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Study may help to explain how liver cells regenerate.

[Hoffman-LaRoche and Maxim Combine Forces for New HCV Combination Therapy](#)

Pegasys, a pegylated interferon is being tested for use with Maximine, a drug believed to reverse immune suppression.

[Treatment Advocate: A Little About the HCV Global Conference, Some Incredible People and a Little Chinese Medicine](#)

While pricey, the English version of the Chinese Pharmacopoeia is the bible of Chinese medicine.

September 2000's Advocate:

FDA Advisory Panel Recommends Approval of Hoffmann-LaRoche's Viral Load Test

By Alan Franciscus
Editor

The U.S. Food and Drug Administration's (FDA) Advisory Panel recommended FDA approval for Roche's qualitative viral load test - Version 2.0 of Amplicor and COBAS Amplicor HCV Test, version 2. The panel also recommended that a warning label be included because certain uncommon genotypes would not be detected by the tests and that heparin (a organic compound that prevents blood clotting) may lead to a false-positive test result (a test that indicates that a disease is not present when in fact it is).

If approved, this would be the first FDA approved test to measure the hepatitis C virus.

There are two types of viral load tests - 'qualitative' and 'quantitative'. Qualitative measures the presence of virus while 'quantitative' measures the amount of virus. Roche has developed both tests, but has only submitted their 'qualitative' test to the FDA for approval. Roche is expected to submit their 'quantitative' viral load test to the FDA later this year.

Currently, there are two types of viral load tests commonly used but have not been approved by the FDA:

1. Polymerase Chain Reaction or PCR measures the amount of HCV in your blood. These tests are very sensitive and can measure viral load down to <100 virus particles milliliter.
2. Branched-Chain DNA Assay - a method that is easier (and cheaper) to apply to a large number of samples, but only measures viral >200,000 viral particles be milliliter.

The HCV viral load tests that are currently used have also been controversial because the results vary depending on the way the sample blood is handled and stored. Furthermore, results may vary from lab to lab. These tests are considered experimental and therefore may not be covered by some insurance companies. FDA approval would practically guarantee reimbursement by insurance companies.

Another benefit of an FDA approved viral load test is that it will be standardized and reported in international units, which will make it easier to compare results from different types of tests.

The value of the quantative test for HCV is questionable since the amount of virus detected does not correlate with disease progression. However, this test is considered important for measuring virus before, during, and after treatment with interferon or interferon and ribavirin.

A low viral load prior to treatment may 'predict' a better response and most doctors believe that if you do not go 'undetectable' (clear or eliminate HCV) within 3 months, individuals are unlikely to clear the virus while on treatment. And if you clear the virus on treatment and remain virus free for one year, the chances are extremely good that you have cleared the virus for good.

September 2000's Advocate:

Healthwise: African Americans and Hepatitis C Differences in Treatment Response, Cirrhosis Rates Need More Study

By Lucinda K. Porter, RN

The impact of the hepatitis C virus (HCV) in the African American community is cause for grave concern. Among people ages 30 to 50 years old, one in ten African Americans is infected with HCV. African Americans are twice as likely as Caucasians to be infected with HCV and are more likely to be infected with genotype I.

Explanations for this include a variety of social and economic factors that place African Americans at greater risk for contracting HCV. African Americans are more likely to be employed in situations that may increase their risks of acquiring HCV.

Employment in occupations such as health care workers, janitorial, and military services can carry with it increased risks. Sickle cell anemia is another condition that affects African Americans, a condition that sometimes requires blood transfusions.

Anyone who received any blood products prior to 1992 should be tested for the presence of HCV. A history of nasal or injection drug use is also primary risk factors for chronic HCV infection. Young African American males are especially at high risk for drug related acquisition of HCV.

In a recent article in JAMA , David Thomas and others at John Hopkins School of Medicine, published the results of a seven-year study on the natural history of HCV infection. Their analysis showed that viral clearance was nearly five times more likely in whites than in blacks. This may explain some of the disproportionately high rates of infection in African Americans of all ages.

In May, a paper was presented at Digestive Disease Week 2000 suggesting that HCV-infected African Americans are less likely to progress to cirrhosis than non-African Americans. Since one usually associates progression to cirrhosis with a lower likelihood of response to antiviral therapy, it is clear that more investigation is necessary.

