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HCV Advocate

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Hep C and ALTs -- What is Normal?

By Alan Franciscus
Editor

Twenty to thirty percent of people with HCV have persistently normal alanine aminotransferase (ALT) levels. It is currently recommended that HCV+ individuals with normal ALT levels should not be treated with antiviral medications and followed simply by measuring their ALT levels.

However, emerging data suggests that it may not be this simple. What does this mean for the patient that has persistently normal ALT counts? Should they be biopsied and treated? This is a 'hot' area of research and some recent findings are changing the way the medical profession views this group of HCV+ patients.

We know that most HCV+ individuals with persistently normal ALT levels have a less serious disease progression and milder disease.

The National Institutes of Health (NIH) and European consensus conferences recommended no liver biopsy or antiviral therapy in patients with persistently normal ALT levels outside of clinical trials due to the assumed mild disease progression and low response rates to current antiviral therapy. Some medical professionals dismiss this group as healthy 'carriers' and offer minimal medical follow-up. However, some of these patients with normal ALT's do not fit so neatly into this category and researchers are finding that a small percentage of these patients may have moderate to severe liver damage.

Alanine aminotransferase (ALT's - formally called SGPT) is produced in the liver in response to liver injury or cell death. This injury is not specific to HCV inflammation, but can come from a variety of agents such as alcohol, medications and other substances that can produce liver injury. This is usually,

but not always, the first indication that someone may be infected with HCV. Normal values: 0-48 IU/L

It should be noted that many experts believe the normal ALT range value for women should be lower than the range value for men. In fact, women populate a large part of this 'normal group'. The lower ALT levels in women might be explained by the production of estrogen which is believed to lower ALT levels.

Biopsy

In a recent study by Edmund J Bini and others (AASLD abstract #485) 43 patients with persistently normal ALT levels and 96 with abnormal ALT levels were followed. Normal levels were defined by 3 normal ALT readings taken at least 1 month apart. The researchers found that the abnormal ALT levels group had significantly more advanced liver disease than patients with normal ALT's. However, 28% of the patients with normal ALT's had advanced liver disease, which led the researchers to recommend that all patients with normal ALT's undergo a liver biopsy for disease staging.

In a different study by Luis Balart, MD and others, over 300 patients with persistently normal ALT levels defined as 3 normal ALT levels readings taken 6 weeks apart for a period of 6 months were studied. It was found that most of these patients had mild liver

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Shattering Some Common Myths About Hepatitis C

By Lucinda K. Porter, RN

I have a sentimental streak. I believe in the notion of Santa Claus. I know it is a myth, but it is one that I hold on to until evidence convinces me otherwise.

HealthWise

However, when I hear the so-called “facts”, I realize that myths can be harmful. May

your New Year be filled with good health and truths rather than myths.

Myth #1: Hepatitis C virus (HCV) is a sexually transmitted disease (STD). This is not a complete myth. HCV can be transmitted sexually, but this is a very unlikely route of transmission. HCV is categorized as a blood-borne pathogen and is not considered to be an STD. See the December 2000 issue of the HCV Advocate for more information about this issue.

Myth #2: HCV is easily passed via household contact. When patients are first diagnosed with HCV, prevention of transmission to others is usually the first priority. I get many questions regarding sharing eating utensils, kissing, hugging, etc. Again, HCV is a blood-borne pathogen and nonsexual transmission to other household members is extremely unlikely. People are discouraged from sharing razors, toothbrushes and any other personal hygiene articles that may remotely come in contact with blood. Even if these articles are accidentally shared, the risk is theoretical and very low.

Myth #3: A diagnosis of HCV means one should start putting their affairs in order. I applaud the patients who have the courage to ask the hardest questions, “Am I going to die from this?” and “How much longer do I have?” Many of us think about these things and unless we talk about them, they eat away inside of us. The truth is, the vast majority of us will die with HCV, not of HCV. Some people use their HCV diagnosis as an opportunity to improve their health habits. There is a Chinese proverb that says that a person with an illness will outlive a person without an illness. The point is that sometimes an illness is an incentive to take better care of ourselves.

