Primary Care Treatment of Hepatitis C

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Conflicts to Disclose

• None

• Generic/scientific names only in this talk – some can be very lengthy!
Background

• Chronic hepatitis C infection
  • 2.7 million Americans
  • 185 million people worldwide
  • Mainly asymptomatic
  • 3 x the number of people with HIV
Etiology

• Single stranded RNA virus in the Flaviviridae family
• Uses the hepatocytes to replicate thousands of times amounting to hundreds of thousands to millions of replications
• Six genotypes with multiple subtypes
  • GT1 most common in the world, 75% of cases in the US are GT1
  • GT2/3 make up 20-29% of cases in the US
  • GT2 is more common in West Africa
  • GT3 is more common on the Indian Subcontinent
  • GT4 is more common in the Middle East and Central Africa
  • GT5 is more common in Southern Africa
  • GT6 is more common in Southeast Asia
Worldwide Hepatitis C Genotype Distribution
Transmission

• Blood to blood contact
  • IV drug use
  • Accidental needle sticks
  • Non-sterile tattoos
  • Vertical transmission
  • Blood transplant/organ transplant prior to 1992
  • Less common: sexual contact, sharing razor/toothbrush
Acute: Usually asymptomatic but may cause:
  - Fever, fatigue, nausea, vomiting, dark urine, and jaundice
  - 15-25% of infected patients clear the viral infection

Chronic: seen in 75-85% of infected individuals, typically asymptomatic until liver fibrosis/cirrhosis
  - Weakness, fatigue, weight loss, vomiting, and jaundice

End stage liver disease
  - Hepatic encephalopathy, ascites, esophageal varices, coagulopathy, and hepatocellular carcinoma
Screening/Diagnosis

- Hepatitis C Antibody testing – primary test
  - Current or former IVDU
  - Received a blood transfusion or organ transplant prior to 1992
  - On hemodialysis
  - Healthcare worker stuck by a needle
  - Current HIV infection
  - Persistently elevated liver enzyme tests
  - Any person born between 1945-1965
Screening/Diagnosis, cont.

- If the antibody test is positive, there is reflex testing for both HCV RNA Quantitative (viral load) and HCV Genotype (to determine treatment course)
Screening/Diagnosis, cont.

• Need testing to determine the genotype (1-6)
  • Necessary for treatment regimen

• Need testing for cirrhosis
  • This is also necessary for treatment regimen
  • Past: liver biopsy
  • Now: blood testing for indirect markers that gives a risk score for the patient’s level of fibrosis
    • F0-4 (F4 is cirrhosis)
Complications

- 75-85% of patients infected with HCV develop chronic infection
- 5-20% of chronically infected patients will develop cirrhosis over 20 years of disease
- 1-5% of chronically infected patients will die from this disease
  - Liver failure
  - HCC (5 year mortality of 85%)
- Patients with active disease are contagious

This is why we treat this disease!!
Treatment

• Goal of treatment is SVR (sustained virologic response)
  • No detectable virus at 12 or 24 weeks
  • “cure”

• Past
  • For decades, only pegylated interferon and ribavirin
    • Injections, multiple side effects, and monitoring
  • 2011 – boceprevir and telaprevir added
    • Complicated treatment regimen with only slightly more efficacy
  • 2013 – first DAAs (direct acting antivirals) hit the market revolutionizing the treatment regimen
• DAAs: Sofosbuvir, simeprevir, ombitasvir/paritaprevir/ritonavir/dasabuvir, ledipasvir/sofosbuvir, and sofosbuvir/velpatasvir have improved SVR rates while decreasing adverse side effects.
  • Treatment regimen is different for each of these medications
    • Depends on what medications are covered by local insurance plans
    • Depends on the patient’s genotype, level of fibrosis, and if they have ever been on treatment in the past.
Treatment, cont.

- Free iPhone and Android app “HCV Treatment Path” walks through the treatment regimen, personalized to the patient’s information (genotype, cirrhosis status, treatment history)
  - Based on American Association for the Study of Liver Diseases (AASLD) guidelines
  - Algorithm based with links to research
Treatment, cont.

• Ensure all patients with HCV are immunized for Hepatitis A and B
• Counsel to avoid alcohol, tobacco, and hepatotoxic agents
• Unsure if safe in pregnancy – use non hormonal contraception
Treatment Controversy

• Very expensive in the United States as compared to the prior generations of treatment
  • Cash pricing for the new DAAs were listed at over $1000 per pill
  • 12 week regimen over $100,000

• However, a cost analysis was performed that shows that treatment early in the disease shows improvement in cost per quality adjusted life years gained over waiting until the disease progresses.

• Early treatment can avoid liver transplantation that costs over $700,000 in direct costs.

• End stage liver disease can cost an estimated $60,000 per year.
My experience

• National Health Service Corps Scholar
  • Started practicing in a community health center in Titusville
  • 90% of my patients uninsured
  • 25% homeless
    • Higher rates of HCV in lower SES patients
  • Unable to make any referrals to specialists for non life-threatening disease

• I saw a need to obtain treatment for these patients and decided to go through all of the steps to make it happen
My experience, cont.

- Read as many studies as I could find on treatment
  - Especially the AASLD treatment guidelines that are referred to in the HCV Treatment path phone app
  - Reviewed the VA treatment protocol

- Spoke with gastroenterology and infectious disease colleagues and was given encouragement to find a way to provide treatment

- Wrote a protocol to be internally published throughout my organization and signed off by my medical director
My experience, cont

• Worked with pharmaceutical representatives to have access to their patient assistance program to obtain the medications for free or cheap

• Worked with local hospital to obtain lab testing for a greatly reduced price

• 12 week course could be completed for around $150 out of pocket for the patient including visits, meds, and labs.
My experience, cont

• Moved onto a new practice seeing patients who are employed by a single company that is self insured.

• Was able to negotiate with my medical director and the client (company) to allow me to continue treatment for my new patients.
Hurdles

• My company
  • I had to show that my protocol was sound and proof that I was having comparable success to specialists who were currently treating

• My client
  • I had to show that I could not only perform as well as the specialists, but with less cost

• Pharmacy Benefit Manager
  • Formulary change
  • “acting as a specialist”
Future Considerations

• Screening
  • Continue to work with my colleagues (11 full time DO/MD/NP/PAs)
  • Ongoing study in my office to increase appropriate screening rates
    • No screening means no diagnosis means no treatment!

• Treatment
  • FSACOFP discussion on primary care treatment
  • Considering a discussion with the client for directing patients from outside of my office to me for treatment
  • Discussing expanding my experience and treatment protocol to the 600 other sites that my company has around the country
Thank You!

(not a book about Hep C....

....that has to wait until at least 4 years old)