

HCV ADVOCATE

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Hepatitis C Support Project

May, 1999

National Hepatitis Congress

by Barry Howe

Thanks to the Hepatitis Foundation International, I was able to attend and participate in the National Hepatitis Congress as a delegate from the Hepatitis C Support Project in Washington D.C. on March 27 through March 19, 1999. The conference was held at Georgetown University and included speakers from the medical professional, Centers for Disease Control (CDC) and National Institutes of Health (NIH), government officials from disability and social security, and patient advocates the United States and Canada.

I arrived on Friday afternoon and during the short cab ride from the airport to Georgetown, I was awestruck by our nation's capitol. Having never been back east, I was overwhelmed by the architecture and sheer grandeur of the buildings, monuments, etc. That evening a few other early arrivals and myself took a short cab ride to the Lincoln Monument and played tourist for a couple hours looking at the sights. A truly remarkable experience!

Saturday was spent meeting with patient advocates and support group leaders from all across the country. I was able

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Treatment Advocate

by Joe Shaw

A recent discussion on an internet news group led me to put together my thoughts on Western vs. Alternative Medicine. Here are two examples of very wrongheaded thinking:

Example One: Western Medicine BAD!

Alternative Medicine GOOD!

Example Two: Western Medicine GOOD!

Alternative Medicine BAD!

Wake up! It's not an either/or thing, they're complementary. There's good to be said for both and there's certainly plenty bad to be said of both. Being on combo treatment doesn't stop us from taking Milk Thistle or other supplements or going to the chiropractor or drinking green tea or practicing meditation? NO! Just as we should question a medical doctor, if we think they're wrong (which, unfortunately isn't rare), we should question alternative therapies as well. Our well-being depends on using our critical thinking skills (with the few brain cells left) to decide what's best for us.

Neither Western or Alternative Medicine have all the answers--in fact--neither one have that many answers at all. If you look at the plethora of studies that come out every day on health related issues in the media--you will find that most of them boil down to this essence: If you eat a balanced diet and exercise moderately on a regular basis, you have a reasonable chance at being healthy. DUH!

That's all Western Medicine and Alternative Medicine have been able to teach us: common sense. So when we criticize a doctor's treatment decision for a person or find something critical about an alternative therapy--we do so because we ought to get all the info we can to make our own informed decision. We all know that there are plenty of unscrupulous people out there--both medically trained western doctors and alternative health care practitioners--who are only looking at their own financial interests and exploiting the sick and suffering. Modern day carpetbaggers, hucksters and snake oil salesmen. We ignore this at our own peril.

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HCV ADVOCATE

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INFO UPDATES

Diabetes and Hepatitis C Virus: Is There a Correlation?

By Lynn Shawn

The Hepatitis Place - <http://www.hepplace.com>

The hepatitis C virus (HCV) infection is known to be associated with a variety of extra-hepatic manifestations in many individuals. Several recent studies have viewed diabetes mellitus as one of the extra-hepatic disorders associated with HCV.

In general, patients with liver disease are known to have a higher prevalence of glucose intolerance. Most patients with cirrhosis of the liver have detectable insulin resistance. This correlation has led to several preliminary studies correlating hepatitis C virus and diabetes mellitus. The results of these studies show indications that the hepatitis C virus (HCV) infection may be an additional risk factor for the development of diabetes mellitus.

Simo's study demonstrated that diabetes mellitus is more frequent in patients with chronic hepatitis C than in liver disease due to other causes. (Simo) Additionally, the data from another study has suggested that hepatitis C virus infection may actually be an additional risk factor for the development of diabetes mellitus. (Mason)

Simo's study examined patient liver function and found that 72.3 percent of the anti-HCV positive patients presented with elevated liver function tests. (Many times, diabetic patients have abnormal liver function tests which is often due to fatty infiltration of the liver.) Simo's study also investigated the influence of several epidemiological and clinical factors on HCV infection. The study concluded that "a higher prevalence of HCV infection was observed in diabetic patients in comparison with blood donors ... The lack of any particular epidemiological factor for HCV infection in our diabetic population suggests that HCV may have a direct role in the development of diabetes". Researchers of Simo's study now believe that diabetic patients with an abnormal liver function test should always be tested for hepatitis C. (Simo)

