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“UPDATE: HCV”

November/December 2015

Hepatitis C Virus is a serious public health issue, and until recently, was untreatable. There are 5 types of viral hepatitis, each of which is caused by different types of viruses: Hepatitis A virus (HAV), Hepatitis B virus (HBV), Hepatitis C virus (HCV), Hepatitis D virus (HDV), and Hepatitis E virus (HEV). In this lesson we discuss the significance of new therapies.



Pharmacists will be able to:

1. Recognize the prevalence of HCV in the U.S.
2. List the types of HCV and their signs.
3. Discuss the mode of transmission of HCV.
4. Describe methods of diagnosis.
5. Relate the mechanism of action of protease inhibitors, their adverse effects and effectiveness when used in combination therapy.

Technicians will be able to:

1. Recognize the prevalence of HCV in the U.S.
2. List the types of HCV and their signs.
3. Discuss the mode of transmission of HCV.
4. Describe methods of diagnosis

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BACKGROUND

Hepatitis is a common contagious, insidious infection that occurs worldwide and is caused primarily by various types of viruses that lead to inflammation. There are 5 types of viral hepatitis, each of which is caused by different types of viruses: Hepatitis A virus (HAV), Hepatitis B virus (HBV), Hepatitis C virus (HCV), Hepatitis D virus (HDV), and Hepatitis E virus (HEV). These various types have different modes of transmission and respond differently to treatment. However, they show certain similar clinical characteristics such as nausea, vomiting, abdominal distress, loss of appetite and jaundice. As a result, the type of infection cannot be confirmed on the basis of signs and symptoms but on serological examinations.

In the scope of this lesson emphases will be placed on Hepatitis C.

HEPATITIS C VIRUS (HCV)

Hepatitis C virus (HCV), often referred to as Hep C, is an infection of the liver caused by a blood-borne virus. The virus is a small enveloped, single-stranded 50 nanometer RNA virus that belongs to the hepacivirus genus in the flaviviridae family. It was isolated in 1989. Prior to giving the name HCV to this virus, it was known as non-A, non-B (NANB) hepatitis. HCV exists in at least 7 types of genomes (called genotypes) and many subtypes. The seventh genotype was discovered in 2013. Genomes are identified by number "1" through "7", and the subtypes by letters starting with "a". The numbers and subtypes are identified and arranged in the order of the discovery of the genotype. Genotypes differ from each other. The most commonly encountered genotype in the US is type "1", accounting for more than 70% of the cases, and subtype "a" is the most common subtype. Knowing the genotype is essential for treatment selection. The genotype can be identified through blood tests. One of the characteristics of HCV is its constant mutation and reproduction mostly in the liver cells.

HCV appears in two forms: **acute** and **chronic**.

ACUTE HCV

This type usually shows no signs or symptoms of the infection and may not emerge for months or years, if ever. As a result many patients have the disease and are not aware of its presence. From 15% to 50% of patients with acute HCV recover within 6 months without resorting to treatment. However, the remainder will become chronically ill and infected with HCV for years facing the possibility of developing cirrhosis or cancer of the liver.

CHRONIC HCV

The majority of sufferers are classified as having chronic HCV. It develops when the body's immune system fails to destroy the virus. If left untreated, it may result in serious complications some of which can be fatal. A complication such as cirrhosis of the liver may also occur. It develops when the healthy liver cells are replaced by fibrous tissue which later on becomes hard. Conversion of the healthy liver cells to scar tissue signals the beginning of liver failure and loss of liver ability to function normally. Liver failure is characterized by fluid retention resulting in swelling of the abdomen (ascites), legs, and eventually the rest of the body, itchy skin, jaundice, wasting, hematemesis (vomiting of blood) and tendency to bleed or bruise easily. Development of chronicity occurs as a result of ignoring the acute infection after the exposure to the virus. The HCV RNA appears in the blood stream during the acute phase and beyond. Only one third of patients complain of signs and symptoms of hepatitis C. Aminotransferase

levels are normal in 40% of patients, even though the HCV RNA remains in the serum. In these patients only biopsy can reveal the chronicity of the infection. About 20% of patients with chronic hepatitis C for 20 years or more may develop cirrhosis of the liver especially male patients who drink more than 2 fluid ounces of alcohol daily. The rates of development of cirrhosis in patients with chronic hepatitis C and whose aminotransferase levels are constantly normal are low.