The frequency of response to antiviral treatment in African American patients is still unknown. The high prevalence of genotype I suggests that African Americans may be less likely to respond to treatment. African Americans are not well represented in medical research.

There has been a well-founded history of distrust of the U.S. medical system by African Americans. This factor impedes the process of having a fairly distributed number of participants in clinical trials. Further research in this area is needed in order to assess the safety and efficacy of treatment in African Americans.

Stanford University Medical Center is currently recruiting non-Hispanic African American volunteers for a drug study. Volunteers must be 18 years or older with chronic hepatitis C who have never received prior antiviral treatment for hepatitis C infection (e.g., interferon, ribavirin). This study will evaluate the effectiveness of a new drug (Pegasys) in combination with ribavirin.

The study provides free study-related physical exams, medications and diagnostic tests. Pegasys is administered by self-injection. Two liver biopsies are required. Ability to come to Stanford area for many regularly scheduled visits is also required. Subjects must meet study criteria in order to participate.

Volunteers with chronic hepatitis C who are interested in participation in this study directed by Gabriel Garcia, MD, should contact: Lucinda Porter, RN @ Liver Research Stanford University School of Medicine (650) 724-7057

For those of you with Internet service, the JAMA article can be accessed at: HIVandHepatitis.com Thomas, David L. et al "The Natural History of Hepatitis C Virus Infection" JAMA July 26, 2000- Vol.284, No.4

Another article on the subject and posted at the same website is: "New Study Shows African Americans with Chronic Hepatitis C Have Lower Rate of Cirrhosis than Caucasians: Researchers conclude this group may "lack immune recognition of HCV-infected liver cells" by Harvey S. Bartnof, MD This article discusses the following 2 papers presented at a recent major conference: Reddy R. HCV infection in the African American patient. Oral presentation S223 at Digestive Disease Week 2000; May 21-24, 2000; San Diego, California. Wiley TE and others. The natural history of hepatitis C in African Americans. Abstract and oral presentation 3585 at Digestive Disease Week 2000; May 21-24, 2000; San Diego, California.

Lucinda K. Porter, RN is a research nurse and patient educator at Stanford in the area of hepatology. She co-facilitates a support group and is active in many aspects of hepatitis C education. In addition to being HCV positive, she has a life which include her husband and teenaged daughter.

September 2000's Advocate:

Liver Cells in Bone Marrow: Exciting New Research for Future Therapies

By Alan Franciscus
Editor

Recent findings have suggested that liver cells may be produced from stem cells in bone marrow. In a new study reported in the July issue of *Hepatology*, researchers proved that bone marrow produces stem cells capable of becoming human liver cells.

"We have proven that in humans there are stem cells for the liver in the bone marrow," says Neil Theise, MD, associate professor of pathology at New York University School of Medicine and lead author of the study. "These cells potentially could be used as a source of cells for liver transplants, as a pool of cells for the development of an artificial liver, and in gene therapy to treat many liver diseases."

Blood cells are made in the bone marrow from stem cells. Stem cells have the ability to replicate and divide into different types of cells. When a stem cell replicates or divides, one cell remains a stem cell and the other cell goes on to become a blood cell. The type of blood cell they become depends upon what cytokines (hormone-like messenger molecules that cells use to communicate) or hormones they are exposed to. This and other studies have debunked the common belief that stem cells could only make blood cells but in fact can make other types of cells such as liver cells.

In this new study, two women with leukemia received bone marrow transplants from male donors, and four men with severe liver disease received liver transplants from female donors. The researchers followed the Y chromosomes, which are only found in males to track the stem cells. Using fluorescent microscopy, they found the Y chromosomes in all the patients' liver cells. In the women, the only possible source of the Y chromosomes was from the bone marrow donated from the men. This study may help explain how the liver has the ability to regenerate and opens up a whole new area of research into treating many different types of liver disease.

September 2000's Advocate:

Hoffman-LaRoche and Maxim Combine Forces for New HCV Combination Therapy

By Alan Franciscus
Editor

Maxim Pharmaceuticals and F. Hoffmann-La Roche LTd, have entered into an agreement to collaborate on an investigational HCV treatment approach with a combination of Maxim's Maxamine and Roche's Pegasys (pegylated interferon).

