Pretreatment Evaluation
Disclosures

- Research supported by Gilead Sciences Inc.:
  - Site investigator for HIV/HCV SWITCH Registry Study
  - Key personnel for FOCUS HCV Screening Program through Vanderbilt University Medical Center Emergency Department
Objective

At the end of this lecture, the learner will be able to:

- Outline the appropriate evaluation of a person infected with HCV in order to assess the benefits and risks of treatment and in anticipation of treatment with direct acting antiviral therapy
Two Stories

Beth
- Young woman with two children
- Alcohol use
- Intravenous drug use
- Elevated liver function tests
- HCV antibody and RNA positive

Charles
- Older man with comorbidities
- Rare alcohol use
- No drug use
- Elevated liver function tests and low platelets
- HCV antibody and RNA positive
Questions

- How do we determine how HCV has impacted each patient?
- How do we assess liver disease and comorbidities to inform clinical care and HCV treatment?
- How do we reduce harm while moving towards treatment?
Targeted History and Exam

**History**
- Disease History
  - When? How? Why?
  - Prior Staging
  - Prior Treatment
- Symptoms of chronic HCV infection:
  - Fatigue
  - Arthralgias
  - Chronic abdominal pain
  - Insomnia
  - *Many patients are asymptomatic!*
- Symptoms of advanced liver disease:
  - Upper GI bleeding
  - Ascites
  - Hepatic encephalopathy
  - Liver failure
- Medication History
- Alcohol Use History
- Substance Use History

**Physical**
- *May be normal without evidence of disease!*
- Focus on stigmata of chronic liver disease:
  - Palmar erythema
  - Spider nevi
  - Gynecomastia
  - Jaundice
  - Ascites
  - Asterixis
  - Encephalopathy
- Evaluate for stigmata of injection drug use
  - Track marks
  - Thrombophlebitis
  - Skin scarring

Suggested Laboratory Testing

- HCV RNA & Genotype
  - Therapy options
- CBC
  - Evaluate cell lines
- CMP
  - Including LFTs and albumin
- PT/INR
  - Check synthetic function
- HAV and HBV testing
  - Rule out co-infection
  - Evaluate vaccination status
- HIV testing
  - Rule out co-infection
- Vitamin D
  - Often low in patients with HCV
- Urine drug screen
  - Evaluate for ongoing drug use
- Consider:
  - Hemoglobin A1C
    - Evaluate for metabolic disease
  - ANA screen
    - Evaluate for autoimmune disease

Hepatitis B Virus Reactivation Associated With Direct-Acting Antiviral Therapy for Chronic Hepatitis C Virus: A Review of Cases Reported to the U.S. Food and Drug Administration Adverse Event Reporting System

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Case Series

- 29 cases reported from 11/2013 – 10/2016
  - 13 occurred in patients with positive sAg
  - 4 occurred in patients with negative sAg
  - 12 occurred with unknown baseline sAg status
- 2 deaths and 1 liver transplant
- Resulted in boxed warning with all DAA therapies
Treating HCV In Setting of HBV

- Treat HBV based on guideline recommendations

- Consider closer monitoring of HBV and associated liver disease while on DAA therapy if not on anti-HBV treatment
QUESTION REGARDING STAGING
Staging Liver Disease

- Importance of Staging
  - Identify patients with greatest need for therapy
  - Identify patients for cirrhosis-specific care
  - Triage resources

- Types of Staging
  - Liver biopsy
  - Biomarkers
  - Elastography
Liver Biopsy To Stage Liver Fibrosis

- Historical gold standard
- May be helpful in evaluating other causes of liver disease
- Results may be impacted by quality of specimen (i.e. length of biopsy)
- Limited by invasive nature of test, cost, and access to proceduralist
Biomarker Testing to Stage Liver Fibrosis

- Ideally would allow staging of liver disease without invasive procedures or specialized imaging
- Multiple scoring systems and proprietary tests available but vary in utility

- **APRI**
  - AST-To-Platelet Ratio Index
  - \[
  \frac{\text{AST} / \text{ULN}}{\text{PLT}} \times 100
  \]

- **FIB-4 Index**
  - \[
  \text{Age} \times \frac{\text{AST}}{\text{PLT} \times (\text{ALT})^{1/2}}
  \]

- **Fibrosure®**
  - Multiple known inputs and proprietary equation
  - Recognized by many payers

[References]
Elastography

- Measures mechanical shear wave velocity, which is proportional to liver stiffness
- Multiple methods (transient, magnetic resonance, acoustic radiation force impulse)
- Available in multiple locations throughout Tennessee in both private practices, imaging centers, hospitals, and HIV Centers of Excellence
Notes About Anatomic Imaging

- Anatomic imaging (i.e. ultrasound, CT, MRI) are NOT adequate for staging
  - However, if advanced fibrotic changes are present, they likely correlate with tissue pathology
- Appropriate for hepatocellular carcinoma monitoring
- Reasonable to consider in any patient undergoing HCV evaluation with unknown or suspected advanced fibrosis
Interventions to Reduce Progression of Liver Disease

- Immunization for Hepatitis A and B
- Alcohol abstinence
- Appropriate acetaminophen use
- Avoiding NSAIDs
Counseling to Reduce Transmission of HCV

- Avoid blood borne exposure
  - Shared personal devices such as razors or nail clippers
  - Barrier protection for intimate contact
  - Safer approaches to injection drug use
QUESTIONS?