PREVALENCE

There are 3.2 million Americans and 170 million people globally who are infected with chronic HCV. Many more are undiagnosed. Every year 3-4 million people worldwide are newly infected. About 75% of HCV is in baby boomers (individuals born in the US between 1945 & 1965). Moreover, this group is more likely to have contracted the infection than other persons who were born in different years. It is estimated that about 16,500 deaths occurred in 2010 as a result of HCV complications. Data collected by the CDC from studies conducted from 2006-2008 by the Chronic Hepatitis Cohort Study (CHCS) and studies conducted between 2001-2008 by the National and Nutrition Examination Survey (NHANES) shows that there are 3.2 million persons in the US with chronic HCV infection. Of those there are about 1.6 million (50%) patients whose infections were detected, 1.0 - 1.2 million (32% - 38%) were referred to health care facilities, 630,000 – 750,000 (20% - 23%) had HCV DNA test, 380,000 – 560,000 (12% - 18%) underwent liver biopsies, and 220,000 – 360,000 (7% - 11%) were treated for the infection. It is estimated that by 2020 1 million people, which is about 37% of patients with chronic HCV, will develop cirrhosis of the liver.

SYMPTOMS

The average duration of the incubation period of the virus is about 50 days. During the first 1-2 weeks following exposure, the virus gains access to hepatocytes. HCV RNA is detectable in the serum and remains as such throughout the clinical course of the infection. Once in the hepatocytes, the virus releases the genome and starts the replication process. Formation of antibody begins late, sometimes after the start of the clinical manifestation and/or signs such as a rise in the aminotransferase. Antibodies to a certain genotype will not confer resistance to another type. When the infection resolves, HCV RNA becomes detectable in the serum.

Following the onset of the infection, approximately 80% of individuals do not experience any symptoms. About 20% of the cases may experience mild symptoms such as fatigue, loss of appetite, flu-like symptoms, itchy skin, nausea, vomiting, abdominal stress, tenderness, low grade fever, and fluctuation (either low or high) in the blood level of liver enzymes. Dark cola-colored urine as a result of hyperbilirubinemia, and pale feces appear once cirrhosis develops and the liver begins to fail.

MODE OF TRANSMISSION

HCV is a blood-borne virus and is transmitted mainly through blood-to-blood contact as in parenteral injection (50 – 60% of cases) and contaminated blood products (4%). In the past, blood transfusions were estimated to cause 90% of HCV cases. The decrease in this number is due to improved procedures for blood donor selection and screening. HCV is considered the most prominent cause of chronic blood-borne infections in the US. The risk of transmission through perinatal exposure is low, and that through sexual contact is rare. In certain groups of patients with HCV RNA who have multiple sexual partners, the risk is higher. A significant

percentage of HIV patients may acquire HCV due to weakened immune systems. HCV may be transmitted to infants during delivery, though it is rare. The virus is not transmitted through breast feeding, food, water and physical contact such as touching, kissing, or sharing food utensils with an infected person. Persons who are at risk of acquiring HCV include those who inject medication such as insulin, recipients of blood transfusions, kidney dialysis patients, organ transplant patients, health centers with inadequate bacterial and viral control, patients who undergo tattooing and piercing using infected needles, sharing contaminated needles among IV medication users and parenteral use of recreational drugs (approximately 33% of persons who use injectable illicit drugs develop HCV). Since 1992 blood and blood products are tested for the presence of HCV prior to infusions, hemolysis and organ transplant. Health workers are at risk from accidental needle sticks contaminated with HCV. Accidental blood splash in the eyes or nose have rarely caused HCV. The CDC recommends that tests should be conducted on persons who receive blood transfusions from HCV suspects; those who were born between 1945 and 1965; or receive kidney dialysis; or those who were born to mothers suffering from hepatitis C.

DIAGNOSIS

Diagnosis of HCV is made by monitoring hepatic transaminase levels, presence of clinical symptoms, and finding of HCN antibodies in serum. The antibodies can be detected within 2 to 3 months after onset of infection. Blood testing is the most reliable diagnostic tool. Tests such as Antibody Enzyme Immunoassay or ELISA are useful. It should be kept in mind that the antibodies may not be detectable until weeks or months after the appearance of the clinical symptoms. The presence of the antibodies does not confer immunity to the patient. It only indicates that the patient has been exposed to HCV. It does not indicate the presence of the virus in the body. Confirmation of the presence of the virus is achieved by conducting HCV viral load testing. It reveals the presence of genetic mutant HCV RNA. Quantitative HCV RNA tests may be conducted to determine the amount of HCV in the blood. Other tests for confirmation include: TMA (transcription – mediated amplification), PCR (polymerase chain reaction), and bDNA (branched DNA). These tests cannot predict when or if a patient will develop cirrhosis or liver failure. However, it can assist in determining the length and status of the treatment. Other tests may be used to determine the constituents of the virus. Such information will assist in implying the duration and type of treatment. To monitor the health status of the liver, blood tests must be conducted to measure the concentration of the liver enzymes. Usually, the enzyme levels rise during infection due to the presence of damage to liver cells. These tests are usually for: alanine aminotransferase (ALT also known as SGPT); aspartate aminotransferase (AST also known as SGOT); alkaline phosphatase (ALP or ALK Phos) ; and gamma glutamyl transpeptidase (GGT or GGTP). Even though albumin and bilirubin levels in the blood remain normal for most patients with hepatitis C, low albumin level and elevated bilirubin may indicate cirrhosis. Liver biopsy may be needed as it allows visual examination of the liver tissue.