Mason's study concluded that there was "a relatively strong association between HCV infection and diabetes". The data from this study also determined that diabetics have an increased frequency of HCV infection, particularly with genotype 2a". Furthermore, Mason's study suggested that it is possible that HCV infection may serve as an "additional risk factor for the development of diabetes, beyond that attributable to chronic liver disease alone." (Mason)

When 20-year renal transplant recipients were studied for the impact of a hepatitis B or hepatitis C infection, it was found that diabetes mellitus was significantly more common in those with than without viral hepatitis (11/15 vs. 10/39). (Younossi)

Following these correlations with hepatitis C and diabetes, an article by Ramesh Prasad continues on to report that clinicians should be aware of the possible occurrence of Type I membranoproliferative glomerulonephritis and cryoglobulinemia in patients with diabetes mellitus and HCV infection. (Ramesh Prasad) Other studies have already correlated these additional extra-hepatic manifestations in HCV infection as well. (Fayyazi, Kerr)

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Clinical Research and J.Q. Patient

by *Lin Maslow,, RN - Clinical Research Nurse*

Research. Where would we be without it? Where are we going with it? Of the many questions one might have about clinical research, the most important are the ones you ask yourself when deciding whether or not to participate in a trial. This brief look inside the world of medical research will help you get the answers you need to make the right decision for yourself.

In the United States, the Food and Drug Administration (FDA) APPROVES AND regulates clinical trials. Though there have been recent changes in FDA policies, especially those regarding inclusion of pediatric populations, increased women-oriented studies and a streamlined approval process, the basic concepts of conducting scientifically valid and clinically useful investigations are fairly standard. Key concepts will be underscored.

Briefly, the scenario is as follows: A company develops a product, whether it be a medication, device, process, etc., and applies to the FDA to test the product in humans. The company is referred to as the Sponsor. In order to make it easier, let's say the product will be a new drug. Once the Sponsor has collected enough data regarding the drug's chemical properties and has studied the drug in animals to determine if it has pharmacological value and any toxicities, the FDA will consider the application for human testing. The Sponsor then contracts with physicians who are known as Investigators. Research may be conducted in a variety of sites. These include large teaching hospitals, outpatient clinics and private doctor's offices. The trial may take place at once site or be a multi-center trial, with several Investigators across the country or the world.

There are three Phases of clinical trials. An FDA table is provided here to simplify the definitions and qualities of each phase:

	# of Patients	Length	Purpose	% of Drugs Successfully Tested
<u>Phase 1</u>	20-100	Several months	Mainly Safety	70 %
<u>Phase 2</u>	Up to several hundred	Several month to 2 years	Some short-term Safety buy mainly Efficacy	33%
<u>Phase 3</u>	Several hundred or thousand	1-4 years	Safety, Dosage, Efficacy	25-30 %

Safety, Tolerability, Efficacy (effectiveness), and Dosing/Administration are the major areas of focus in clinical research. Trials in each phase are designed to assess how well a drug meets these criteria. Phase I trials involve healthy subjects so that a person's illness is not a factor in determining if the drug is safe. Phase 2 trials are conducted by seeking people that have the condition that the drug is supposed to treat. It is important to remember that drugs are not usually "cures," but rather aim at relieving symptoms or changing physical conditions, such as lowering blood pressure.

Efforts are made to reduce biases on the parts of the investigators in a number of ways. Some important design elements that help assure objectivity are Controlled Trials, Randomization and Blinding. Many trials are "controlled" in that they have two groups of similar patients, all having the same disease or condition. Ideally, these people should also be similar in age, weight, overall health status, etc. One group will receive the experimental treatment, thus earning the title of Treatment Group. The other group, the Control Group, will receive either no treatment, a placebo (something inactive that resembles the experimental drug), an already proven effective medication, or a different dose of the experimental drug.

Randomization is how Investigators and Sponsors attempt to make the Control and Treatment Groups as similar as possible. Another technique is to actually match patients by several attributes, but that is tedious, difficult and limiting. Blinding is another method used to eliminate Selection Bias, in which healthier patients are chosen to receive the study

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Clinical Trials - continued from page 3 -

drug. These patients may be more likely to have better outcomes, thus skewing or overrating the results. We wouldn't want that, now would we? Studies can be "single-blinded," where the patients do not know if they are in the Treatment or Control Group. In "double-blinded" study, neither the patient, the Investigator nor the Sponsor's analysts know which group the subject is in. Assigning patients randomly and using blinded studies, when the number of participants is large enough, can provide similarity in the groups and also removes the responsibility from the Investigator and Sponsor.