Myth #4: Since more HIV/HCV coinfecting

individuals seem to be dying from HCV, HCV must be more serious than HIV. This could not be further from the truth. Because of improvements in disease management, HIV-infected individuals are living longer. So long in fact, that they must now deal with other chronic diseases. Many HIV medications are hard on the liver, which may have had a greater impact on those co-infected with HCV. Furthermore, little was known about how to manage the co-infected patient. With research, time, and experience, much more is known about this issue.

Myth #5: The higher the viral load the worse the prognosis. Viral load does not correlate with symptoms or the amount of liver damage. There are people with very high viral loads who have no liver damage and those with low viral loads who have extensive damage. A subsequent lower viral load does not indicate that someone is “getting rid of the virus” except under certain circumstances. In general, those with chronic HCV do not spontaneously “lose” the virus. Additionally, the measurement of viral load is not a precise process. The usefulness of viral load is reserved for the following 2 purposes: a) to confirm that a person with HCV antibody actually has chronic infection with HCV present in their blood; and b) to determine if a person is responding to antiviral therapy.

Myth #6: Genotype 1 is the worse genotype. Genotype 1 is the least likely genotype to respond to antiviral treatment, but in terms of prognosis, it has no significance.

Myth #7: HCV can be treated with herbs and supplements and since these are natural, they are safe. I have a high regard for the practice of holistic medicine. Many of the pharmaceutical drugs we use have their origins as herbs used by folk practitioners. However, herbs and supplements are powerful and need to be treated with the same respect as other drugs. Arsenic is natural, but we know enough to avoid it. However, many of us see the word “natural” on a supplement and we assume natural means safe.

Myth #8: HCV cannot be cured. Cured is a word that is not typically applied to the eradication of HCV in an individual. Although insufficient time has passed to unequivocally use the “cure” word, approxi-

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Is Hep C a Liver Disease? Does Your Doctor Know For Sure?

By C.D. Mazoff, PhD
Contributing Editor

This last summer I was invited to give a talk to a gathering in Nelson, British Columbia (cross the Golden Gate, and go north until you see the first grizzly bear and then hang a right). In the audience were 2 physicians and several nurses. I opened with the following sentence. "I'm not here to cause an argument, and I don't want anyone to get upset. I'm also not a medical doctor, but in my opinion, hepatitis C is NOT a liver disease; it causes liver disease among other things. To my relief, nobody laughed, and nobody left.

This fall I had a chance to repeat myself at the Washington Hepatitis C Summit in Seattle Washington (cross the Golden Gate, and go north until you see the first salmon and then hang a left). This time I put the question to Dr. Robert L. Carithers, Director of Hepatology at the University of Washington. His response was "yes, calling hepatitis C a liver disease was more due to lazy infectious disease specialists than aggressive hepatologists."

So if hepatitis C is NOT a liver disease, why is it called a liver disease? And what does this have to do with you and me anyways? Isn't it just a technicality? A semantic quibble? No.

How many times have we heard the story of someone who, not feeling well, goes to the doctor and is told a version of the following: "Oh, well you have hepatitis C, but not to worry. It's the best kind to have. And as to your symptoms, well they must be in your head because your liver isn't scarred enough to be causing them. Here take these antidepressants and go home." But doctor," you protest, "I'm so tired and achy, it can't be in my head. I'm losing my job, I can't concentrate, I think I might need to apply for disability. Could you write me a letter?"

So, the doctor writes a letter that goes something like this: patient is slightly narcissistic and perhaps undergoing personal problems. The illness is not serious, and most likely temporary. I have prescribed an anti-depressant.

How it works:

When a liver becomes heavily scarred, no matter what the cause, it can no longer do its job of converting food into energy and of cleaning up after itself. It

gets sloppy and leaves by-products in your system, some of which act like poisons. These "toxins" can be measured through blood tests. A person with this condition-end stage liver disease-will need to take special medicines to try to help compensate for the liver dysfunction. Hence, the term "de-compensated" cirrhosis.

Those who hold that hepatitis C is a liver disease will only acknowledge "symptoms" at the point of decompensation. Up until then, anything you experience is caused by something else, not the hepatitis C, so they believe.

