

HEPSQUADS

Making a Difference in Your Community.

a quarterly training
newsletter from
the Hepatitis C
Support Project

www.hcvadvocate.org

DDW Conference: Update on HCV

Alan Franciscus
Editor-in-Chief

THE DIGESTIVE DISEASE Weekly Conference was held in May 2003 in Orlando, FL. This conference is one of the premiere research conferences on diseases of the digestive system including the liver and hepatitis. This report will feature a summary of the information on hepatitis C. Please visit our web site www.hcvadvocate.org for additional DDW conference coverage.

Peg-Intron

Flamm and colleagues discussed the interim data on a clinical trial that compared the effectiveness of Peg-Intron at 1.0 mcg/kg/wk plus ribavirin compared with a higher dose of 1.5 mcg/kg/wk plus ribavirin in genotype 1 and genotype 2 & 3 patients. To date, one hundred and three patients out of 246 study participants have completed at least 24 weeks of therapy.

The authors reported that 24 week viral response rates were identical in both groups. As expected the side effects were lower in the group that received the lower dose of Peg-Intron plus ribavirin.

This would be good news for patients if the study results can be confirmed at the end of the study since fewer side effects can translate into less people stopping therapy, which could lead to a better chance of eradicating HCV.

Pegasys & Children

The prevalence of children infected with hepatitis C in the United States is estimated at 0.2% in children under 12 years and 0.4% in those children aged 12 to 19 years. New infections are mainly acquired by mother to child transmission.

Schwartz and colleagues presented data on the safety, efficacy (effectiveness), viral kinetics, and pharmacokinetics of 48 weeks of treatment with Pegasys in 14 children aged 2 to 8 years with chronic hepatitis C. In adults, Pegasys is a fixed dose for all patients regardless of weight, but for this trial the children were dosed by surface body weight.

Of the 14 children enrolled in this study, 5 withdrew after completing 24 to 47 weeks of treatment. The reasons for treatment withdrawal were adverse events (2), elevated triglycerides (1), administration error (last dose not taken), and refusal to continue with treat-

PHARMACOKINETICS (PK)

is the study of the metabolism and action of drugs with an emphasis on the time required for absorption, duration of action, distribution in the body and the method that it is eliminated. PK is important in understanding how a drug works in the body and helps to establish the safety of the new drug.

PHARMACODYNAMICS (PD)

is the study of drugs and their actions on living organisms.

ment. Of the remaining 9 children, 6 achieved a sustained virological response.

The authors concluded that Pegasys monotherapy based on body weight was safe, effective and well tolerated in children. They also concluded that the sustained virological response rate (42.9%) was similar to that found in adults.

Pegasys & Methadone

Studies have found that up to 90% of injection drug users

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HEPSQUADS

Executive Director
Editor-in-Chief,
HCSP publications
Alan Franciscus

Contributing Writers
Liz Highleyman
Heather Lusk

Design and Production
Paula Fener

Contact information:
The Hepatitis C Support Project
PO Box 427037
San Francisco, CA 94142-7037

www.hcvadvocate.org

HEPSQUADS NEWS ROUNDUP

Liz Highleyman

RECENT CONFERENCE NEWS

The 10th Conference on Retroviruses and Opportunistic Infections took place February 10-14 in Boston. Although this conference primarily focused on HIV, there were several presentations related to viral hepatitis. HCV/HIV and HBV/HIV coinfection continue to draw increasing attention. Researchers reported that HCV-related liver failure is now one of the major causes of death among people with HIV. A team from Harvard and Johns Hopkins found that a majority of people with HIV (65%) have some evidence of past or current HBV infection. New data was also presented confirming that liver transplants can be successfully performed in people with HIV, and that HIV positive and HIV negative people have similar post-transplant survival rates—almost 91% after one year.

Several presentations looked at an apparently harmless relative of HCV known as GBV-C (formerly called hepatitis G virus) that is associated with slow HIV disease progression and lower HIV-related mortality. Don't look for GBV-C to make an appearance as an HIV treatment anytime soon, but understanding how GBV-C and HIV interact may provide insights that could lead to the development of new anti-HIV therapies. For the complete Retrovirus conference program and abstracts, see www.retroconference.org/2003.

