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Recent, albeit limited, experience has demonstrated the feasibility and effectiveness of treating chronic HCV in people who use illicit injection drugs, known as injection drug users (IDUs). Treatment for drug and alcohol abuse should be made available to all patients who want and need it. However, few data are available on HCV treatment in active IDUs who are not in drug treatment programs. Thus, it is recommended that treatment of active injection drug use be considered on a case-by-case basis, and that active injection drug use in and of itself not be used to exclude such patients from antiviral therapy.

HIV Co-infection

Although there are no HCV therapies specifically approved for patients co-infected with HIV, these patients should be considered for treatment.

Alcohol and HCV

Alcohol is an important cofactor in the progression of HCV liver disease to cirrhosis and HCC. A history of alcohol abuse is not a contraindication to therapy; however, continued alcohol use during therapy adversely affects response to treatment, and alcohol abstinence is strongly recommended before and during antiviral therapy. Heavy alcohol consumption of >80 g/day seriously compromises HCV treatment. Furthermore, safe levels of alcohol consumption are still unclear, and even moderate levels of consumption may accelerate disease progression in some patients.

Recommendations to be made to patients to prevent transmission of hepatitis C

The large reservoir of individuals infected with HCV provides a source of transmission to others at risk. Direct percutaneous exposure is the most efficient method for transmitting HCV, and injection drug use accounts for more than two-thirds of all new infections in the United States. Methadone treatment programs, needle and syringe exchange programs, and comprehensive risk-modifying educational programs have been shown to be effective in preventing HIV transmission and are likely to be useful for decreasing HCV transmission. Ensuring access to sterile syringes through physician prescription and pharmacy sales of syringes to IDUs can also be helpful. IDUs should be educated about the importance of hand washing before and after giving injections, not using the others' injection equipment, and avoiding any contact with blood from other persons. HCV prevention education should be a high priority in correctional settings.

In the United States, the estimated seroprevalence of HCV is 2 to 3 percent among partners of HCV-infected persons who are in long-term monogamous relationships and is 4 to 6 percent among persons with multiple sex partners, sex workers, and men who have sex with men (those at risk for sexually transmitted diseases). One study found the risk of HCV infection to be threefold higher for female than male sexual partners. Because of the low risk of HCV transmission, monogamous couples do not need to use barrier protection (condoms) although they should be advised that condoms may reduce the risk of transmission. There is no evidence that kissing, hugging, sneezing, coughing, food,

water, sharing eating utensils or drinking glasses, casual contact, or other contact without exposure to blood is associated with HCV transmission for correctional staff.

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RECOMMENDATIONS

- Educate the American public on the transmission of HCV in order to better identify affected individuals and to institute preventive measures.

- Promote the establishment of screening tests for all groups at high risk of HCV infection, including IDUs and incarcerated individuals.

- Institute measures to reduce transmission of HCV among IDUs, including providing access to sterile syringes through needle exchange, physician prescription, and pharmacy sales; and expanding the Nation's capacity to provide treatment for substance abuse. Physicians and pharmacists should be educated to recognize that providing IDUs with access to sterile syringes and education in safe injection practices may be lifesaving.

- Encourage a comprehensive approach to promote the collaboration among health professionals concerned with management of addiction. Primary care physicians, and specialists should be involved in various aspects of HCV management - to deal with the complex societal, medical, and psychiatric issues of IDUs afflicted by the disease.

Summary
National Institutes of Health
Consensus Development Conference Statement
Management of Hepatitis C
Final Statement

*The complete 44-page document can be found at http://www.nih.gov/.

The NIH Consensus Development Conference on Management of Hepatitis C: 2002 was held June 10 - 12, 2002. The final statement was published September 12, 2002. The "Final Statement" contains the following disclaimers:

1. "This statement is not a policy statement of the NIH or the Federal Government" and
2. "Thus, it provides a "snapshot in time" of the state of knowledge".

The Virus

The lack of a vigorous T-lymphocyte response and the high propensity of the virus to mutate appear to promote a high rate of chronic infection. The extensive genetic heterogeneity of Hepatitis C virus (HCV) has important diagnostic and clinical implications, perhaps explaining difficulties in vaccine development and the lack of response to therapy. Genotype 1 accounts for 70 to 75 percent of all HCV infections in the United States and is associated with a lower rate of response to treatment.

HCV replicates preferentially in hepatocytes but is not directly cytopathic. During chronic infection, HCV RNA reaches high levels, generally ranging from 10^5 to 10^7 international units (IU)/mL, but the levels can fluctuate widely. However, within the same individual, RNA levels are usually relatively stable.

