Pretreatment Evaluation and Fibrosis Staging

This is a PDF version of the following document:
Module 8: HCV Test and Cure
Lesson 3: Pretreatment Evaluation and Fibrosis Staging

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Pretreatment Evaluation

Initial Pretreatment Evaluation

When a patient enters care for management of HCV, it is important to confirm the individual has chronic HCV infection (e.g., they are viremic based on a positive HCV RNA) as opposed to resolved HCV (positive HCV antibody with a negative or undetectable HCV RNA). During the initial evaluation, it is similarly important to obtain a thorough history and perform a careful physical examination, focusing on risk factors for HCV acquisition, current or past substance use disorders, significant medical comorbidities, current medications, and manifestations of chronic liver disease. Determining cirrhosis status is a high priority before treatment is started, and it can be done with readily available non-invasive laboratory markers.

Pretreatment Laboratory Evaluation

A core set of laboratory tests are indicated for persons prior to treatment for HCV.[1] The major goals of the initial laboratory evaluation are to: (1) confirm chronic HCV infection using either laboratory-based or point-of-care HCV RNA testing; (2) evaluate liver injury and function; (3) obtain markers for Aspartate Aminotransferase-to-Platelet Ratio Index (APRI) or FIB-4 calculation; and (4) evaluate for co-occurring viral infections. The following summarizes the major tests that should be obtained prior to or at the time of treatment initiation.[2,3,4] The subsequent section addresses recommended laboratory tests and the timing of ordering these tests based on the cirrhosis status of the adult with chronic HCV.

- **HCV RNA Test**: A positive HCV RNA test is required to establish current HCV infection. Two options exist for HCV RNA testing: (1) laboratory-based HCV RNA testing (requires phlebotomy) and (2) point-of-care HCV RNA qualitative test (requires fingerstick for sample).
- **Complete Blood Count (CBC) with Platelet Count**: The platelet count can be reduced in persons with cirrhosis and the platelet count value is required for calculating a FIB-4 score.
- **Hepatic Function Panel**: The hepatic function panel (e.g., albumin, total and direct bilirubin, alanine aminotransferase [ALT], and aspartate aminotransferase [AST]) provides information on hepatic function and inflammation, as well as being essential for calculating a FIB-4 score.
- **Calculated Glomerular Filtration Rate (eGFR)**: This is important to determine renal function.
- **International Normalized Ratio (INR)**: This lab test is ordered to assess hepatic function. Persons with decompensated cirrhosis will typically have a significantly elevated INR.
- **HIV-1/2 Antigen-Antibody Immunoassay**: Infection with HIV can significantly impact progression of liver disease with chronic HCV. Therefore, it is important to identify and treat any person who has coinfection with HIV.
- **Hepatitis B Serology Triple Screen**: The recommended triple screen consists of hepatitis B surface

antigen (HBsAg), hepatitis B surface antibody (anti-HBs), and hepatitis B core antibody (anti-HBc). It is important to identify persons who have coinfection with active hepatitis B virus (HBV) infection since this will impact HCV treatment options. Life-threatening liver injury has occurred in the setting of direct-acting antiviral (DAA) therapy in individuals who have chronic HBV coinfection and are not on antiviral therapy. In addition, some individuals with prior HBV infection can reactivate HBV during HCV treatment, although this rarely occurs. All persons with chronic HCV who are non-immune to HBV should receive hepatitis B vaccination.

- **Hepatitis A IgG**: Persons with chronic HCV who develop hepatitis A virus (HAV) infection can have severe liver compromise. Therefore, it is important to identify persons who are non-immune to HAV and in need of immunization.
- **HCV Genotype**: A baseline HCV genotype is not needed prior to treatment for most patients owing to the availability of highly effective pangenotypic DAA regimens, including glecaprevir-pibrentasvir and sofosbuvir-velpatasvir. If, however, the patient has compensated cirrhosis and treatment with sofosbuvir-velpatasvir is being considered, an HCV genotype is recommended. Patients with HCV genotype 3 infection and cirrhosis who are being considered for treatment with sofosbuvir-velpatasvir will require testing for resistance-associated substitutions, as the presence of Y93H substitution would require the addition of ribavirin to sofosbuvir-velpatasvir.[5,6,7]

[Q] Indication for HCV Genotype

Laboratory Testing for Adults with Chronic HCV WITHOUT Cirrhosis

As outlined below, for the simplified treatment approach, the following summarizes the AASLD/IDSA hepatitis C guidance for pretreatment laboratory testing recommendations in adults with chronic HCV without cirrhosis (Figure 1).[8]