Those who hold that hepatitis C is a systemic disorder see the situation rather differently. They see a system under attack by a virus that multiplies very very quickly, producing viral loads much higher than in HIV. They see an overworked and confused immune system trying to cope with a virus that mutates rapidly to avoid detection. They see a virus that directly inflames muscle, nerve, joint and heart tissue; that triggers all sorts of immune irregularities.

Is it any wonder then that many persons with hepatitis C not undergoing treatment, nevertheless experience symptoms similar to those on Interferon: sweats, aches, blurred vision, dry mouth, fever, memory loss, confusion, irritability, and so on. Surely all of these people cannot be making it up, so what then is causing all of this? Answer a body under attack from a virus.

There are several studies showing that symptoms reported by hepatitis C sufferers often bear no correlation to enzyme levels, stage of scarring or liver dysfunction. Puzzled researchers have come up with various theories to explain the aches and the "fatigue."

1. Fatigue is caused by metabolic dysfunction
2. Fatigue is caused by a blunting of the stress response
3. Fatigue is caused by altered transmission of nerve impulses in serotonin pathways
4. Muscle aches are caused by direct activity of virus on muscle tissue
5. Confusion and memory problems are caused by the virus hiding in the brain.
6. Tiredness and achiness are caused by heightened

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Hep C & ALTs

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disease, but a small percentage had more advanced disease, and some patients were found to have cirrhosis. Based on his study, Dr. Balart recommended that other factors should be considered when evaluating these patients and a biopsy should be considered.

Treatment

This is a much more complex issue. In a recent study conducted by Dr. Mitchell L. Shiffman and colleagues, it was found that response to interferon monotherapy was similar in both normal (58 patients) and abnormal (37 patients) ALT level groups. The researchers concluded that persons with persistently normal ALTs should undergo a liver biopsy and considered for treatment if the liver is damaged. These findings have been collaborated by previous studies.

However, some evidence suggests that antiviral treatment for a small segment of this group could be counterproductive. Some patients do not respond to treatment, but develop elevated ALT levels that continued to be elevated after treatment is stopped. The big question is - can antiviral treatment for this subset of patients make the disease worse? This is a very important issue that is now being studied.

This area of research is expanding and deserves more attention. It is hoped that a patient with normal ALT values will at the very least be offered additional liver function tests and a liver biopsy if necessary to establish if severe disease is present and given the option for antiviral treatment.

Common tests used to measure liver function:

Liver function tests include a variety of tests to help gauge the health of the liver. Measuring ALT's does not give a complete picture of liver health. A list of the more common liver function tests follow with the normal values listed. It is important to remember that 'normal values' vary from lab-to-lab and can be influenced by the way the blood samples are handled. Treatment decisions should never be made based on one test and always consult with a medical professional to accurately interpret test results.

Albumin is a blood protein produced by the liver. It is responsible for keeping fluids and salts within blood vessels. If the liver does not produce enough albumin, water retention in the form of swelling occurs usually in the feet and ankles. Normal values: 3.2-5.0g

Alkaline Phosphatase (AP) is an enzyme mainly found in the liver and is responsible for phosphorus metabolism, which delivers energy to the cell. Elevated levels of AP along with elevated GGT indicate that something is wrong in the liver. Normal values: 35-115 IU/L

Aspartate Aminotransferase (AST - formerly called SGOT) is a liver enzyme used for amino acid metabolism. Elevated levels indicate liver injury. Tests for this enzyme and ALT are the most frequently used blood tests to watch changes in liver inflammation. Normal values: 0-42 IU/L

Bilirubin is a waste product produced by the

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Is It or Isn't It?

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immune reaction (cytokines)¹

In many cases, the above symptoms may also be caused by what are called “extrahepatic” illnesses that have been triggered by the hepatitis C virus and your body’s response to it: but there are specific tests for these other conditions, and should you develop one, if your doctor is thorough, he or she should find it.

But what if they don’t? Does that mean you’re making it up? Sad to say, many doctors around the world still perceive hepatitis C as a slowly moving, non-life threatening, and non-disabling liver disease for the majority of those who have it. And as long as this perspective obtains, it’s not going to be easy for you. Some physicians and researchers understand the seriousness of the illness and the effects the viral activity has on many of us, but they are in a minority.

