib	77-80%	68-73%

Sofosbuvir-Based Treatment for HCV and HIV Coinfection

Treatment (All Interferon-free)	Overall SVR*
Geno 1 Sof + Rib x 24 wks	76%, 85%
Geno 2 Sof + Rib x 12 wks	88%, 88%
Geno 3 Sof + Rib x 24 wks	92%, 89%

Photon 1, Photon 2 studies

Off-Label Treatments

Currently seen in practice

Simeprevir-Sofosbuvir for Genotype 1 Interferon-Ineligible

- Not currently FDA approved but is included in AASLD/IDSA Guidelines
- Sofosbuvir plus simeprevir with or without ribavirin for 12 weeks
- Based on Phase 2 Cosmos Trial (n-167)
  - SVR was 96% with ribavirin and

    93% without ribavirin

Alternative Treatment for Genotype 3 AASLD/IDSA Guidelines

- Sofosbuvir plus peginterferon and ribavirin x 12 weeks
- Overall SVR (Phase 2 studies) 97%
- SVR in advanced fibrosis 83%

Cost of New Medications*

- Sofosbuvir x 12 weeks: $84,000
- Sofosbuvir x 24 weeks: $168,000
- Simeprevir x 12 weeks: $66,360
- Sofosbuvir + Simeprevir x 12 weeks: $150,360

* Using Manufacturer's Retail Price

On the Horizon

Drugs expected to be approved by the FDA by end of 2014

Interferon-Free Treatment for Genotype 1

Ledipasvir-Sofosbuvir Fixed Dose Combo (1 pill once/day)/Gilead – FDA approval expected by Oct 10, 2014

Expect FDA Approval October-December 2014:

- Daclatasvir-Asunaprevir/Bristol Meyers Squibb
- 3D Regimen/Abbvie
- Combining Simeprevir with Sofosbuvir/Janssen Supplemental New Drug Application

Raising the Bar:
≥ 95% Cure Rates
For All In the Future

Benefits of Hepatitis C Treatment

- Sustained virologic response (SVR) results in a 90% reduction in cirrhosis and 70% reduction in liver cancer [1,2,3]

[1]Morgan, RL et al. Ann Intern Med. 2013;158 (5 Pt 1):329-337.

[2]van der Meer, et al. JAMA. 2012;308(24):2584-2593.

[3]Veldt, BJ et al. Ann Intern Med. 2007;147(10):677-684.

Hepatitis C Treatment Coverage

Medicare Part D

Obtain prior authorization

AK Medicaid

Covers *F3-F4 Fibrosis Only

AK Marketplace Insurance Plans

Moda, Premera

Cover *F3-F4 Fibrosis Only

Private Insurance

Obtain Prior Authorization

Uninsured

Send to Gilead Support Path (Sof)/ Janssen Patient Assistance (Sim)

*F3-F4 Fibrosis = Advanced fibrosis of the liver (bridging fibrosis or cirrhosis)

Treatment Reimbursement

- Write Rx, start prior authorization process for persons with insurance coverage
- Uninsured and Those Denied Coverage from Insurance
  - Contact Gilead Support Path (Sofosbuvir)
    - 1-855-7-MYPATH (1-855-769-7284)
    - SOVALDI.com/support
  - Janssen Prescription Assistance (Simeprevir)
    - 1-855-5-OLYSIO (1-855-565-9746)
    - janssenprescriptionassistance.com

Updated AASLD/IDSA Recommendations for Testing, Managing and Treating Hepatitis C

August 11, 2014 revision included new section:

In Whom and When to Initiate Treatment

When and in Whom to Initiate Treatment

"…clinicians should treat HCV-infected patients with antiviral therapy with the goal of achieving SVR, preferably early in the course of their chronic HCV infection before the development of severe liver disease and other complications."

"Limitations of workforce and societal resources may limit the feasibility of treating all patients within a short period of time. Therefore, when such limitations exist, initiation of therapy should be prioritized first to those specific populations that will derive the most benefit or have the greatest impact on further HCV transmission. Others should be treated as resources allow."

http://hcv guidelines.org

Project ECHO®

Grading System

Classification	Description
Class I	Conditions for which there is evidence and/or general agreement that a given diagnostic evaluation, procedure, or treatment is beneficial, useful, and effective
Class II	Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness and efficacy of a diagnostic evaluation, procedure, or treatment
Class IIa	Weight of evidence and/or opinion is in favor of usefulness and efficacy
Class IIb	Usefulness and efficacy are less well established by evidence and/or opinion
Class III	Conditions for which there is evidence and/or general agreement that a diagnostic evaluation, procedure, or treatment is not useful and effective or if it in some cases may be harmful