- **Obtain Within 6 Months of Starting HCV Treatment**: The following laboratory studies should be obtained within 6 months of initiating HCV treatment. If they were obtained more than 6 months prior to initiating HCV treatment, they should be repeated.
    - Complete blood count (CBC) with platelet count
    - Hepatic function panel (i.e., albumin, total and direct bilirubin, ALT, AST)
    - Calculated glomerular filtration rate (eGFR)
- **Obtain Any Time Before Starting HCV Treatment**: The following laboratory studies must be obtained any time before starting HCV treatment.
    - Quantitative HCV RNA (HCV viral load)
    - HIV-1/2 antigen-antibody immunoassay
    - Hepatitis B serologic triple screen (HBsAg, anti-HBs, and anti-HBc)
- **Obtain Soon Before Initiating HCV Treatment**: The following test, if applicable, should be obtained just before initiating HCV antiviral therapy
    - Serum pregnancy testing for women of childbearing age. In addition, counseling about pregnancy risks of HCV medication should be offered to women with childbearing potential. Treatment of HCV can be considered during pregnancy on an individual basis after a discussion about the potential risks and benefits.

Laboratory Testing for Adults with Chronic HCV WITH Compensated Cirrhosis

As outlined below, for the simplified treatment approach, the following summarizes the AASLD/IDSA hepatitis C guidance for pretreatment laboratory testing recommendations in adults with chronic HCV with compensated cirrhosis (Figure 2).[4]

- **Obtain Within 3 Months of Starting HCV Treatment**: The following laboratory studies should be obtained within 3 months of initiating HCV treatment. If they were obtained more than 3 months prior to initiating HCV treatment, they should be repeated.
    - CBC with platelet count

    - International normalized ratio (INR)
    - Hepatic function panel (i.e., albumin, total and direct bilirubin, ALT, AST)
    - Calculated glomerular filtration rate (eGFR)
- **Obtain Any Time Before Starting HCV Treatment**: The following laboratory studies must be obtained any time before starting HCV treatment.
    - Quantitative HCV RNA (HCV viral load)
    - HIV-1/2 antigen-antibody immunoassay
    - Hepatitis B serology
    - HCV genotype (if planned treatment with sofosbuvir-velpatasvir)
- **Obtain Soon Before Initiating HCV Treatment**: The following test, if applicable, should be obtained just before initiating HCV antiviral therapy
    - Serum pregnancy testing for women of childbearing age. In addition, counseling about pregnancy risks of HCV medication should be offered to persons with childbearing potential. Treatment of HCV can be considered during pregnancy on an individual basis after a discussion about the potential risks and benefits.

Evaluation and Staging of Liver Fibrosis

Rationale for Staging Liver Fibrosis

Hepatic fibrosis is a dynamic scarring process that occurs over time in patients with chronic HCV and can lead to cirrhosis.[9,10] Staging liver disease (or determining fibrosis severity) is best performed before starting HCV treatment because that is when these tests have been validated. It is important to evaluate for liver fibrosis and cirrhosis in patients with chronic HCV for multiple reasons:

1. The degree of liver fibrosis can impact HCV treatment decisions. The simplified treatment approach is slightly different for individuals without cirrhosis versus those with compensated cirrhosis. In addition, the simplified treatment approach is not recommended for patients with decompensated cirrhosis.
2. Fibrosis staging helps identify patients who have cirrhosis and require ongoing hepatocellular carcinoma (HCC) screening and possibly screening for gastroesophageal varices.
3. Patients who have cirrhosis identified by fibrosis staging should have further evaluation to determine if they have compensated or decompensated cirrhosis. Patients with decompensated cirrhosis may need additional urgent medical evaluation and management, including urgent referral to a specialist for treatment of ascites and volume overload, esophageal varices, encephalopathy, and consideration for liver transplant.

Fibrosis Assessment Tests

Historically, hepatic fibrosis was assessed via liver biopsy; however, liver biopsy is no longer required for cirrhosis assessment. Instead, there are now several noninvasive methods to estimate hepatic fibrosis that are recommended and commonly used in clinical practice. These include laboratory-based calculations (e.g., APRI, FIB-4, FibroSure) and elastography (e.g., FibroScan).