Many hepatitis C groups take an active position with respect to education and advocacy. The Hepatitis C Support project in San Francisco is one, HepCBC in Canada is another. Fighting for your rights and educating physicians when you’re ill is not fun, but if we don’t do it, who will? I encourage you to find a local active support group and to help change the way we are treated. If not for yourself,

then for someone you love.

¹ Bibliographical references can be found in The Advocate’s Guide to Hepatitis C: A Handbook of Symptoms and Their Causes. HepCBC-Hepatitis C Education and Prevention Society, 2000, Victoria, BC. http://www.hepcbc.org/Advocates_Guide.pdf

Hep C & ALTs

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liver. A healthy liver will convert these bile salts into water-soluble substances that are excreted by the body. When the liver is damaged it is unable to convert these bile salts into a water-soluble substances leading into a buildup of toxic yellowish liquid which produces jaundice (yellowing of the skin). This is seen in some acute cases of hepatitis C and in end stage liver disease. Normal values: 0-1.3mg

Gamma-Glutamyltranspeptidase (GGT) is a liver enzyme used in metabolizing glutamate (an amino acid). High levels of GGT may indicate blockage and damage to bile ducts. Normal values: 30-60 IU/L

Platelets are blood cells that help the blood to clot. Low platelet counts indicate liver damage. Platelets counts are also followed closely during interferon therapy. Normal values: 130-400 thousand/MCL

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Good News for HCV+ Patients With Cirrhosis

Results of Pegasys Clinical Trial in HCV+ Patients with Cirrhosis Reported in New Journal of Medicine

By Alan Franciscus
Editor

The results of a phase II/III clinical trial of Pegasys for treating HCV + patients with cirrhosis by Dr. J. Heathcote and others was reported in the December issue of the New England Journal of Medicine.

This trial studied the effectiveness of Pegasys (Roche's Peginterferon alfa-2a) in treating HCV+ patients with compensated liver cirrhosis for 48 weeks with treatment followed by 24 weeks of follow-up. This study is particularly important because this patient population is considered a difficult group to treat with current antiviral medications.

This study measured the sustained virologic response (elimination of HCV at end of 48-week treatment and 24 week follow-up), and biochemical response (normalization of alanine aminotransferase (ALT) levels) and histologic response (improved liver health).

The study enrolled 271 patients worldwide with cirrhosis or bridging fibrosis and randomized into three treatment arms:

1. Interferon (Roferon) - dose: 3 million unit , injected three times a week - 88 patients.
2. Pegylated Interferon (Pegasys) - dose 90 µg, injected once weekly - 96 patients
3. Pegylated Interferon (Pegasys) - dose 180µg, injected once weekly - 87 patients

Ten percent of the patients in this study discontinued therapy because of side effects.

Side effects for all three treatment arms were similarly tolerated. It should be noted that only 56% of study participants were infected with HCV genotype 1 - the most prevalent genotype in the United States and the most difficult to treat with interferon.

The authors of this study concluded that Pegasys 180 µg injected once weekly is significantly more effective than 3 million units of interferon (Roferon) injected three times a week.

The virologic and histologic response rates of patients in this study treated with Pegasys 180 µg are very encouraging and will provide new options for patients with cirrhosis who currently have very few options. For information on Roche clinical trials, call 866-GO-WINGS.

Source: New England Journal of Medicine, December 2000

Results		
Arm # 1	Arm #2	Arm #3
Sustained Virologic Response		
8 %	15 %	30 %
Sustained Biochemical Response		
15 %	20 %	34 %
Histologic Response*		
31 %	44 %	54 %
*184 patients with biopsies before and after treatment.		

NIH Information About the HALT-C Trial for Treatment Non-Responders

This study will test whether long-term antiviral therapy with interferon can prevent liver disease from progressing in patients with chronic hepatitis C infection-a long-lasting viral infection affecting the liver. About 1,200 patients in 10 centers across the United States will be enrolled in this study to determine the best treatment for patients with advanced scarring of the liver who do not respond to short-term interferon therapy. These patients are at the greatest risk of going developing liver cirrhosis, liver failure or liver cancer.

