THE NEW WORLD OF HEPATITIS C TREATMENT

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OBJECTIVES

• Review:
  • Epidemiology
  • Etiology
  • Clinical Manifestations of viral HCV
• Discuss the workup and evaluation of the patient infected with Hepatitis C
• Compare and contrast therapy modalities for the effective treatment of acute and chronic Hepatitis C.
DISCLAIMER

• From:
  • American Association for the Study of Liver Diseases
  -AND-
  • Infectious Diseases Society of America’s website – Also applies to today’s topic:

• NOTICE: Guidance for hepatitis C treatment in adults is changing constantly with the advent of new therapies and other developments. A static version of this guidance, such as printouts of this website material, booklets, slides, and other materials, may be outdated by the time you read this. We urge you to review this guidance on this website (www.hcvguidelines.org) for the latest recommendations.
HEPATITIS C - EPIDEMIOLOGY

- WHO reports 150 million infected
- 3-4 Million person in USA chronically infected
  - ½ are unaware of status
- 700,000 die annually from HCV related disease

HEPATITIS C - ETIOLOGY

- Blood to blood transfer
- IVDU
- Intranasal drugs
- Health Care
- Vertical
- Non-Sterile Tattoos/Piercings
- Unknown
- Sexual *
SCREENING GUIDELINES * CDC

- EVERYONE born between 1945-1965 – USPSTF agrees
- People with IVDU history; even one time
  - * annual screenings for ongoing
- Recipients of blood products prior to 1992
- Transplant patients prior to 1992
- Hemodialysis patients
- Healthcare workers
- HIV patients
- People with exposures or symptomatic patients
WHAT ABOUT PREGNANCY?

- Not recommended routinely in US per CDC
- Follow other guidelines
- Test on infants born to infected mothers unreliable until >18 mo.
HEPATITIS C TIMELINE

• Incubation period is 2 weeks- 6 months
• >15% globally spontaneously clear virus within 6 mo.
• Up to 85% develop chronic HCV
• Risk of cirrhosis is 15-30% within 20 years
• Cirrhosis leads to death in >20% of patients
• Hepatocellular Carcinoma (HCC) in 5% of Cirrhotic Patients BUT Unpredictable!
• Hepatitis C is the LEADING cause of liver transplantation
FIGURE 2.2 Natural history of HCV infection

- HCV infection
- Chronic infection (55–85%)
- Mild fibrosis
- Moderate to severe fibrosis
- Cirrhosis (15–30%)
- Decompensated cirrhosis

Spontaneous resolution (15–45%)

Hepatocellular carcinoma (2–4% per year in cirrhosis)
ACUTE HEPATITIS C – CLINICAL MANIFESTATIONS

• Up to 80% of patients are asymptomatic!
• Symptoms could include:
  • Fever
  • Fatigue
  • Decreased appetite
  • N/V
  • Abdominal pain
  • Jaundice
  • Arthralgias
SIGNS OF CHRONIC HEPATITIS C

- Typically NONE
- End stage patients may develop symptoms of liver failure
- Pruritus
- Fatigue
- Skin or oral mucosa changes
- Vasculitis
  - Cryoglobulinemia
SIGNS OF ESLD

- Often few or NONE when compensated
- Ascites
- Asterixis
- Palmar Erythema
- Spider Angiomata
- Umbilical hernia/Caput medusa
HCV WORKUP

- Screen with antibody
- HCV RNA PCR (Quant. or Qual.)
- Genotype
- Imaging
- AFP
- Enzymes*  MOST OFTEN NORMAL!
FIGURE 2.1 Global distribution of genotypes of HCV (18)
R/O OTHER CO-MORBIDITIES

- ETOH
- NASH
- HIV
- HBV * Black Box Warning
- Vaccinate for HAV
- Wilson’s Disease
- Autoimmune Hepatitis
- Alpha-1 Antitrypsin Def.
- CBC
- CMP
- Hemochromatosis
- Cancers (HCC)
HCV LABS DECODED

- HCV AB +
- HCV AB –
- HCV NAT +
- HCV RNA PCR Qual +
- HCV RNA PCR Quant. >50
- HCV RNA PCR Quant. <50
- Genotype
- HCV Ab+/HCV RNA -

- Exposed
- Not Exposed
- Current Viral Activity/Infection (25IU/mL min)
- Active Disease vs. low suppression
- Active Disease (viral load)
- Viral Suppression vs. Cure (length)
- Type determines treatments
- Exposed vs. False positive vs. treated (no disease)

https://www.cdc.gov/hepatitis/hcv/pdfs/hcv_graph.pdf
ACUTE VS. CHRONIC HCV

- Six months
- Cannot be detected until >4 weeks by antibody
- Can be detected as early as 2 weeks by RNA
- Acute = ? Better chance to clear
- Treat both? Cost effective vs. patient centered
- Special considerations in immune compromise
IMAGING

- Ultrasound
- CT Scan
- MRI
- Elastography
LIVER BIOPSY?