Maxim's Maxamine is a medication that is believed to reverse immune suppression that is 'turned off' by viruses such as HCV. It is also in clinical trials for treatment of various forms of cancer. Roche's Pegasys is a pegylated interferon, a form of time-released interferon, which is awaiting FDA approval. Interferon acts as an antiviral, immune-regulating chemical that suppresses and kills HCV. It is believed that the combination of these two drugs will further strengthen the immune response to fight and kill the hepatitis C virus.

The agreement between the two companies will allow Roche to perform the clinical trials and pick up the related costs. However, the third party costs, will be shared by both Roche and Maxim. Each company will retain marketing and revenue for their own separate products.

Maxim reports that results from a interim 24-week Phase II dose-ranging study of Maximine and interferon showed a complete viral response (elimination of HCV) in 69 percent of all patients, compared to the 29 percent or less than is commonly observed in patients treated with interferon only. At this time, it is considered an investigational drug and safety, as well as efficacy, has not been established.

Roche's Pegasys interferon has completed Phase III clinical trials and results suggest a response rate similar to results obtained by treatment with the combination of interferon and ribavirin. Another combination, Pegasys and ribavirin recently completed Phase II trials and results show promise of a better response rate than Pegasys or interferon alone. Phase III clinical trials of Pegasys and interferon are expected to begin soon.

It is important to note the different steps or phases involved in the process of testing a new drug. Phase I studies prove drug safety within healthy persons. Phase II studies are used to obtain information on safety and effectiveness of a drug with people who have the condition. Phase III studies are large scaled (hundreds to thousands of patients) testing to acquire safety, dosage, and effectiveness information. Once a phase III study is successfully completed, the information is submitted to the FDA for approval of marketing to the public. Approved drugs may enter into Phase IV studies to compare the drug with other drugs in the market, monitor a drug's long-term effectiveness and impact on a patient's quality of life, and cost effectiveness of the drug to other therapies. The most valuable information is usually collected once a drug is marketed to the public.

It is too early to tell if the combination of these two drugs will provide an effective or improved therapy for treating HCV. However, it does hold promise especially for those individuals who do not respond to treatment with the combination of interferon and ribavirin.

Source: Company press release, FDA table on clinical trials and Centerwatch.

September 2000's Advocate:

Treatment Advocate: A Little About the HCV Global Conference, Some Incredible People and a Little Chinese Medicine

By Joe Shaw

It's been a week since the HCV Global Foundation 2000 Conference and I'm still riding the wave of exhilaration that comes from meeting with other people with HCV, many of them amazing people doing courageous work. I met activists visiting prisons with information about hepatitis C and brave people who run needle exchanges which save hundreds of lives each year. I met a marvelous woman who runs a support group in Yuba City, California and also, through her church, ministers to women with small children, after they are released from prison. I met another fellow hepper who amazed me with her encyclopedic knowledge of how the immune system works, as well as the liver and other organs. I thought she had to be a doctor, but she was just empowered with knowledge. A lady from Portland living with HCV, whose husband and daughter have hepatitis C as well, shared with me her family's struggles with the disease. She works for an organization that helps families who have children with infectious diseases. I also had the opportunity to meet with an exciting new coalition of groups and organizations from across the country who are committed to working together to provide a unified voice for HCV organizations. It's about time. And last, but certainly not least, I met many of you, the people who read this newsletter. Thanks so much for your encouragement and support. I am extremely happy that I had the chance to meet so many of you.

Now I turn my attention to alternative medicine. I recently came across several different studies and other information about aspects of alternative medicine, and I thought I'd share some of this interesting stuff with you.

I know not very many individuals could afford it, but perhaps you can convince your local library to order it:

Pharmacopoeia of the People's Republic of China (English Edition)

The latest English edition of Chinese Pharmacopoeia compiled by the Pharmacopoeia Commission of the Ministry of Public Health, is an official and authoritative compendium of drugs, covering almost all traditional Chinese medicines, most of western medicines and preparations, giving information on the standards of purity, description, test, dosage, precautions, storage, and the strength for each drug Dec., 1997; 2 vols; ISBN: 7-5025-2063-5 Pharmacopoeia of the People's Republic of China (English Edition) is a large reference book (2 vols); The price of a set is US\$600 or Canadian Currency \$895 (including airmail postage).