Patient 18 years of age or older with hepatitis C

and advanced scarring who have not responded to previous interferon treatment, either with or without ribavirin, may be eligible for this study.

All patients enrolled in the study will receive interferon injections under the skin once a week and ribavirin by mouth twice a day for 24 weeks. Responders will continue the same treatment for another 24 weeks.

For more information, please contact:
Patient Recruitment Office Bldg 61
10 Cloister Court
Bethesda, Maryland 20892-4754
1-800-411-1222

Study Suggests Possible Clinical Benefit Using Newer HCV Test

A study presented at this year's 51st American Association for the Study of Liver Disease (AASLD) meeting reported on results using a new hepatitis C virus (HCV) test which utilizes a molecular diagnostics technology called "transcription mediated amplification" (TMA). The results of this study showed that more than one-third of the patient samples that tested negative for HCV using the conventional PCR test were actually positive when tested by the new TMA test.

Dr. Stefan Zeuzem of the Zentrum der Inneren Medizin, Frankfurt, Germany, presented results of a study in which 47 patient samples that had previously tested negative for HCV with existing PCR-based assays, were re-tested with the VERSANT HCV Qualitative RNA Assay from Bayer Diagnostics. The results of this new study showed that 36% of patient samples that were negative using the PCR assay were positive by the new TMA test. After being tested with the conventional PCR test, all of these patients had relapsed after treatment was stopped. Dr. Zeuzem speculated that the results may have implications for the treatment of chronic Hepatitis C, such as keeping

patients on therapy longer to avoid relapse. Further research is necessary to confirm these early stage results.

The VERSANT HCV RNA Qualitative Assay, is currently available for Investigational Use Only (the performance characteristics of this product have not been established) in Germany and other parts of Europe. Qualitative testing for HCV using TMA technology is available in the U.S. as a service of the Bayer Reference Testing Laboratory in Emeryville, California.

11/15/00

Reference:

Sarrazin C and others. Detection of residual HCV RNA by transcription-mediated amplification in patients with complete virological response according to PCR-based assays. Abstract 787. Program and Abstracts of the Fifth Congress on Drug Therapy in HIV Infection. October 22-26, 2000, Glasgow, Scotland.

Source: HIV and Hepatitis Treatment Advocates. www.hivandhepatitis.com

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Common Myths

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mately 95 % of patients who have a sustained response 6 months after completion of therapy will have undetectable virus and normal liver enzymes long-term. (4 to 10-year studies) Thus some physicians are now cautiously using the "C" word ("cure").

Myth #9: The chances of responding to treatment are low, so why bother to go through treatment. This is a myth on three levels. First, in some individuals the probability of response is actually quite high. Prediction of response varies among individual situations. Second, we now know that treatment can improve the condition of liver tissue, even if the virus remains. Third, in comparison to HIV in which eradication of the virus does not yet exist, even seemingly low response rates to treatment of HCV are quite encouraging.

Myth #10: The treatment for hepatitis C is chemotherapy. Although interferon is used as treatment for certain cancers, interferon with or without ribavirin is not chemotherapy.

Myth #11: The side effects of interferon plus ribavirin are intolerable. In my experience, most people imagine that treatment will be harder than the reality turns out to be. There are a few exceptions to this, with some people having an unexpectedly difficult time. Conversely, some people find treatment surprisingly easy.

Myth #12: Being a research subject in a clinical trial is like being a guinea pig. Clinical trials are extremely regulated. Research subjects are very closely monitored. Usually quite a lot of information about safety is already known in phase III clinical trials. Clinical trials can be opportunities to try new drugs prior to their availability to the general public.

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Lucinda K. Porter, RN is a research nurse and patient educator at Stanford in the area of hepatology. She cofacilitates 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.

News Briefs

Scientists Replicate HCV Variants in Cell Culture

Until now the biggest stumbling block in HCV research has been that HCV cannot be grown in cell culture. Currently, the only model is the chimpanzee, which is very expensive and severely limits studying HCV life cycle and potential new therapies. Now, an exciting new study published in *Science*, reports that scientists have grown hepatitis C in cell culture.