VACCINATION

As of 2015, there was no reliable vaccine to prevent HCV infection. However, the fact that 1 in 4 people can eliminate the virus from their body without treatment indicates that the immune system is capable of coping with the infection and clearing it from the body. Currently, efforts are continuing to develop a safe and effective HCV vaccine. One vaccine in the

developmental stages has shown promise in early clinical trials. It is being tested in IV drug users. Progress has been slow due to the variable characteristics of HCV. For example, the HCV virus genotype varies in accordance with geography. Type 1 is common in the US and Europe. Type 3 is common in India, the Far East and Australia, and type 4 is common in Africa and the Middle East. The availability of animal models is limited. Furthermore, ethical and cost issues make conducting such research unacceptable. It is difficult to find volunteers for testing a vaccine.

TREATMENT

Only a few years ago there were no effective and safe drugs to treat HCV. Historically the treatment included a combination of drugs given in a variety of doses that often were difficult to tolerate. HCV therapy can suppress multiplication of the virus to the extreme so that it cannot be detected 3 months after completion of treatment. As indicated earlier, most patients are not aware that they are acutely infected. However, the infection can be confirmed if the patient undergoes blood testing. Treatment should be initiated in order to prevent chronicity. Acute hepatitis C may be treated with interferon. Chronic HCV can be treated with antiviral medication that checks the virus and prevents the development of complications. Routine blood tests should be performed to determine the response to therapy.

Important advances have been made in the treatment of HCV. In the past monotherapy with interferon (IFN) was common. However, a combination of IFN and ribavirin (a protease inhibitor) with or without the addition of polyethylene glycol molecules (PEG – IFN) was approved in 1998. The use of combination of protease inhibitors (PI) began to flourish after that. Protease inhibitors are a group of antiviral drugs that are used in the treatment of HIV/AIDS and HCV. They act to inhibit the function of specific enzymes that play an important role in viral replication. Protease, also known as peptidase or proteinase, is an enzyme that hydrolyzes the peptide bonds that link amino acids together in a protein. Boceprevir was approved by the FDA in 2011 followed by approval of telaprevir, also in 2011. In 2014 the manufacturer of telaprevir stopped its sale and distribution. In 2013 a protease inhibitor, sofosbuvir, which is more effective than the earlier drugs, was approved by the FDA as a part of combination therapy. In 2014 the FDA approved the use of an orally administered combination with simeprevir. HCV patients with cirrhosis should take the combination treatment for 24 weeks, and then just sofosbuvir alone for 12 weeks. In December 2014, the FDA approved another combination oral therapy consisting of ombitasvir, paritaprevir, ritonavir and dasabuvir specifically designed for treating genotype 1 chronic hepatitis. Three components, ombitasvir, paritaprevir and ritonavir, are prepared in one tablet, while dasabuvir is prepared in a separate tablet. Pharmacologically ombitasvir is a NS5A inhibitor; paritaprevir inhibits NS3/4A serine protease; while ritonavir is a nonnucleoside NS5B polymerase inhibitor. The component of the second tablet, dasabuvir, is an inhibitor of CYP3A4 enzyme, and has no activity against hepatitis C, but it boosts the activity of paritaprevir.

When treating chronic HCV, it is recommended to follow the guidelines of the Infectious Disease Society of America (IDSA) and the American Association for the Study of Liver Disease (AASLD), in collaboration with the International Antiviral Society – USA.