The Commonly Used Chinese Herbal Medicines (Chinese-English Edition) In a CD-Rom; ISBN: 7-900005-07-2.

Describes 940 kinds of the commonly used Chinese herbal medicines with photos. Most of them also include herbal preparation, action and indication. The price of a CD-ROM set is US \$150 or Canadian Currency \$223 (including EMS postage).

For information on these reference tools contact: Chi Zhenguo (Chi is last name, Zhenguo is first name) Fax: +86 755 6568829 E-mail: szchis@sz.gd.cninfo.net

This is one of two studies from the British Medical Journal August 2000, that compare homeopathic medicines to placebo. The studies were conducted by researchers in Scotland and Australia.

Randomised controlled trial of homoeopathy versus placebo in perennial allergic rhinitis with overview of four trial series.

Objective: To test the hypothesis that homoeopathy is a placebo by examining its effect in patients with allergic rhinitis and so contest the evidence from three previous trials in this series. **Design:** Randomised, double blind, placebo controlled, parallel group, multicentre study. **Setting:** Four general practices and a hospital ear, nose, and throat outpatient department. **Participants:** 51 patients with perennial allergic rhinitis. **Intervention:** Random assignment to an oral 30c homoeopathic preparation of principal inhalant allergen or to placebo.

Main outcome measures: Changes from baseline in nasal inspiratory peak flow and symptom visual analogue scale score over third and fourth weeks after randomisation. **Results:** Fifty patients completed the study. The homoeopathy group had a significant objective improvement in nasal airflow compared with the placebo group (mean difference 19.8 l/min, 95% confidence interval 10.4 to 29.1, $P=0.0001$). Both groups reported improvement in symptoms, with patients taking homoeopathy reporting more improvement in all but one of the centres, which had more patients with aggravations. On average no significant difference between the groups was seen on visual analogue scale scores. Initial aggravations of rhinitis symptoms were more common with homoeopathy than placebo (7 (30%) v 2 (7%), $P=0.04$). Addition of these results to those of three previous trials ($n=253$) showed a mean symptom reduction on visual analogue scores of 28% (10.9 mm) for homoeopathy compared with 3% (1.1 mm) for placebo (95% confidence interval 4.2 to 15.4, $P=0.0007$). **Conclusion:** The objective results reinforce earlier evidence that homoeopathic dilutions differ from placebo.

This study suggests that Qinggan Granula (QTG) reduces and reverses fibrosis in Hepatitis C. From: Chung Hua Kan Tsang Ping Tsa Chih 2000 Apr;8(2):91-3

Pathological study of the therapeutic effect of compound qinggan granula on chronic hepatitis C. Wang L, Ren J, Wang T Shuguang Hospital, Shanghai 200021, China.

Objective: To assess histopathologically the therapeutic effect of Compound Qinggan Granula (QTG) on chronic hepatitis C. **Methods:** Among 48 cases of chronic hepatitis C, 36 were treated by QTG (30g for one time and three times a day) for 6 months, and 12 were not treated with any drugs as control. Liver biopsy was done in all patients before and after the observation except 3 patients who refused to take biopsy again. Specimen were stained with HE and James method, and their grading of inflammation (G), staging of fibrosis (S) and scoring for both were then evaluated. **Results:** In the treatment group, 14 and 26 cases showed a decreasing grading (42. 5%) and inflammation scoring (78.8%), respectively. Score for G was reduced from 8.42 to 5.58 ($P<0.05$). As for the fibrosis, the stage didn't change significantly ($P>0.05$), but the score was reduced in 19 cases (57.6%) from 3.83 to 3.13 ($P<0.05$). In the control group, there were not evident changes for grading and staging. The scoring of G increased from 7 to 8.6 and S from 4.15 to 6.6 ($P<0.05$). **Conclusion:** QTG is effective in treating chronic hepatitis C by attenuating inflammation and stopping or reversing the fibrosis. PMID: 10861113, UI: 20319250

Joe Shaw was diagnosed with HCV in January 1998 and lives with his partner and his two pugs, Willie and Sammie in Long Beach, CA.