

FINAL STATEMENT
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NATIONAL INSTITUTES OF HEALTH
CONSENSUS DEVELOPMENT CONFERENCE STATEMENT
Management of Hepatitis C: 2002
June 10–12, 2002

independent non-Federal Consensus Development Panel. After weighing this scientific evidence, the panel drafted a statement, addressing the following key questions:

€# What is the natural history of hepatitis C?

€# What is the most appropriate approach to diagnose and monitor patients?

€# What is the most effective therapy for hepatitis C?

€# Which patients with hepatic

1. **What is the natural history of hepatitis C?**

(EIA) in only 50 to 70 percent of patients at the onset of symptoms, increasing to more than 90 percent after 3 months. Within an average of 4 to 12 weeks, liver cell injury is manifested by

Extrahepatic Manifestations of HCV

Patients with chronic HCV can present with extrahepatic manifestations or syndromes

HCV Serologic Assays

of fibrosis and inflammation not currently widely available or well validated. No single test or

study. In general, a baseline assessment of liver histology offers a valuable standard for subsequent comparisons. However, the appropriate

HIV Screening

Significant overlap exists for risk factors for HCV and HIV. Therefore, patients with documented HIV infection should be routinely screened for HCV. HCV patients at risk for HIV infection should be offered testing for evidence of HIV infection with appropriate pretest and posttest counseling.

3. What is the most effective therapy for hepatitis C?

Since the 1997 NIH Consensus Development Conference on the Management of Hepatitis C, several important therapeutic advances have occurred, particularly with combination therapy with ribavirin and the introduction of pegylated interferons. Combination therapy results in better treatment responses than monotherapy, but the highest response rates have been achieved with pegylated interferon in combination with ribavirin. Genotype determinations influence treatment decisions. Currently the best indicator of effective treatment is an SVR, defined by the absence of detectable HCV RNA in the serum as shown by a qualitative HCV RNA assay with lower limit of detection of 50 IU/mL or less at 24 w

in combination with ribavirin. Factors associated with successful therapy included genotypes other than 1, lower baseline viral levels, less fibrosis or inflammation on liver biopsy, and lower

long-term followup found no difference in developm

However, most patients relapse again when they are re-treated with the same regimen that was used originally. Extending the duration of re-treatment without changing the dose or regimen may reduce the relapse rate, but this has not yet been proven prospectively.

Failure to respond to optimal therapy with pegylated interferon and ribavirin presents a significant problem, particularly in the presence of advanced fibrosis or cirrhosis. Currently, several large-scale, multicenter U.S. trials are evaluating the role of maintenance therapy with pegylated interferon alone in

Side Effects of Treatment

In registration trials of pegylated interferon and ribavirin, significant side effects resulted in discontinuation of treatment in approximately 10 to 14 percent of patients. Major side effects of combination therapy include influenza-like symptoms, hematologic abnormalities, and

than in patients without cirrhosis. Further studies are needed to evaluate whether long-term anti-viral therapy will delay histological disease progression to cirrhosis. Liver transplantation offers the primary treatment option for patients with deco

Some patients may benefit from treatment even if the liver disease is mild. Given the long life expectancy of children and their better tolerance to drugs, the long-term safety of these medications needs to be studied in children.

Acute Hepatitis C

Acute hepatitis C is uncommonly recognized and diagnosed because most patients do not

contraindication to HCV treatment. Efforts should be made to promote collaboration between experts in HCV and healthcare providers specializing in substance-abuse treatment. HCV therapy has been successful even when the patients have not abstained from continued drug or alcohol use or are on daily methadone. 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

All HIV-infected persons should be screened for HCV. Patients with chronic hepatitis C and concurrent HIV infection may have an accelerated course of HCV disease. Therefore, although there are no HCV therapies specifically approved for patients co-infected with HIV, these patients should be considered for treatment. Thus far, studies have enrolled only patients

15 months of age. Positive anti-HCV in infants prior to 15 months

examining the development and progression of fibrosis is, therefore, essential for

€# There is a need to more clearly establish the role of liver biopsy in the therapeutic management of patients with chronic hepatitis C. Biopsy techniques and their side

€#

and quantifying the viral level. Although there is little correlation between viral level and disease manifestations, these assays have proven useful in identifying those patients who are more likely to benefit from treatment and, particularly, in de

further evaluation of the rate of spontaneous cl

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

- €# Expand the delineation of disease manifestations, noninvasive tests, and the role of the liver biopsy, so that the application of current treatment practices may be refined.

- €# Establish a Hepatitis Clinical Research Network for the purpose of conducting research related to the natural history, prevention, and treatment of hepatitis C.

- €# Organize RCTs to extend treatment to special populations not represented in current clinical trials and to determine the

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