Dr. Charles M. Rice and colleagues from Washington School of Medicine, St. Louis, identified several HCV RNA elements that can replicate under its own control in cell culture and studied their characteristics.

One of the findings suggests that the HCV nonstructural region NS5A is important for HCV replication in vitro (test tube). If this is proven to be correct it will greatly enhance the ability of scientists to develop new drugs against HCV. This is one of the major breakthroughs in research and has the potential to change the landscape of HCV research.

Source: *Science* 2000, *Reuters* 2000

How Ribavirin Works - "A Genetic Meltdown"

Researchers reported in the December 2000 issue of *Nature Medicine* that ribavirin works by making the hepatitis C virus mutate at such a fast rate that it disables the virus rendering it useless.

It has long been a mystery how ribavirin works on the hepatitis C virus. It does not seem to be effective as a single agent, but when combined with interferon it is effective for up to 45% of patients treated. Now, a study by Sane Crotty, who is a Howard Hughes Medical Institute pre-doctoral fellow at University of California, San Francisco and researchers at Schering-Plough Research Institute have identified how ribavirin works.

It has been theorized that ribavirin blocks viral protein production to stop the replication process of HCV. To test this theory, scientists tried to find out how ribavirin incorporates into the host RNA and see if it interrupts the replication process. This did not prove out. However, the scientists took it one step

further and tested the drug's effect on poliovirus, which has a very fast rate of mutation. What they found was that ribavirin increased the mutation rate so much that the virus started to die.

Understanding how ribavirin works will help researchers develop more effective ribavirin like drugs to treat HCV.

Source: *Nature Medicine*, December 2000

Liver Toxicity Associated with HIV Medications

Two recent reports have described liver toxicity problems associated with the use of HIV medications and the need for careful monitoring of patients taking these medications— especially if a patient is co-infected with either hepatitis B or hepatitis C.

Protease Inhibitors and Liver Toxicities

Reuters Health reported on information presented in the December issue of *Antimicrobial Agents and Chemotherapy* recommending that medical professionals evaluate patients' liver enzyme levels and viral co-infections before initiating protease inhibitor (PI) anti HIV medications.

This study found that in individuals treated with PIs that co-infection with HBV or HCV noticeably increased the likelihood of developing liver toxicities. The researchers also noted that because phase III clinical trials generally excluded people with abnormal liver enzymes, we are seeing more liver related complications from anti-HIV medications since they are now used in the general unselected population. The researchers also stressed the need to monitor patients on PIs for more potential adverse effects.

Source: *Reuters Health*, HIV and Hepatitis Treatment Advocate -www.hivandhepatitis.com

Viramune and Liver Toxicity

In a different article published by HIV and Hepatitis Treatment Advocates, *Viramune* (nevirapine) toxicity was discussed. Increasing reports are surfacing on the potential for liver problems in people taking the non-nucleoside analog reverse transcriptase inhibitor (nNRTI) anti-HIV drug *Viramune*.

A letter was issued to doctor's from Boehringer-Ingelheim \ Roxanne Laboratories at the 5th Interna-

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Fremont

Susan Lear (510) 872-5182

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For Info Call: (650) 367-5998

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Viramune

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tional Congress on Drug Therapy in HIV Infection suggesting that closer monitoring of liver function tests during the first few months of Viramune is advisable for people with a history of liver disease and for women. In another warning the European Medicine's Evaluation Agency (EMA) advised particularly close monitoring of patient's liver function during the first couple of months with Viramune therapy.

It was stressed that even though these liver toxicities were reported, these and other anti-HIV drugs could be used safely as long as patients were carefully monitored.

Source: HIV and Hepatitis Treatment Advocates, www.hivandhepatitis.com

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California Pacific Medical Center
Linda Brooks (415) 202-1504 or (415) 202-1506

Stanford University Hospital
Stanford Liver Research Clinic (650) 724-7057

Quest Medical Research
Dr. Jay Lalezari (HIV/HCV Co-infection trials)
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