- **FIB-4**: The FIB-4 value is calculated using an individual's age, AST, ALT, and platelet count. A threshold value of less than 1.45 has a sensitivity of 74% and a negative predictive value of 95% for excluding advanced fibrosis (≥F3).[11] A threshold greater than 3.25 has a positive predictive value for advanced fibrosis of 65 to 82% and is 98% specific for cirrhosis.[11,12] A patient should be presumed to have cirrhosis if the FIB-4 score is greater than 3.25.[4]
- **Transient Elastography (FibroScan)**: Transient elastography (FibroScan) is a noninvasive device that estimates liver stiffness and amount of fat in the liver; the scan takes about 5 to 10 minutes and can be done in a clinic or office-based setting.[13] Liver stiffness measurements are performed using an ultrasound transducer probe that measures the shear wave velocity, with results reported in kilopascal (kPa) units. Studies evaluating transient elastography have demonstrated reproducible performance across a variety of patient populations, including persons with HCV.[14,15,16] Transient elastography is generally considered to be the most accurate noninvasive testing for liver fibrosis in patients with chronic HCV and a patient should be presumed to have cirrhosis if they have a FibroScan stiffness score greater than 12.5 kPa.[4,16] The FibroScan also performs a controlled attenuation parameter (CAP) measurement that estimates the amount of fat in the liver; the CAP score is reported in units of decibels per meter (dB/m).
- **Aspartate Aminotransferase-to-Platelet Ratio Index (APRI)**: The APRI is calculated using an individual's AST level, corrected for the upper limit of normal, and platelet count. It has been studied in persons both with HCV monoinfection and with HCV/HIV coinfection.[17,18] In a meta-analysis of 40 studies, an APRI cutoff of 0.7 was 77% sensitive and 72% specific for significant hepatic fibrosis (≥F2) in persons with HCV.[19] A cutoff of 1.0 was 61% sensitive and 64% specific for severe fibrosis (≥F3) and 76% sensitive and 72% specific for cirrhosis (F4).[19] Also, a patient with chronic HCV should be presumed to have cirrhosis if they have a platelet count less than 150,000/mm^3, without another attributable cause for thrombocytopenia.[4]
- **FibroTest (FibroSURE)**: The FibroTest, which is also known by the name FibroSURE, is a proprietary test that includes the individual's age, sex, and five biochemical markers (alpha-2-macroglobulin,

haptoglobin, gamma-glutamyl transferase [GGT], apolipoprotein A1, and total bilirubin). In a meta-analysis of 30 studies, FibroTest was found to have a mean standardized area under the receiver operating characteristic (AUROC) curve of 85% for distinguishing moderate to severe fibrosis (≥F2) from mild fibrosis.[20] Similar results were also found in a prospective comparison of FibroTest and liver biopsy.[21]

[Activity] B. Fibroscan: A Clinician s Guide

Presumptive Evidence of Cirrhosis

For the purpose of the AASLD/IDSA simplified treatment algorithm, a patient is presumed to have cirrhosis if they have any of the following:[4]

- FIB-4 score greater than 3.25
- Transient elastography (FibroScan) score greater than 12.5 kPa
- Noninvasive serologic test (e.g., FibroSure, Enhanced Liver Fibrosis Test, etc.) with a value above the proprietary listed cutoff that indicates cirrhosis
- Evidence of cirrhosis based on clinical findings, low platelet count (less than 150,000/mm^3) or radiographic findings, such as splenomegaly or evidence of portal hypertension (e.g., recanalized umbilical vein)
- A prior liver biopsy that shows cirrhosis

[Q] Presumptive Evidence of Cirrhosis with Noninvasive Testing

Which Noninvasive Fibrosis Test to Choose

The choice of noninvasive testing to stage fibrosis in patients with HCV will often depend on the resources available to each clinic. The AASLD/IDSA simplified algorithm for the treatment of HCV recommends calculating a FIB-4 score in all patients for fibrosis staging.[4] The FIB-4 score, as noted above, can be calculated using three routine laboratory values (platelet count, AST, and ALT) and may be sufficient in most cases.[4,8] If available, some experts also recommend obtaining a FibroScan, since this test represents one of the more accurate noninvasive methods for evaluating hepatic fibrosis in patients with HCV. The major limitation to FibroScan is cost and lack of access to this test in many health care settings. In primary care settings and other settings where FibroScan is often used when non-invasive markers of fibrosis are discordant or there are other aspects of the patient’s history and/or examination that introduce uncertainty regarding fibrosis stage.

[Activity] C. Calculating FIB-4 Score

Identifying Patients with Decompensated Cirrhosis

For all patients with presumed or documented cirrhosis, it is important to identify those individuals who have decompensated cirrhosis (moderate or severe hepatic impairment). Decompensated cirrhosis is defined by the presence of a Child-Turcotte-Pugh (CTP) score of ≥7 (class B = 7-9 or Class C = 10-15). A CTP score can be determined easily with a CTP calculator, which requires assessment of two clinical findings (encephalopathy and ascites) in combination with three laboratory values (serum bilirubin, serum albumin, and INR).[22] All individuals with a CTP score of ≥7 (class B or C) should be considered to have decompensated cirrhosis and promptly referred to a hepatologist (or other comparable expert) experienced in managing persons with decompensated cirrhosis.[23] The simplified treatment approach should not be used in persons with decompensated cirrhosis.[Q] HCV Treatment in Persons with Decompensated Cirrhosis