Epidemiology

Although difficult to assess accurately, the incidence of HCV infections declined sharply in the late 1980s. However, the estimated prevalence of HCV in the U.S. is at least 1.8 percent of the population and a fourfold increase in the number of adults diagnosed with chronic HCV infection is projected from 1990 to 2015. Currently, persons aged 40 to 59 years have the highest prevalence of HCV infection, and in this age group, the prevalence is highest in African Americans (6.1%). High HCV seroprevalence rates (from 15-50 percent) have occurred in specific subpopulation, such as homeless, incarcerated persons, injection drug users, and persons with hemophilia who were treated with clotting factors before 1992. The highest seroprevalence rates (70 to more than 90 percent) have been reported in the last of these two groups

Chronic Infection

Persistence of HCV infection is diagnosed by the detection of HCV RNA in the blood for at least 6 months. In general, prospective studies have shown that 60 to 85 percent of HCV-infected persons develop chronic infection.

The most important sequelae of chronic HCV infection are progressive liver fibrosis leading to cirrhosis, end-stage liver disease, and Hepatocellular Carcinoma (HCC). Estimates of the proportion of chronically infected persons who develop cirrhosis 20 years after initial infection vary widely from 2 to 4 percent in studies of children and young women to as high as 20 to 30 percent in middle-aged transfused subjects. The actual risk is likely intermediate between these two ranges, on the order of 10 to 15 percent. There is little evidence that virologic factors, including viral load, viral genotype, and quasi-species diversity significantly affect the risk of progression of liver disease. However, many host factors increase this risk, including:

- Older age at time of infection,
- Male gender,
- Immunosuppression such as that associated with HIV infection, and
- Concurrent chronic hepatitis B infection.
- Higher levels of alcohol use play an important role in promoting the development of progressive liver disease, with strong evidence for the detrimental effects of 30 g/day in men (~ equivalent to 2 beers, 2 glasses of wine, or 2 mixed drinks) and 20 g/day in women.
- Conversely, individuals infected at a younger age have little or no disease progression over several decades.

Hepatocellular Carcinoma

HCC rarely occurs in the absence of cirrhosis or advanced fibrosis. Risk factors for HCC in persons with chronic HCV infection are largely the same as those for the development of decompensated cirrhosis. Some but not all studies suggest that treatment with interferon and ribavirin may reduce the risk of developing HCC in HCV patients with cirrhosis, but more data are needed.

HCV Serologic Assays

Enzyme immunoassay (EIA) tests are reproducible, inexpensive, and FDA-approved for use in the diagnosis of HCV infection. The very high sensitivity (low rate of false negative) and specificity (low rate of false positive) of the version 3 (third-generation) EIAs (sensitivity of greater than 99 percent, specificity of 99 percent in immunocompetent patients) obviate the need for a confirmatory immunoblot assay in the diagnosis of individual patients with clinical liver disease, particularly those with risk factors for HCV infection.

Qualitative HCV RNA Assays

Chronic HCV infection in a patient with a positive EIA test should be confirmed by a qualitative HCV RNA assay with a lower limit of detection of 50 IU/mL or less (approximately 100 viral genes/mL). A single positive qualitative assay for HCV RNA

confirms active HCV replication, but a single negative assay does not exclude viremia and may reflect only a transient decline in viral level below the level of detection of the assay.

Until future studies determine whether the sustained virological response (SVR) will be sustained over the long term following successful antiviral treatment, periodic measurements of HCV RNA may need to be performed.

Quantitative HCV RNA Assays

Testing for HCV RNA level (or viral load) with a quantitative assay provides accurate information on HCV viral levels. Significant variability exists between available assays. The clinical utility of serial HCV viral levels in a patient is predicated on continued use of the same specific quantitative assay that was used in the initial determination of the viral level. While there is little correlation between disease severity or disease progression with the absolute level of HCV RNA, quantitative determination of the HCV level provides important information on the likelihood of response to treatment in patients undergoing antiviral therapy.

ALT

Testing for serum ALT levels is the most inexpensive and noninvasive, but relatively insensitive, means of assessing disease activity. Serial determinations of ALT levels over time may provide a better means of assessing liver injury, but the accuracy of this approach has not been well documented. Patients who initially have a normal ALT level should undergo serial measurements over several months to confirm the persistence of normal ALT levels. Although loss or reduction in HCV RNA is the primary indicator of response to antiviral therapy, the resolution of elevated ALT levels with antiviral therapy appears to be an important indicator of disease response.

Noninvasive Tests of Fibrosis

No single test or panel of serologic markers can provide an accurate assessment of intermediate stages of hepatic fibrosis. Similarly, quantitative tests of liver function and radiologic imaging of the liver are sensitive for diagnosing advanced cirrhosis but are not useful in assessing hepatic fibrosis and early cirrhosis.

Liver Biopsy

Liver biopsy provides a unique source of information on fibrosis and assessment of histology. The information obtained on liver biopsy allows affected individuals to make more informed choices about the initiation or postponement of antiviral treatment. Thus, the liver biopsy is a useful part of the informed consent process.

In general, a baseline assessment of liver histology offers a valuable standard for subsequent comparisons. However, the appropriate interval for subsequent evaluations is yet to be determined.

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