Once an Investigator agrees to participate in a Sponsor's trial, there are several other people involved. Understanding the roles of these people may help in knowing who to ask questions and what to expect. The Sponsor will either run the trial "in-house," using its own employees to coordinate and run the study, or they will contract in out to Contract Research Organization (CRO). This is an agency that specializes in running clinical trials. An individual, at either the Sponsor or the CRO, who is the liaison to the Investigators and their nurses and staff is called a Clinical Research Associate (CRA). They are responsible for keeping the Investigators informed of changes to the study, information regarding the product, and overall operation of the study.

How can you fit into this heavily regulated and impersonally oriented world of subjects and risks and benefits? If you are not receiving care at a major teaching hospital, you should call the department that specializes in the disease or condition you have. Inquire about active research studies going on. Also, some are advertised in free weekly newspapers and outside clinics. Ask your own doctor about them and discuss any trials you are considering with your primary health care provider. If the doctor or nurse practitioner does not know about the trial, ask them to find out about it for you, or ask their office nurse for assistance. In this way, many doctors practicing in the community are educated to type and variety of research going on that may benefit their patients.

Consider what phase the trial is in. Maybe waiting for a Phase 3 trial is more appropriate to your situation, maybe not. Find out if the trial involves inpatient stays at a hospital or research unit, how many outpatient visits are involved. Are there any specimens you will have to collect at home and bring in? You should be told of all the lab draws, procedures and costs associated with the study. Research subjects have rights under the law and these should be explained to you and a copy of the Consent Form and Experimental Subject's Bill of Rights should be given to you. Informed Consent, in which the study is thoroughly explained to the patient by the Investigator or Study Nurse, and the patient is given an opportunity to ask questions, is an important legal and medical convention that tries to assure that people understand fully the risks and benefits of participating in a particular trial.

By understanding how studies are designed and conducted, you can narrow down your search for ones that will be more appropriate for you. Ask a lot of questions. Also remember that many studies do not necessarily offer any benefit to any individual, but rather may help many others in the not too distant future. There is something important and special to be said of those who volunteer their time and possibly tissue to the advancement of science and medicine

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HealthWise

BASIC HEPATITIS C INFO

Here is some basic information related to chronic infection with hepatitis C. This information was compiled because the members of the Redwood City support group expressed the hope that we could find a way to help those who have been newly diagnosed. Many of us have been frustrated or afraid, especially during the period that follows the initial diagnosis. Although this may sound trite, this does pass. Hopefully this information will assist you in your process of learning how to live with this virus. May you live well.

Do's

- Protect yourself from hepatitis A and B – get immunized (unless you have been previously infected)
- Join a support group
- Educate yourself
- Find satisfactory medical care
- Keep copies of your medical records, especially current lab and biopsy results
- Exercise
- Get plenty of rest
- Learn to manage stress
- Practice moderation
- Know what you are ingesting – everything passes through the liver
- Discuss vitamin, mineral, and herbal supplementation with your doctor
- Drink generous amounts of water
- Notify your dentist and health care practitioner that you have hepatitis C
- Carry info in your wallet or purse listing your medications along with your doctors' names, address, and phone numbers
- Use adhesive strips to cover wounds
- Use care when disposing of sanitary products
- Use barrier contraception when appropriate
- Practice careful breast care when nursing
- Floss your teeth
- Label your toothbrush, razor, and nail clippers – remind others not to use
- In spite of all of the above, laugh and enjoy life

Don'ts

- Do not drink alcohol
- Do not exceed 2000 mg of Tylenol daily
- Do not share drug paraphernalia
- Do not take iron supplementation or multi-vitamin with iron without discussing it with your doctor
- Do not donate blood
- Do not jump into immediate treatment without weighing all of your options
- Do not obsess over whether or not one can pass this to others – just do the best you can and use common sense

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For more information about hepatitis C, please contact the following organizations:

- American Liver Foundation 800-223-0179 <http://www.liverfoundation.org/>
- Hepatitis Foundation International 800-891-0707 <http://www.hepfi.org/>
- Hep C Connection 800-522-4372 <http://www.hepc-connection.org>

Now on with the rest of the treatment information and other assorted Hepatitis C odds and ends. Just remember: this info comes from the internet and we can't vouch for its accuracy. If you'd e-mail me at joesha@yahoo.com, I will try to help you get more information on any of the items in this column.