- In the past always, now to stage/decisions
- Metavir (F0-F4) vs. Ishak fibrosis score (0-6)
- Resource Limited settings
- Cost/Risk vs. Benefit

- APRI
  - AST to Platelet Ration Index
    - http://www.hepatitisc.uw.edu/page/clinical-calculators/apri

https://www.niddk.nih.gov/health-information/health-topics/diagnostic-tests/liver-biopsy/Pages/diagnostic-test.aspx
PATIENT COUNSELING

- Abstinence from ETOH
- Vaccinate for HAV & HBV
- Evaluate for other conditions
- Fibrosis Evaluation/ Prognosis Discussion
- Avoid Spread to others
- Pneumococcal vaccination if cirrhosis
TREATMENTS – A HISTORICAL TIMELINE

1990s
- Nothing – Non A/Non B until 1991
- Interferon

2000s
- Peg Interferon
- Ribavirin

2011+
- Protease Inhibitors
- Direct Acting Antivirals
CONTRAINDICATIONS - RIBAVIRIN

- Pregnancy or lack of contraception
- Breastfeeding
- Severe disease
- Cardiac failure
- COPD
- Previous sensitivity
- Didanosine co-administration
- Anemia
- Neutropenia
- Thrombocytopenia
- Renal failure or Creat. >1.5
- Sickle Cell Disease
- CAD
- Thalessemia
### INTERFERON

#### CONTRAINDICATIONS
- Depression or Psychosis
- Epilepsy
- Autoimmune Disease
- Decompensated Cirrhosis
- Pregnancy or lack of Contraception
- Cardiac Failure
- Transplant
- COPD

#### RELATIVE CONTRAINDICATIONS
- Anemia
- Seurm Creat >1.5
- Sickle Cell disease
- CAD
- Thyroid disease
- Ophthalmological disease
- Colitis
- Pancreatitis
NEWER TREATMENTS ALREADY FADED

• Graveyard:

• Telaprevir and boceprevir should no longer be used
  • These 2 first-generation Protease were recommended in the 2014 guidelines. Evidence now shows that they result in more frequent adverse effects and less frequent cures compared with newer DAA-based regimens. Thus, these 2 medicines are no longer recommended by WHO
DIRECT ACTING ANTIVIRALS (DAA)

- Cure Rates >90% in typically <3 months
- Genotype Specific
- Many in Pipeline
- Resistance possible – test NS5A in some regimens
**CONTRAINDICATIONS***

- **Ledipasvir/sofosbuvir**
  - Amiodarone co-administration
  - P-glycoprotein (gp) inducers
  - Renal failure (eGFR <30mL/min/1.73m2)
- **Daclatasvir**
  - Drugs inducing or inhibiting CYP3A
- **Sofosbuvir**
  - Amiodarone co-administration (caution with beta blockers)
  - Renal failure
- **Ombitasvir/paritaprevir/ritonavir +/- dasabuvir**
  - Child-Pugh Class B and C Cirrhosis
  - Inducers or Inhibitors of CYP3A or CYP2C8
  - Untreated HIV
- **Simeprevir**
  - Child-Pugh Class B and C cirrhosis
  - CYP3a Interaction
DAA- SIDE EFFECTS

• Few
• Fatigue
• Anemia <10%
<table>
<thead>
<tr>
<th>Concomitant Medications</th>
<th>Dadatasvir</th>
<th>Ledipasvir</th>
<th>Paritaprevir / Ritonavir / Ombitasvir + Dasaavir</th>
<th>Simeprevir</th>
<th>Sofosbuvir</th>
<th>Elbasvir / Grazoprevir</th>
<th>Velpatasvir</th>
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</tbody>
</table>

*Some drug interactions are not class specific; see product prescribing information for specific drugs within a class.

