Treatment of Acute HCV Infection

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Module 5: Treatment of Hepatitis C Infection
Lesson 5: Treatment of Acute HCV Infection

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Background

Epidemiology of Acute HCV

The estimated number of acute hepatitis C cases yearly in the United States is based on Centers for Disease Control and Prevention (CDC) viral hepatitis surveillance data (Figure 1).[1] In 2021, there were an estimated 69,800 new hepatitis C infections in the United States.[1] From 2013 through 2021, the number of cases of acute hepatitis C increased approximately 2-fold.[1] Key epidemiologic features include:[1]

- Case numbers and rates were much higher in men than in women,
- By age, the highest number of rates were seen in persons 20 to 39 years of age,
- By race and ethnicity, the highest rates were in American Indian/Alaskan Native people and White people, *and*
- There was major state-by-state variation in rates of acute HCV.

The epidemics of opioid and stimulant use in the United States are the predominant force driving the increase in new HCV infections, particularly in young adults.[2,3] In addition, an increase in acute HCV infections has been recognized among men who have sex with men, particularly men living with HIV infection who engage in condomless anal sex and use methamphetamine associated with sex.[4]

Definition of Acute HCV Infection

Most experts define acute HCV infection as the 6-month time period following the acquisition of HCV.[5,6,7] The definition of acute HCV infection does not depend on the presence or absence of symptoms associated with the acute HCV infection because most infections are subclinical. The preferred accepted laboratory diagnosis of acute HCV infection includes documentation of either of the two following criteria:

- A positive (detectable) HCV RNA in conjunction with a negative HCV antibody, *or*
- Positive HCV antibody with documentation of a negative HCV antibody in the past 12 months

Factors Associated with Recent HCV Acquisition

All persons with a confirmed case of acute HCV should be interviewed to identify any risk factors for acquiring HCV infection during the 2 weeks to 6 months prior to illness onset. Knowledge of risk factors is important from an epidemiology perspective and can help identify individuals who may be at high risk of transmitting HCV to others.

Differentiating Acute HCV infection from HCV Reinfection

Reinfection with HCV after achieving a sustained virologic response (SVR) is uncommon, but it can occur, especially for persons who continue or resume activities that place them at risk for acquiring HCV.[8,9] Individuals with HCV infection who achieve an SVR will have a permanently positive HCV antibody test. Therefore, for persons with HCV who achieve an SVR (at 12 weeks or later after completing HCV treatment), a diagnosis of HCV reinfection is based on the new presence of HCV RNA.[10] It is important to distinguish reinfection from relapse following an undetectable HCV RNA at the end of treatment. When relapse occurs, it almost always occurs within the first 12 weeks after completing therapy. Therefore, if an individual has an SVR at 12 weeks or later after completing treatment and subsequently has detectable HCV RNA, a diagnosis of HCV reinfection should be suspected. In this situation, an HCV genotype should be ordered and compared to the HCV genotype with the initial HCV infection. The finding of distinct genotypes confirms reinfection. Note, however, that persons can become reinfected with the same genotype and finding the same HCV genotype does not rule out reinfection. Viral sequence analysis can differentiate HCV infections that are the same genotype, but this test is not routinely performed for clinical purposes.[10]

Spontaneous Clearance of HCV Following Acute Infection

Following acquisition of HCV, an estimated 25 to 35% of persons will have spontaneous clearance of HCV 12 months after HCV acquisition.[11,12,13] Several more recent reports suggest the proportion of persons who spontaneously clear may be even higher.[14,15] Studies have shown that if spontaneous clearance occurs, it almost always occurs within 12 months of acquiring HCV (Figure 2); failure to clear HCV by 12 months is a strong predictor of developing chronic HCV infection.[11,16] Investigators have identified several factors that predict a higher likelihood of spontaneous clearance, including host IL28B CC genotype, female sex, and infection with HCV genotype 1.[11,17,18] In contrast, lower rates of spontaneous clearance occur in males, Black persons, and those with HIV coinfection.[11,19,20]

Comprehensive Clinical Care during Workup for Acute HCV

Additional Laboratory Evaluation

During the initial evaluation for possible acute HCV infection, all persons should also have the following tests performed:

- Testing for HIV infection (even if previously negative)
- Testing for acute hepatitis B virus (HBV) infection (HBsAg, anti-HBc IgM, anti-HBc IgG), unless previously documented to have a positive and sufficient hepatitis B surface antibody titer (greater than 10 or 12 IU/L by most assays)
- Comprehensive testing for sexually transmitted diseases if their risk factor for acute HCV was sexual activity

For more detailed discussion of the approach to persons newly diagnosed with HCV, see the lesson Initial Evaluation of Persons with Chronic HCV.