[Activity] D. Calculating a CTP Score

Summary Points

- Comprehensive clinical and laboratory assessment is essential prior to initiating HCV treatment, including history and physical, complete CBC, liver function tests, INR, and testing for HIV, hepatitis A, and hepatitis B infection.
- An essential pre-treatment goal is to assess the degree of hepatic fibrosis and determine cirrhosis status.
- Laboratory testing is timed based on whether a person has chronic HCV infection without cirrhosis or chronic HCV with compensated cirrhosis.
- Fibrosis staging impacts HCV treatment decisions, identifies patients who have cirrhosis and require ongoing HCC screening and patients with compensated or decompensated cirrhosis who may need additional evaluation and management.
- There are now several noninvasive tests available for fibrosis staging, including laboratory-based calculations and transient elastography, eliminating the need for liver biopsy for cirrhosis assessment.
- Transient elastography (FibroScan) is generally considered the most accurate noninvasive testing for liver fibrosis in patients with chronic HCV but the use of transient elastography is limited in some settings due to cost and lack of access.
- All patients with presumed or documented cirrhosis should be assessed for decompensated cirrhosis and, if present, be promptly referred to a hepatologist or other comparable expert experienced in managing persons with decompensated cirrhosis.

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Figures

Figure 1 Pretreatment Laboratory Testing in Adults with Chronic HCV WITHOUT Cirrhosis

Source: AASLD-IDSA. HCV Guidance: Recommendations for testing, management, and treating hepatitis C. Simplified HCV Treatment for Treatment-Naïve Adults Without Cirrhosis

Table based on AASLD-IDSA Simplified Treatment Algorithm

Pretreatment Laboratory Assessment in Adults with Chronic HCV WITHOUT Cirrhosis

Test	Within 6 Months of Treatment	Any Time Before Treatment	Soon Before Treatment
CBC	✓		
Hepatic Function Panel*	✓		
Renal Function (eGFR)	✓		
Quantitative HCV RNA		✓	
HIV Antigen/ Antibody		✓	
Hepatitis B Serology ^		✓	
Pregnancy Test+			✓

LEGEND:

* Testing includes albumin, total and direct bilirubin, alanine aminotransferase (ALT), and aspartate aminotransferase (AST)

^ AALSD-IDSA guidance recommends hepatitis B surface antigen (HBsAg); current guidelines from Centers for Disease Control and Prevention recommend triple screen with HBsAg, hepatitis B surface antibody (anti-HBs); and hepatitis B core antibody (anti-HBc).

+ In addition, counseling about pregnancy risks of HCV medication should be offered to women with childbearing potential. Treatment of HCV can be considered during pregnancy on an individual basis after a discussion about the potential risks and benefits.

ABBREVIATIONS:

AASLD = American Association for the Study of Liver Diseases
IDSA = Infectious Diseases Society of America
HCV = hepatitis C virus
CBC = complete blood count
eGFR = estimated glomerular filtration rate

Figure 2 Pretreatment Laboratory Testing in Adults with Chronic HCV WITH Compensated Cirrhosis

Source: AASLD-IDSA. HCV Guidance: Recommendations for testing, management, and treating hepatitis C. Simplified HCV Treatment for Treatment-Naïve Adults With Compensated Cirrhosis

Table based on AASLD-IDSA Simplified Treatment Algorithm

Pretreatment Laboratory Assessment in Adults with Chronic HCV WITH COMPENSATED Cirrhosis

Test	Within 3 Months of Treatment	Any Time Before Treatment	Soon Before Treatment
CBC	✓		
INR	✓		
Hepatic Function Panel*	✓		
Renal Function (eGFR)	✓		
Quantitative HCV RNA		✓	
HIV Antigen/ Antibody		✓	
Hepatitis B Serology ^		✓	
HCV Genotype		✓ #	
Pregnancy Test+			✓

LEGEND:

* Testing includes albumin, total and direct bilirubin, alanine aminotransferase (ALT), and aspartate aminotransferase (AST)

^ AALSD-IDSA guidance recommends hepatitis B surface antigen (HBsAg); current guidelines from Centers for Disease Control and Prevention recommend triple screen with HBsAg, hepatitis B surface antibody (anti-HBs); and hepatitis B core antibody (anti-HBc).

If treating with sofosbuvir-velpatasvir

+ In addition, counseling about pregnancy risks of HCV medication should be offered to women with childbearing potential. Treatment of HCV can be considered during pregnancy on an individual basis after a discussion about the potential risks and benefits.

ABBREVIATIONS:

AASLD = American Association for the Study of Liver Diseases
IDSA = Infectious Diseases Society of America
HCV = hepatitis C virus
CBC = complete blood count
INR = international normalized ratio (also known as prothrombin time)
eGFR = estimated glomerular filtration rate