**Requires a daclatasvir dose modification.
## Monitoring on Therapy

<table>
<thead>
<tr>
<th>Time</th>
<th>DAA alone</th>
<th>DAA + ribavirin</th>
<th>DAA + pegylated interferon + ribavirin</th>
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<tr>
<td></td>
<td>FBC, renal, liver function</td>
<td>Adherence, side-effects</td>
<td>HCV RNA</td>
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<td>Baseline</td>
<td>X</td>
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<td>Week 1</td>
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<td>Week 12</td>
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<tr>
<td>Week 12 after end of treatment</td>
<td>X</td>
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<tr>
<td>Week 24 after end of treatment</td>
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</tbody>
</table>

ALT: alanine aminotransferase; DAA: direct-acting antiviral; FBC: full blood count
• http://www.hcvguidelines.org/

• Cirrhosis – longer durations of tx

• Multiple regimens

• Various alternatives

• Testing for each
<table>
<thead>
<tr>
<th>Genotype 1 a &amp; b</th>
<th>Genotype 2</th>
<th>Genotype 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sofosbuvir</strong> 400/velpatasvir100 x 12 weeks</td>
<td><strong>Sofosbuvir</strong> 400/velpatasvir100 x 12 weeks</td>
<td><strong>Sofosbuvir</strong> 400/velpatasvir100 x 12 weeks</td>
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<tr>
<td>Ledipasvir 90/sofosbuvir 400 x 12 weeks</td>
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<tr>
<td>Simeprevir 150/sofosbuvir 400 x 12 weeks</td>
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</table>
WHO GUIDELINES

- Already Outdated?
- World view/ not necessarily American
- Look for new guidelines
## Summary of recommended preferred regimens with treatment durations

### Persons without cirrhosis

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Daclatasvir/sofosbuvir</th>
<th>Ledipasvir/sofosbuvir</th>
<th>Sofosbuvir/ribavirin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotype 1</td>
<td>12 weeks</td>
<td>12 weeks</td>
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<tr>
<td>Genotype 2</td>
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<td>12 weeks</td>
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<td>Genotype 3</td>
<td></td>
<td></td>
<td>24 weeks</td>
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<tr>
<td>Genotype 4</td>
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<td>12 weeks</td>
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<tr>
<td>Genotype 5</td>
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<td></td>
<td>12 weeks</td>
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<tr>
<td>Genotype 6</td>
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<td>12 weeks</td>
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</table>

### Persons with cirrhosis

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Daclatasvir/sofosbuvir</th>
<th>Daclatasvir/sofosbuvir/ribavirin</th>
<th>Ledipasvir/sofosbuvir</th>
<th>Ledipasvir/sofosbuvir/ribavirin</th>
<th>Sofosbuvir/ribavirin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotype 1</td>
<td>24 weeks</td>
<td>12 weeks</td>
<td>24 weeks</td>
<td>12 weeks</td>
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<tr>
<td>Genotype 2</td>
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<td>16 weeks</td>
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<td>Genotype 3</td>
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<td>Genotype 5</td>
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<td>Genotype 6</td>
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<td>24 weeks</td>
<td>12 weeks</td>
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</table>

* Treatment durations are adapted from the 2015 guidelines of the American Association for the Study of Liver Diseases (AASLD) and European Association for the Study of the Liver (EASL).

a Treatment may be shortened to 8 weeks in treatment-naive persons without cirrhosis if their baseline HCV RNA level is below 6 million (6.8 log) IU/mL. The duration of treatment should be shortened with caution.

b If platelet count <75 x 10^9/μL, then 24 weeks' treatment with ribavirin should be given.
### Summary of recommended alternative regimens with treatment durations

*Persons without cirrhosis*

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Simeprevir/sofosbuvir</th>
<th>Daclatasvir/sofosbuvir</th>
<th>Ombitasvir/paritaprevir/ritonavir/dasabuvir</th>
<th>Ombitasvir/paritaprevir/ritonavir/ribavirin</th>
<th>Sofosbuvir/pegylated interferon/ribavirin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotype 1</td>
<td>12 weeks(^a)</td>
<td></td>
<td>12 weeks(^b)</td>
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<tr>
<td>Genotype 2</td>
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<td>Genotype 3</td>
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<td>Genotype 4</td>
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<td>Genotype 5</td>
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<td>Genotype 6</td>
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<td>12 weeks</td>
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</table>

* Treatment durations are adapted from 2015 AASLD and EASL guidelines.

\(^a\) If genotype 1a-infected patient is positive for the Q80K variant, a simeprevir/sofosbuvir regimen should not be chosen.

\(^b\) For genotype 1a-infected patients, treat with ombitasvir/paritaprevir/ritonavir/dasabuvir and ribavirin; for genotype 1b-infected patients, treat with ombitasvir/paritaprevir/ritonavir/dasabuvir.
### Persons with cirrhosis

These regimens should be prescribed only to persons with compensated cirrhosis because they can cause liver failure and death when prescribed to persons with decompensated cirrhosis. Therefore, they should be used only in settings where specialized care is available and where the degree of cirrhosis (compensated vs decompensated) can accurately be assessed.