Some Facts About Hepatitis C

- * Caring for Hepatitis C patients costs at least \$600 million each year, experts say.
- * Preliminary results in a study of IV drug users at the New York Academy of Medicine found that only 7% had the HIV virus, but 50% had Hepatitis C.
- * At risk to contract Hepatitis C: those who ever injected or snorted drugs—even once.
- * At least 28,000 new cases of Hepatitis C are diagnosed each year.
- * About 4 million Americans have Hepatitis C.
- * One third of all liver transplants are done on end stage Hepatitis C patients.

Congressman Seeks Hearings on Schering-Plough Marketing of Rebetron -Spurred by angry patient advocates, U.S. Rep. Frank Pallone Jr. (D-New Jersey) plans to seek congressional hearings into the controversial marketing of a Hepatitis C medication sold by Schering-Plough Corp. At issue is the pricing and packaging of Rebetron, which is actually a kit that includes two products -- the drug maker's own injectable interferon (Intron A) and a pill (Ribavirin) that it licensed exclusively from another company. At issue is that some patients would like to combine the pill with other brands of interferon currently available. As a result, many advocacy groups are upset that Schering-Plough won't unbundle—or sell separately—the two drugs in the kit. The outcry has also ensnared the Food and Drug Administration. Patient groups worry other drugs needed to treat different illnesses will one day be subject to similarly restrictive marketing. *Source: Bergen (New Jersey) Record*

Zadaxin Approved In Vietnam For Hepatitis B, Singapore For Hepatitis C -SciClone Pharmaceuticals' Zadaxin thymosin alpha 1, has been approved in Vietnam for the treatment of hepatitis B. The company also reported that Singapore has expanded its Zadaxin marketing approval to include the treatment of hepatitis C. Zadaxin now is approved for marketing in 12 countries. It is approved for the treatment of hepatitis B in Cambodia, the People's Republic of China, Kuwait, Myanmar, Peru, the Philippines, Singapore, Venezuela and Vietnam; for the treatment of hepatitis C in Cambodia, Myanmar, the Philippines, Singapore and Venezuela; and as an influenza vaccine adjuvant in Argentina, Italy and Mexico. Zadaxin plus alpha interferon is used as a safer combination therapy for hepatitis C than alpha interferon plus other drugs. The combination of Zadaxin plus alpha interferon for the treatment of hepatitis C has doubled the efficacy of alpha interferon alone without increasing the risk of side effects or toxicities.

Source: Company Press Release

The effects of a high dose, short course of interferon on hepatitis C -To shorten the period of interferon (IFN) treatment for chronic hepatitis C, this study investigated the clinical efficacy of a regimen using a higher dose and a shorter treatment period. Fifty chronic hepatitis C patients who were hepatitis C virus (HCV)-RNA positive and who were histologically diagnosed as having chronic hepatitis, took part in the study. Virus levels were measured before and 2 weeks after starting the treatment. Natural IFN alpha, 10 MU, i.m. was administered daily for 2 consecutive weeks and then three times per week for the subsequent 14 weeks (total dose 560 MU). Patients who were HCV-RNA negative at the completion of the therapy and 6 months later, were evaluated as sustained responders (SR; 32%). Those who were not HCV-RNA negative at the two time points were evaluated as non-responders. Low virus level and HCV-RNA genotype 2a/2b were the predictors for good prognosis, whereas the numbers of nucleotide differences and clone differences in HVR were not. Sustained responder patients became HCV-RNA negative 2 weeks after starting the treatment at a significantly higher rate, whereas no non-responder patients were HCV-RNA negative at that time. The SR rate (32%) was equivalent to those reported in previous 24 week treatment studies. This IFN therapy using a higher dose and a shorter period was useful. *SOURCE: Journal of Gastroenterology and Hepatology 1999 Jan*

How soon can a virological sustained response be determined after withdrawal of interferon therapy in chronic hepatitis C? -Hepatitis C virus (HCV)-RNA status and alanine aminotransferase (ALT) levels determined shortly after interferon (IFN) therapy in patients with chronic hepatitis C do not predict long-term response. To determine the virological