Level of Evidence	Description
Level A	Data derived from multiple randomized clinical trials or meta-analyses
Level B	Data derived from a single randomized trial, or nonrandomized studies
Level C	Consensus opinion of experts, case studies, or standard of care

Adapted from the American College of Cardiology and the AHA Practice Guidelines

When and in Whom to Initiate HCV Treatment

The goal of treatment is to reduce all-cause mortality and liver-related health adverse consequences, including ESLD and HCC, by the achievement of SVR (Class I, Level A)

Treatment is recommended for patients with chronic HCV infection (Class I, Level A)

- Treatment is assigned the highest priority for patients with advanced fibrosis, compensated cirrhosis, or severe extrahepatic HCV, and for LT recipients
- Based on available resources, treatment should be prioritized as necessary so that patients at high risk for liver-related complications and severe extrahepatic complications are given high priority

http://hcv guidelines.org

Project ECHO

Complications and Extrahepatic Disease Where Treatment is Most Likely to Provide the Most Immediate and Impactful Benefits

Highest Priority for Treatment Owing to Highest Risk for Severe Complications
Advanced fibrosis (Metavir F3) or compensated cirrhosis (Metavir F4) (Class I, Level A)
Organ transplant (Class I, Level B)
Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (eg, vasculitis) (Class I, Level B)
Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis (MPGN) (Class IIa, Level B)

http://hcv guidelines.org

Complications and Extrahepatic Disease Where Treatment is Most Likely to Provide the Most Immediate and Impactful Benefits

High Priority for Treatment Owing to High Risk for Complications
Fibrosis (Metavir F2) (Class 1, Level B)
HIV-1 coinfection (Class 1, Level B)
Hepatitis B virus (HBV) coinfection (Class IIa, Level C)
Other coexistent liver disease (eg, [NASH]) Class IIa, Level C)
Debilitating fatigue (Class IIa, Level B)
Type 2 diabetes mellitus (insulin resistant) (Class IIa, Level B)
Porphyria cutanea tarda (Class IIb, Level C)

http://hcv guidelines.org

Treating Persons at Risk of Transmitting HCV

"Successful treatment of HCV-infected persons at greatest risk for transmission represents a formidable tool to help stop HCV transmission in those who continue to engage in high-risk behaviors. To guide implementation of hepatitis C treatment as a prevention strategy, studies are needed to define the best candidates for treatment to stop transmission, the additional interventions needed to maximize the benefits of HCV treatment (e.g., preventing reinfection), and the cost effectiveness of the strategies when used in the target population."

http://hcv guidelines.org

Persons Whose Risk of HCV Transmission is High and in Whom HCV Treatment May Yield Transmission Reduction Benefits

High HCV Transmission Risk*
MSM with high-risk sexual practices
Active IDUs
Incarcerated persons
Persons on long-term hemodialysis
(Rating: Class IIa, Level C)

*Patients at high risk of transmitting HCV should be counseled on ways to decrease transmission and minimize the risk of reinfection

http://hcv guidelines.org

Project ECHO

Populations Unlikely To Benefit from HCV Treatment

- Limited life expectancy (< 12 months) where treatment would not improve symptoms or prognosis

Articles on Hepatitis C Treatment Issues

- Can hepatitis C be eradicated in the U.S.? Brian Edlin and Emily Winkelstein; *Antiviral Research,* 110 (2014), 79-93.
- Researchers: Sovaldi Analysis Could Be Used In Lawsuits Against Medicaid. Inside CMS (online); 9/25/14.
- Drug Pricing: A New Prescription. Sylvia Westphal, *The Boston Globe*, 9/14/14.
- $1000 Hepatitis Pill Shows Why Fixing Healthcare Costs is So Hard: Critics Raise Concerns About Sovaldi. Margo Sanger-Katz, *The New York Times, 8/2/14.*
- Demand for expensive hepatitis C drug strains insurers: When 'miracle' cures, cost collide. Robert Weisman. *The Boston Globe*, 6/1/14.

Treatment Guidance

Visit ANTHC Liver Disease & Hepatitis Program Website – Treatment Page

http://www.anthctoday.org/community/hep/providers/treatment/index.html

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  - Ronni Marks, HepatitisCMsg.Org
  - Michael Ninburg, HepEducation.org
  - Jules Levin, Natap.org

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