At the 10th International Symposium on Viral Hepatitis and Liver Disease held in April in Atlanta, researchers reported that among HCV-infected patients who had received two sequential biopsies, fibrosis progressed in 33%, improved in 13%, and showed no change in 54%; the factors most strongly associated with progression were older age, higher degree of fibrosis at first biopsy, and elevated ALT levels. At the same meeting researchers also reported that HCV infection appears to be associated with a greater risk of developing type 2 diabetes. Looking at data from the National Health and Nutrition Examination Survey (NHANES III), they found that people with HCV were four times more likely to have this type of diabetes. Finally, another research team reported that receiving the combination hepatitis A and B vaccine (Twinrix) on an accelerated 21-day schedule may be more effective—producing a stronger immune response—than the current 6-month schedule.

The European Association for the study of the Liver (EASL) annual meeting, scheduled for late March in Istanbul, Turkey, was postponed due to the war in Iraq. The conference has been rescheduled for July in Geneva, Switzerland. Abstracts are already available on the HCV Advocate web site (www.hcvadvocate.org/EASL-HCV.htm).

For more information, see www.easl.ch/easl2003.

TRANSMISSION NEWS

French researchers reported in the March 2003 issue of the *Journal of Medical Virology* that HCV was present in the semen of more than 25% of the participants in their study of 35 HCV/HIV coinfecting men. There was no association between semen level and HCV viral load, HIV viral load, duration of HIV infection, type of HIV treatment, or CD4 cell count. In a related study, another group of researchers found HCV RNA in the semen of 25% of Egyptian men infected with HCV (but not HIV); in this study, HCV in the semen did correlate with higher blood HCV viral load. Although HCV is not commonly transmitted through sexual activity, some recent studies suggest that sexual transmission rates—especially among men who have sex with men—may be higher than previously believed. Coinfection with HIV is known to increase the likelihood of sexual transmission of HCV.

In other transmission news, Texas researchers reported in the May 12, 2003 issue of the *Archives of Internal Medicine* that tattooing may be responsible for more cases of hepatitis C transmission than previously believed, but because only a small amount of the virus is injected under the skin, HCV contracted in this manner is unlikely to cause acute symptoms.

NEW APPROVALS

In April, Bayer Healthcare announced that the FDA had granted pre-marketing approval for its Versant HCV RNA 3.0 bDNA assay. This is the first (and so far only) FDA-approved quantitative test to measure HCV viral load. The same month, Schering-Plough reported that the FDA had granted priority review status to ribavirin for the treatment of hepatitis C in children (in combination with interferon). Currently there are no approved treatments for pediatric HCV.

NEW DRUGS

In the April 17, 2003 online edition of *Science* magazine two research teams from the U.S. and Canada reported that they had discovered new information about how HCV evades the immune system by blocking human host cells' production of interferon regulatory factors 3 and 7 (IRF3, IRF7), which help defend against infection.

New insights about HCV's lifecycle and activity offer new targets for drug development. The U.S. team found that in laboratory tests, Schering-Plough's experimental HCV protease inhibitor SCH-6 appears to help restore cells' natural immune response to the virus. Boehringer Ingelheim is also developing an HCV protease inhibitor.

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Legislators Introduce Federal HCV Plan

Liz Highleyman

ON MAY 23, SENATORS Kay Bailey Hutchison (R-TX) and Edward Kennedy (D-MA) introduced the Hepatitis C Epidemic Control and Prevention Act (S 1143), a bill that would require the federal government to develop a comprehensive national treatment and prevention plan for hepatitis C—the first federal response to the HCV epidemic. The legislation would create HCV public awareness campaigns; implement screening, counseling, and surveillance

programs; and fund professional training and HCV research.

The bill is supported by the National Hepatitis C Advocacy Council, a new coalition composed of nearly two dozen organizations—including the Hepatitis C Support Project—spearheading the same kind of advocacy around HCV that has successfully garnered more attention and funding for HIV/AIDS.

It is currently estimated that 4 million people in the U.S. are

infected with HCV and about 15,000 die from complications related to the disease each year. Researchers estimated in the April 2003 issue of *Liver Transplantation* that while the rate of new HCV infections has decreased dramatically, the prevalence of cirrhosis and its complications will likely increase over the next 10-20 years: decompensated cirrhosis by more than 100%, liver cancer by about 80%, and liver-related deaths by 180%. If untreated, as

many as one-third of people infected in the past may develop cirrhosis by the year 2020.

Please write or call your congress members and ask them to support this important legislation. A House of Representatives companion bill to S1143 is expected to be introduced within weeks.

See www.senate.gov and www.house.gov for addresses and phone numbers.