PROTEASE INHIBITORS

RIBAVIRIN

Ribavirin is a nucleoside analogue that is used as antiviral medication when given in combination with injectable pegylated interferon. Interferons are naturally occurring proteins that are formed and secreted by the body's immune system to boost its response to the presence of bacteria, viruses and cancer. Monotherapy with ribavirin or other PIs is not effective in treating HCV. This drug inhibits polymerase activity and, subsequently, inhibits synthesis of viral DNA and RNA which are essential for the multiplication and spread of virus. Even though it may reduce the quantity of virus in the blood, it does not provide a cure of the disease. By reducing the multiplication of the virus, it assists the liver to recover. Furthermore, it does not prevent transmission of the infection to another individual.

Ribavirin is given orally in tablet and capsule forms in a daily dose from 800 mg to 1200 mg taken in two divided doses. The usual duration of therapy is from 24-48 weeks. However, the physician will determine the dose and duration depending on the extent of the infection, patient's age, weight and response to treatment. The patient must adhere to the time of the daily administration in order to keep a constant blood level of the drug, thereby achieving better therapeutic response. The medication should be taken with meals along with extra water to minimize side effects and reduce kidney damage by increasing frequency of urination.

Side effects include nausea, diarrhea, headache, dizziness, blurred vision, insomnia, fatigue, irregular heartbeat, flu-like symptoms such as low grade fever, sore throat, cough and muscle aches. Patients who are allergic to ribavirin may experience serious side effects such as skin rash, difficulty in breathing, swelling of face and tongue. Since the drug may cause dizziness and blurred vision, patients should refrain from driving, use of machinery, or performing activities that require alertness and normal vision until these side effects subside. Avoidance of intake of alcohol is essential. Breast feeding while undergoing therapy is not recommended even though passage of the drug in the milk has not been confirmed. The drug should not be used during pregnancy due to the possibility of causing birth defects.

In December 2013 the FDA approved the use of a combination of sofosbuvir with ribavirin for treating HCV genotypes 2 and 3. The dose of sofosbuvir is a 400 mg tablet once daily, and the ribavirin dose is one tablet twice daily. The dose is dependent on the patient's weight but normally 1000 mg/75 Kg body weight. As stated earlier, ribavirin must be given in combination with other anti HCV medications. Thus if for some reason one of these medications is discontinued, the other must be discontinued. The duration of treating genotype 2 with this combination is 12 weeks, and for genotype 3 is 24 weeks. Only 1% of patients taking this combination experienced adverse effects.

BOCEPREVIR

Boceprevar is a protease inhibitor that is used to treat chronic HCV genotype 1 infection in adults who did not undergo any treatment before, or treatment has not been successful. Boceprevir should be given in combination with ribavirin and peginterferon. Its safety and effectiveness in treating young adults and children under the age of 18 have not been confirmed. Even though it reduces the quantity of chronic HCV in the blood, it does not prevent the spread and transmission of the infection. It is available orally in the form of capsules to be taken with food three times daily. The regimen consists of taking peginterferon and ribavirin for 4 weeks followed

by taking boceprevir, peginterferon and ribavirin together for 12 to 24 weeks. Once the entire regimen has been completed the intake of boceprevir will be discontinued. However, the patient may take the other two for a period of time decided upon by the physician. Duration of the treatment is dependent on blood concentration level of the virus HCV RNA at the end of weeks 8, 12, and 24.

TELAPREVIR

Telaprevir is another protease inhibitor that inhibits hepatitis C virus enzyme NS3 4A serine protease. It is used specifically to treat hepatic genotype 1 chronic infection, but it is unsafe and ineffective against other hepatitis C virus genotypes. It is administered orally. Telaprevir is more effective than standard therapy when used in patients with genotype 1 chronic HCV in a combination of telaprevir, pegylated interferon and ribavirin. Side effects include rash that resulted in fatalities. Because of the skin rash it may cause, the FDA has added a new warning on the package insert highlighting the skin rash. In August 12, 2014 the manufacturer of telaprevir announced discontinuation of production of the drug.

SOFOSBUVIR

Sofosbuvir is a nucleotide analog polymerase inhibitor that is used with ribavirin or in combination with other drugs for treating HCV. It inhibits the enzyme NS5 B polymerase, thus mediating HCV RNA multiplication. Most patients do not need to use peginterferon when using sofosbuvir in combination with other protease inhibitors. Its use as an ingredient in combination therapy was approved in December 2013. One year later the FDA approved its use in combination with simeprevir for treating patients with chronic HCV genotype 1. The use of sofosbuvir along with daclatasvir in the treatment of genotype 3 chronic hepatitis C infection was approved in July 2015. Sofosbuvir based medication resulted in higher cure rate (absence of virus in blood stream), lesser adverse effects and shorter duration of therapy. Sofosbuvir use permitted the elimination of concurrent use of peginterferon which was an essential component of combination therapy prior to December 2013. Thus the severe adverse effects caused by peginterferon are no longer encountered by patients. However, the FDA in 2013 approved the use of sofosbuvir in combination with ribavirin for treating chronic HCV genotype 2 and 3 and with injected peginterferon and ribavirin for treating chronic HCV genotypes 1 and 4. In 2014 sofosbuvir in combination with ledipasvir was approved for patients with chronic HCV genotype 1 without the use of peginterferon.