Consideration for HIV Preexposure Prophylaxis

Regardless of whether a patient suspected of acute HCV infection does or does not have HCV, they should be evaluated and considered for HIV preexposure prophylaxis (PrEP), since persons engaging in activities that place them at risk of acquiring acute HCV will also be at risk of acquiring HIV.

Additional Counseling for Risk Reduction

Persons diagnosed with acute HCV should receive counseling on how to reduce their risk of transmitting HCV to others. For persons who inject drugs, they should be counseled to not share any injection equipment with others, including needles, syringes, cookers, cottons, and water. For persons at risk of transmitting HCV sexually, condoms can reduce their risk of transmitting HCV to a partner. Finally, all persons with HCV should be counseled on avoiding exposure to hepatotoxic agents, such as alcohol or high-dose acetaminophen. For additional information on patient counseling, see the lesson in Module 1 Counseling for Prevention of HCV Transmission.

Acute HCV Treatment Data

Overall, treatment of acute HCV infection has been shown to result in high SVR rates, even prior to the modern era of treatment with direct-acting antiviral (DAA) medications. Studies of peginterferon alpha-2b monotherapy in intent-to-treat analyses showed SVR rates of 71 to 96%.[21,22] A meta-analysis of 22 studies (n = 1,075) using either standard interferon or peginterferon monotherapy reported an overall SVR rate of 78%.[21] The SVR rates observed with interferon-based therapy for acute HCV are significantly higher than SVR rates observed with interferon- or peginterferon-based treatment of chronic HCV. With interferon-based therapy, the highest SVR rates in the acute infection setting have occurred in persons who received treatment within 12 weeks following acute HCV diagnosis.[22,23] Highly successful outcomes were seen even in populations traditionally considered harder to cure, including in persons who inject drugs and persons with HIV. The following summarizes limited data on the newer DAA regimens in clinical trials that are underway or completed for the treatment of acute HCV infection.

Glecaprevir-Pibrentasvir

- **Glecaprevir-Pibrentasvir (Australian Study)**: In this open-label, single-arm, multicenter, international pilot study, adults with recent HCV (duration of HCV infection less than 12 months) received glecaprevir-pibrentasvir for 6 weeks.[24] Most (90%) were men who had sex with men, and (83%) had HCV genotype 1 infection.[24] The SVR12 rates were 90% (27 of 30) in the intention-to-treat group and 96% (27 of 28) in the per-protocol group.[24]

- **Glecaprevir-Pibrentasvir (PURGE-C)**: The aim of this phase 2, open-label single-arm trial is to assess the efficacy of a fixed dose combination of glecaprevir-pibrentasvir given for 4 weeks in participants with acute HCV, with or without HIV-1 coinfection (NCT04042740). The estimated completion of this study is 2023.

- **Glecaprevir-Pibrentasvir (TARGET-3D Part II)**: In this phase 3, open-label study, investigators enrolled 83 adults with recent HCV infection (acquired within 12 months) who received either (1) paritaprevir-ritonavir-ombitasvir and dasabuvir with or without ribavirin for 8 weeks, (2) glecaprevir-pibrentasvir for 6 weeks, or (3) glecaprevir-pibrentasvir for 4 weeks. Preliminary results for the 4 week glecaprevir-pibrentasvir arm (n = 23) showed that 70% of the participants had HIV coinfection, 35% had recent injection drug use, and 74% had HCV genotype 1.[25] The median estimated duration of HCV infection at the baseline evaluation was 7 weeks.[25] In the intention-to-treat and per-protocol analyses, 78% and 82% of individuals, respectively, achieved an SVR12.[25]

Ledipasvir-Sofosbuvir

- **Ledipasvir-Sofosbuvir (HepNet Acute HCV IV)**: This prospective, single-arm study enrolled 20 individuals in Germany with acute HCV genotype 1 monoinfection.[26] All subjects enrolled received ledipasvir-sofosbuvir for 6 weeks, and 100% (20 of 20) achieved an SVR12.[26] At baseline, 75% (15 of 20) participants had HCV RNA levels less than 100,000 IU/mL, and only 2 had HCV RNA levels greater than 1 million IU/mL.[26]
- **Ledipasvir-Sofosbuvir (Men with HIV in Europe)**: In this open-label, single-arm study, 26 men with HIV in Germany or England who were diagnosed with acute HCV genotype 1 or 4 infection were treated with a 6-week course of ledipasvir-sofosbuvir.[27] Overall, 77% (20 of 26) of the study participants achieved an SVR12.[27]
- **Ledipasvir-Sofosbuvir for 8 weeks in Men with HIV**: In this open-label, phase-1 clinical trial, 27 men with HIV received treatment with 8 weeks of ledipasvir-sofosbuvir for treatment of acute HCV.[28] Nearly all (96%) had genotype 1, and medial baseline HCV RNA was 6.17 log10 IU/mL. All participants achieved an SVR12.[28]
- **Ledipasvir-Sofosbuvir for 8 weeks in Men with HIV in New York City**: In this prospective, open-

label case series, 25 men with HIV and very recent sexually acquired HCV were treated with 8 weeks of ledipasvir-sofosbuvir.[29] All participants had HCV genotype 1, the median peak HCV RNA was 6.2 log10 IU/mL, and the median time from HCV clinical diagnosis to the start of treatment was 18 weeks.[29] Twelve weeks post treatment, all participants achieved an SVR12.[29]