• hcspFACT sheets •


is a publication of the Hepatitis C Support Project. It is a series of fact sheets written by experts in the field of liver disease. They are available for printing at

www.hcvadvocate.org

NEWS ROUNDUP

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In April, SciClone Pharmaceuticals announced results of a study showing that its drug Zadaxin (thymosin alpha 1) plus interferon produced a 74% sustained response rate in patients with difficult-to-treat “precore mutant” HBV—higher than those achieved with either interferon plus lamivudine (3TC, Epivir) or interferon monotherapy.

Finally, in April researchers from Idenix Pharmaceuticals released promising chimpanzee data for its new HCV drug candidate NM283, a nucleoside analog; so far, the drug appears well tolerated and effective in reducing genotype 1 HCV viral load. Researchers also presented Phase II trial data showing that Idenix’ new drug telbivudine appears safe and effective in treating hepatitis B; these results must now be confirmed in larger Phase III trials. 

TRAIN THE TRAINERS WORKSHOP SCHEDULES

Tucson, Arizona
June 26-27, 2003

Sacramento, CA
July 10-11, 2003

Las Vegas, NV
July 24-25, 2003

North Hollywood, CA
July 31 - August 1, 2003

Fresno, CA
August 14-15, 2003

Prescott, AZ
August 21-22, 2003

Anchorage, AK
September 17-18, 2003

Keeping the Message Simple

Alan Franciscus
Editor-in-Chief

IT IS DIFFICULT TO KEEP prevention, support and care messages simple *and* also convey an effective message. A simple message is especially important on initial contact with a new client since it may be the only time that you have that opportunity to educate and advocate. In order to immediately engage a client, a simple non-judgmental message that is to the point and culturally appropriate can be a powerful educational tool and help de-

velop future contact and a long term relationship with a client.

The use of acronyms is one of the most effective tools to use in an educational piece since it is a message that is simple, easy to remember and can immediately engage the client.

A group of workshop participants at a recent training conducted in Phoenix, AZ, developed the following acronym that we thought was well worth sharing with the HepSquad trainers.

ABC'S OF HEP C POSITIVES

- AVOID SHARING ALL DRUG PARAPHERNALIA
- BE AWARE = BLOOD TO BLOOD TRANSMISSION
- CASUAL CONTACT = NO RISK
- HEP = HEALTHY POSITIVE LIFESTYLE ENCOURAGED.
- C+ = VACCINATE AGAINST HEPATITIS A AND HEPATITIS B

Special thanks to the workshop group that created this message:

- Anna Maria Branham, Maricopa County Dept. of Public Health
- RJ Shannon, Arizona Dept. of Health Services
- Ronnie Berger, Body Positives
- Cindy Vargo, Body Positives
- Kimberly Yarbrough, Arizona Association of Community Health Centers
- Billy Leeth, Maricopa County Dept. of Public Health
- Carol Weston, Planned Parenthood of Central and Northern Arizona
- Cee Cee Hofberger, Mountain Park Health Center

CONFERENCE UPDATES

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are infected with hepatitis C and are often treated with methadone maintenance therapy (MMT). Some data has suggested that methadone may interfere with the antiviral activity of interferon.

Sulkowski and colleagues presented data on the pharmacokinetics, pharmacodynamics and antiviral response of patients with hepatitis C infection on methadone maintenance therapy receiving Pegasys. In this study, 24 patients with chronic hepatitis C were treated with single and multiple weekly 180 µg doses of Pegasys. The effect of Pegasys on the methadone pharmacokinetics was measured before and after multiple doses of Pegasys.

well-tolerated in patients with hepatitis C receiving methadone maintenance therapy and that methadone does not impair the antiviral activity of Pegasys.

Hemolytic Anemia

Ribavirin is known to induce hemolytic anemia, which may require that a patient reduce the ribavirin dose or stop therapy, which in turn lowers the chance of achieving a sustained virological response (SVR) rate.

Afdhal and colleagues studied whether epoetin alfa (EPO) treatment could maintain ribavirin dose, increase hemoglobin (Hb) level, and improve the quality of life of people with ribavirin induced anemia. This was a randomized, double-blinded study of 186 patients who developed anemia while being treated with peginterferon plus ribavirin or interferon plus ribavirin. Patients were given EPO or placebo if their hemoglobin level was ≤ 12 g/dL).

The authors reported preliminary results of this study showing that patients with ribavirin induced anemia treated with EPO were able to maintain their ribavirin dose. In addition the authors found that EPO significantly improves anemia and a patient's quality of life. The effect of EPO treatment on sustained virological response rates was not studied in this trial but since EPO improves adherence rates, it may in turn improve sustained virological response rates.