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Daclatasvir/sofosbuvir</th>
<th>Simeprevir/sofosbuvir</th>
<th>Simeprevir/sofosbuvir/ribavirin</th>
<th>Ombitasvir/paritaprevir/ritonavir/dasabuvir</th>
<th>Ombitasvir/paritaprevir/ritonavir/ribavirin</th>
<th>Sofosbuvir/pegylated interferon/ribavirin</th>
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<tbody>
<tr>
<td>Genotype 1</td>
<td>24 weeks(^a)</td>
<td>12 weeks(^a)</td>
<td>24 weeks(^b)</td>
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<td>Genotype 3</td>
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<td>Genotype 4</td>
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<td>Genotype 5</td>
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</tbody>
</table>

* Treatment durations are adapted from 2015 AASLD and EASL guidelines.

* If genotype 1a-infected patient is positive for the Q80K variant, a simeprevir/sofosbuvir regimen should not be chosen.

* For genotype 1a-infected patients, treat with ombitasvir/paritaprevir/ritonavir/dasabuvir and ribavirin for 24 weeks; for genotype 1b-infected patients, treat with ombitasvir/paritaprevir/ritonavir/dasabuvir and ribavirin for 12 weeks.
COSTS

- Different in US than World
- ??????????????????????????????????????
- Cheaper to treat disease even at cost than complications
- Changing rapidly
- Studies show telemedicine saves costs in this disease
<table>
<thead>
<tr>
<th>Drug</th>
<th>Ribavirin ($)*</th>
<th>Pegylated interferon ($)</th>
<th>Sofosbuvir ($)</th>
<th>Ledipasvir/sofosbuvir ($)</th>
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<td>455.18*</td>
<td>300.00</td>
<td>400.00</td>
<td>512.00</td>
</tr>
<tr>
<td>Ukraine</td>
<td>21.19</td>
<td>118.00*</td>
<td>300.00</td>
<td>812.00</td>
<td>512.00</td>
</tr>
</tbody>
</table>

Source: Budget impact analysis (web Appendix 3, 2016)

*Note: pegylated interferon-based regimens generally have a duration of 48 weeks as compared with 12 or 24 weeks for DAA regimens.
**TABLE 7.3** Estimated total cost of treating all persons diagnosed with chronic HCV infection in Brazil, Mongolia, Ukraine (2015 US$) with DAA regimens

<table>
<thead>
<tr>
<th></th>
<th>No. of persons with chronic HCV infection</th>
<th>No. of persons diagnosed</th>
<th>No. achieving SVR</th>
<th>Drug cost (US$)</th>
<th>Other cost (US$)</th>
<th>Total cost (US$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brazil</td>
<td>2 036 570</td>
<td>314 934</td>
<td>299 734</td>
<td>3 324 524 944</td>
<td>65 984 876</td>
<td>3 390 509 821</td>
</tr>
<tr>
<td>Mongolia</td>
<td>198 764</td>
<td>59 629</td>
<td>58 249</td>
<td>81 417 808</td>
<td>19 897 906</td>
<td>101 315 714</td>
</tr>
<tr>
<td>Ukraine</td>
<td>1 024 858</td>
<td>410 783</td>
<td>387 365</td>
<td>972 405 729</td>
<td>227 160 446</td>
<td>1 199 566 175</td>
</tr>
</tbody>
</table>

Source: Number of persons with chronic HCV infection based on reference (13) and diagnosed based on reference (9).
SPECIAL POPULATIONS

- Best Left to Infectious Disease Specialists or Hepatology
  - HIV co-infection
  - Transplant candidates/decompensated cirrhotics
  - Children
  - Renal Failure patients
  - HBV/HCV co-infection
  - Reproductive age Women – OK to treat with EXTENSIVE counseling
PREVENTING SPREAD

- Razors
- Needles
- Screening Tissue
- Sterilization – Tattoos, Hospitals
- Toothbrushes
- PPE / Universal Precautions
- Barrier Contraception
- EDUCATION
THE FUTURE

• Primary Care may take over
• Erradication?
IS IT REALLY A CURE?

- YES!!!!!!!!!!!!!!!!!!!!!!
- Reinfection possible
- SVR (Sustained Viralologic Response)
  - No detected virus 6 months post treatment (also SVR 3)
WORLD HEPATITIS DAY

• July 28th Every Year
QUESTIONS?