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sustained response after the completion of IFN therapy, HCV-RNA was measured at the end of treatment and at 3-4 months and 12 months after the completion of therapy in 537 patients with chronic hepatitis C. In 347 patients, HCV-RNA was not detected by polymerase chain reaction (PCR) at the completion of therapy and 175 of these patients (50%) were still PCR negative 12 months later. In contrast, of the 180 patients who were HCV-RNA negative at 3-4 months after completion of therapy, 99% remained negative at 12 months. Normal ALT levels were found in 80, 93 and 95% of patients who were negative for HCV-RNA either at the end of treatment or at 3-4 months and 12 months after the completion of therapy, respectively. Of patients who were HCV-RNA positive, 30, 15 and 20% were found to have normal ALT levels at the same respective time points. To determine a sustained virological response shortly after the completion of therapy, serum HCV-RNA was serially examined in 66 patients negative for HCV-RNA at the end of therapy. Of 31 patients who relapsed, HCV-RNA reappeared in 33, 80, 97 and 100% of patients by 1, 2, 4 and 8 weeks after the completion of therapy. In conclusion, a sustained virological response could be determined with 97 and 99% certainty at 4 weeks and at 3-4 months after the completion of therapy, respectively. *SOURCE: Journal of Gastroenterology and Hepatology 1999 Jan.*

Medical Web site targets Spanish speakers -Spanish-language medical information on the Internet - A popular medical Web site has begun targeting millions of Spanish-speaking people who have Internet access. The Healthfinder site, with links to 5,000 other health-related Web pages, will give Spanish speakers news and information on issues such as HIV (VIH in Spanish), hepatitis and alcoholism. The web address is : <http://www.healthfinder.gov/justforyou/espanol/default.htm>

People Living With Hepatitis Share Their Coping Strategies -Fifty-seven members of the Hepatitis Information and Support List shared how they cope with chronic hepatitis on a daily basis. They were asked to respond to the following topic: "Three (3) things I do to improve my physical or mental health". The top 10 responses are grouped and tabulated below. Some respondents listed more than 3 things:

- Eat healthily (22 responses)
- Exercise-- as energy allows, walking, yoga, swimming (21)
- Don't sweat the small stuff-- positive thinking, avoid stress (19)
- Seek spiritual help-- prayer, religion (14)
- Learn about hepatitis-- take active role in treatment (12)
- Take naps-- get plenty of rest (11)
- Take milk thistle (10)
- Don't let hepatitis control my life-- pretend I don't have it (10)
- Take one day at a time (10)
- Stay busy-- job, family, hobbies, travel (9)

Phone Company Offers Discounts to People With Disabilities -Some good news for those of us in the US on disability, welfare or SSI. The Bell phone companies offer a price reduction, about \$9 per month. What you have to do is call their residential business office and ask them about the low income program. You'll have to give them your phone number and your Social Security number. They'll ask you about bills and services you pay for - rent, garbage, sewer, even cable. They'll then run it through there system while you're on hold, it only takes about 30 seconds.

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to put faces with names and learn what other groups are doing. A definite bond between all of us developed and in a very short time it seemed we had known each other for years. On Sunday we heard from a wide range of speakers on topics dealing with Hep C. I can't report I heard anything earth shattering; however, there are many dedicated professionals working on new treatment. Research on stopping the formation of fibrosis and actually reversing the process seems hopeful in the initial stages. This particular aspect of HCV treatment research really enlisted my attention, because quite frankly, my illness has progressed to the fibrosis - stage three phase. I was of course at once a captive audience, because those clinical trials which focused upon reversing the damage caused by fibrosis would be miraculous to me. From all I read, fibrosis seems to lead directly to cirrhosis. These new clinical trails appear promising and offer all of us hope. Seeing the hundreds of other delegates contributed to the renewed appreciation for the cause.

No article on the National Hepatitis Congress would be complete without mention of Thelma King Thiel. She founded HFI and is the driving force behind their work. The "Liver Lady" as she refers to herself is a dynamite woman. I must say the notable efforts of this remarkable HCV advocate have not gone unnoticed. I hope in the near future to find similar reserves of energy within myself

I can't emphasize more strongly how involvement within HCV oriented activities can lessen the loneliness and anxiety all of us undertake upon learning how to survive this serious illness. Support groups offer new friendships and opportunity to share your own hopes and fears. Somehow having new friends lessen the loneliness and pain we all know too well.

Together we can make a real significant contribution to our collective health and recovery.