Mother to Child Transmission

Ferrero and colleagues studied 170 women infected with

WHAT IS ANEMIA?

ANEMIA is an acute condition caused by reduced number of red blood cells or a reduced ability of blood to carry oxygen. There are several types of anemia, all with different causes. Symptoms may include fatigue, weakness, dizziness, headache, sore tongue, pale skin, and difficulty breathing.

HEMOLYTIC ANEMIA: a low red blood cell count due to excessive cell destruction, which can be caused by ribavirin.

The authors reported that no patient was required to modify methadone or Pegasys doses during the study and concluded that Pegasys monotherapy was

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Extrahepatic Manifestations Glossary

Extrahepatic means outside the liver. There are many extrahepatic conditions that have been directly linked to hepatitis C, but few people with chronic hepatitis C actually exhibit these disorders or symptoms. Other conditions, such as diabetes, are seen more frequently in people with hepatitis C, but a direct link has not been established. Below are definitions of the more common extrahepatic manifestations.

PORPHYRIA CUTANEA TARDA (PCT)

is a skin condition where the skin is easily bruised and may present with blisters that are sensitive to the sun and bleed easily. The causes of PCT include hepatitis C, excessive iron overload, poisoning by heavy metal, alcoholic liver disease, estrogen, and certain types of anemia. Treatment of PCT includes phlebotomy (for excessive iron overload) and treatment of HCV.

VASCULITIS

is an inflammation of blood vessels characterized by raised, purplish skin discoloration that commonly occurs on the legs. Treatment consists of addressing the cause—hepatitis C.

LICHEN PLANUS

is a skin condition that is characterized by reddish-brown raised round bumps that may be scaly and itch. Lichen usually occurs in the mouth, hair, and nails. Treatment consists of the use of topical lotions/creams or injections of corticosteroids in severe cases. Lichen may become worse during interferon treatment.

RHEUMATIC DISEASES

associated with HCV are frequently reported by people with hepatitis C. The symptoms of rheumatic disease usually include arthralgia (joint pain), and myalgia (muscle pain). Treatment consists of the use of pain medications, light stretching and exercise.

CRYOGLOBULINEMIA (CRYO)

is caused by the presence of cryoglobulins, which are a type of abnormal antibody circulating in the bloodstream. Cryoglobulinemia is common in people with hepatitis C, but very few people actually experience symptomatic disease. Symptoms can include skin rash, joint pain and inflammation, fever, and peripheral neuropathy. Treatment of Cryo consists of treating the cause—hepatitis C.

DIABETES II (DM)

is a disorder of carbohydrate metabolism (elevated blood sugar levels) and occurs more frequently in people with chronic hepatitis C than the general public, but a direct link has not been established.


THYROID DISEASE

(underactive or overactive) is more common in people with HCV than the general public. The majority of cases of thyroid disease in people with hepatitis C is an underactive thyroid. Symptoms of underactive thyroid can include fatigue, dry skin, coarse hair, mental confusion and intolerance to cold temperatures. A blood test is used to diagnosis thyroid disease. Underactive thyroid disease is treated with thyroid replacement therapy.

GLOMERULONEPHRITIS

is an inflammation of the kidney and has been associated with hepatitis C. HCV related glomerulonephritis often responds to treatment with interferon.

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Medical Writers' Circle is a publication of the hepatitis C Support Project. It consists of a series of articles written by medical professionals about the management and treatment of Hepatitis C. The articles are available for printing at

www.hcvadvocate.org

CONFERENCE UPDATES

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HCV versus a group of matched uninfected women to determine the rate of HCV transmission from mother to child and the effect of HCV infection on pregnancy and delivery.

The authors found that the overall mother-to-child transmission rate was low (2.7%) and that HCV infection itself does not have an adverse effect on pregnancy and delivery—there was no difference in the rate of cesarean section, premature delivery, obstetric complications, or low birth weight among HCV infected women as compared to the controls. However, they did find that high HCV viral load and HIV coinfection were associated with higher rates of transmission.

These findings are particularly relevant in counseling HCV infected women considering pregnancy. □□

Success Stories

Do you have a story about your educational efforts that you'd like to share?

You could win a **\$50.00** gift certificate if we publish your story.

Contact
sfhepcat@msn.com
for more details.

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PO Box 427037
San Francisco, CA 94142-7037