Sofosbuvir-Velpatasvir

- **Sofosbuvir-Velpatasvir (REACT)**: In this international phase 4, open-label, randomized trial, 188 participants with recent HCV infection (duration of less than or equal to 12 months) were randomized to receive either 6 weeks or 12 weeks of sofosbuvir-velpatasvir.[30] Nearly all (97%) participants were male, and 69% had HIV coinfection. In the intention-to-treat analysis, 81.7% of participants in the 6-week arm versus 90.5% of participants in the 12-week arm achieved an SVR12.[30]
- **Sofosbuvir-Velpatasvir (HepNet acute HCV-V)**: In this prospective, single-arm, multicenter trial, 20 adults with acute HCV in Germany received treatment with sofosbuvir-velpatasvir for 8 weeks[31]. In the intention-to-treat analysis, 90% of the individuals achieved an SVR12 (2 were lost to follow-up).[31] In the per-protocol analysis, 100% achieved an SVR12.[31]

AASLD-IDSA Guidance for Management of Acute HCV

The American Association for the Study of Liver Diseases and Infectious Diseases Society of America (AASLD-IDSA) Hepatitis C Guidance has recently updated the approach to treating individuals with acute HCV infection.[7] The following summary highlights key recommendations from the AASLD-IDSA HCV Guidance for the management of persons with acute HCV infection.[7]

- **Treatment Approach to Persons with Acute HCV**: Persons diagnosed with acute HCV should promptly start HCV treatment. The initiation of treatment should not be delayed while determining whether spontaneous clearance of HCV has occurred. The rationale for this approach is twofold: (1) immediate treatment can have an impact on reducing HCV transmission to others, and (2) delaying treatment may result in lost follow-up for some persons.
- **Treatment Regimens for Persons with Acute or Recent HCV**: The recommended HCV treatment regimens and duration of therapy are the same for persons with acute HCV as for those with chronic HCV.
- **Counseling**: Persons diagnosed with acute HCV should receive counseling on how to reduce their risk of transmitting HCV to others and how to minimize exposure to any hepatotoxic agent, such as alcohol or acetaminophen.
- **Referral to Addiction Medicine**: Persons with acute HCV who have ongoing injection drug use should have a referral to an addiction medicine specialist.
- **Approach to Persons with Spontaneous HCV Clearance**: Approximately 25 to 35% of persons with acute HCV who do not undergo treatment will spontaneously clear HCV. Individuals who spontaneously clear HCV do not require treatment.

Summary Points

- The number of estimated acute HCV infections has markedly increased since 2013, with the highest number of cases involving persons 20 to 39 years of age.
- Approximately 25 to 35% of persons will spontaneously clear HCV in the first year after infection.
- Individuals undergoing workup for acute HCV infection should also be evaluated for acute or new HBV and HIV infection; if their risk for acquiring HCV was through sexual contact, the evaluation should also include comprehensive testing for sexually transmitted infections.
- Persons with ongoing activities that place them at risk for acquiring HCV infection also are at risk of acquiring HIV infection and thus should be carefully considered for HIV PrEP.
- The AASLD-IDSA HCV Guidance recommends that individuals diagnosed with acute HCV should promptly receive HCV treatment.
- The HCV treatment regimens and duration of therapy are the same for persons with acute and chronic HCV.
- Persons diagnosed with acute HCV should receive counseling on how to reduce their risk of transmitting HCV to others and how to minimize exposure to any hepatotoxic agent, such as alcohol or acetaminophen.

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Figures

Figure 1 Cases of New Acute HCV in the United States

Source: Centers for Disease Control and Prevention (CDC). 2019 Viral Hepatitis Surveillance Report—Hepatitis C. Published May 2021.

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Figure 2 Spontaneous HCV Clearance in First 24 Months after Initial HCV Infection

These estimates for HCV clearance are based on a systematic review and meta-analysis of 43 studies.

Source: Aisyah DN, Shallcross L, Hully AJ, O'Brien A, Hayward A. Assessing hepatitis C spontaneous clearance and understanding associated factors-A systematic review and meta-analysis. J Viral Hepat. 2018;25:680-98.