Sofosbuvir is available in 400 mg tablets to be taken once daily at the same time each day with or without food. Adverse effects when used alone are minimal, but when used in combination with ribavirin, patients complained of headache and fatigue.

SIMEPREVIR

Simeprevir is a hepatitis C virus NS3/4A protease inhibitor that is indicated in treating chronic HCV genotype 1 in combination therapy but not in monotherapy. It is given in triple therapy consisting of simeprevir, peginterferon and ribavirin. Side effects include skin rash and photosensitivity.

OMBITASVIR

Ombitasvir has been approved by the FDA for treating HCV due to its inhibition of enzyme NS5A. It is given orally in a regimen consisting of 4 antivirals: ombitasvir, paritaprevir, ritonavir,

and dasabuvir. The first three drugs are contained in one tablet while dasabuvir in a separate tablet. The regimen (4 medications) may be given with or without ribavirin.

PARITAPREVIR

Paritaprevir is an inhibitor of the NS3-4A serine protease. It has shown to be effective in treating HCV genotype 1.

RITONAVIR

Ritonavir is used mainly to inhibit the enzyme that metabolizes other protease inhibitors. As a result, a higher blood concentration of the other combined drugs is boosted and becomes elevated.

DASABUVIR

Dasabuvir inhibits the enzyme NS5B. It was approved by the FDA in combination with ombitasvir, paritaprevir and ritonavir.

SUMMARY

Hepatitis C virus is a common disease worldwide. There are 3.2 million Americans who are infected with this infection. If left untreated it may lead to complications such as cirrhosis of the liver and liver cancer. There is no complete cure. However, protease inhibitors seem to be effective in reducing the virus.

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1. Does the program meet the learning objectives?

Recognize prevalence of HCV in the U.S. YES NO

List types of HCV & their signs YES NO

Discuss modes of transmission of HCV YES NO

Describe methods of diagnosis of HCV YES NO

List drug therapies YES NO

2. Was the program independent & non-commercial YES NO

Low Relevance 1 2 3 4 5 6 7 Very Relevant

3. Relevance of topic 1 2 3 4 5 6 7

4. What did you like most about this lesson? _____

5. What did you like least about this lesson? _____

Please Mark the Correct Answer(s)

1. People most susceptible to HEP C are:

- A. Elderly---70 years & older
- B. Infants whose mothers were infected during delivery
- C. Persons born between 1945 - 1965
- D. Pregnant females

2. Which factor is false concerning possible transmission of HCV?

- A. Coughing
- B. Sexual contact
- C. Use of contaminated needles
- D. Kidney dialysis

3. Which statement is true concerning HCV?

- A. Symptoms appear a week after exposure
- B. Many patients not aware they're infected
- C. Jaundice occurs due to hyperlipidemia
- D. Cure occurs 12 weeks after therapy starts

4. Swelling of the abdomen is:

- A. Ascites
- B. Hematemesis
- C. Cirrhosis
- D. Hematoma

5. Which of these is true about HCV?

- A. Genotype 4 is most common one in US
- B. Risk in perinatal is extremely high
- C. Exists in at least 7 types of genotypes
- D. None of these

6. Which of these is the most reliable method in the diagnosis of HCV?

- A. Family history
- B. PCR (polymerase chain reaction)
- C. Low level of transaminase
- D. Presence of high fever

7. Which of these is false about Ribavirin?

- A. Third generation antibiotic
- B. One of the first PIs used to treat HCV
- C. May be administered with interferon
- D. Effective only as monotherapy

8. Which of these drugs has been D/C'ed?

- A. Sofosbuvir
- B. Boceprevir
- C. Telaprevir
- D. Ritonavir

9. Which of these is true about HCV?

- A. Infection usually goes away on its own
- B. HCV vaccine has proven to be effective and safe in preventing the infection
- C. May cause liver cancer
- D. Cured infection never returns

10. The incubation period of HCV is:

- A. One week
- B. 50 days
- C. 6 months
- D. 5 days

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