



A NEWSLETTER FOR THE HALT- C TRIAL

# HALT-C NEWS

Hepatitis C Antiviral Long-term Treatment against Cirrhosis

January 2002

Volume 2, Number 1

## A WESTERN MD'S VIEW OF THE USE OF HERBS, SUPPLEMENTS, AND ALTERNATIVE THERAPIES BY PATIENTS WITH HEPATITIS C

Excerpts from: *Living with Hepatitis C: A Survivor's Guide*, 3<sup>rd</sup> Edition, Hatherleigh Press, Inc.  
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According to the *Nutrition Business Journal*, supplements were a \$15.4 billion dollar industry in 1999. Despite the lack of supporting data, the use of these therapies has gained widespread acceptance among patients with hepatitis C. Several factors seem to account for this phenomenon: a history of lack of effective therapies for liver disease in general; incompletely effective treatment for hepatitis C; a general attitude that, "It can't hurt me, and maybe it'll help"; and the relatively mild and slowly progressive nature of hepatitis C. Herbs have been used to treat illness since time began. In fact, many modern pharmaceuticals were discovered in natural sources. Aspirin originally came from the bark of the white willow tree. Cyclosporin, the miracle drug that suppresses the immune system and makes liver transplants possible, was found in a fungus growing in the soil of a plateau in southern Norway.

Quality control of potency and contaminants is a problem. In 1998, California investigators found that "nearly one-third of 260 imported Asian herbals were either spiked with drugs not listed on the label or contained lead, arsenic or mercury." In addition, herbs can interact with other medications you may be taking. For example, St. John's wort, a popular herbal antidepressant, recently has been found to decrease levels of life-sustaining cyclosporine in heart transplant patients.

Here's a list I give to my patients of herbs that have been documented to cause liver problems ranging from hepatitis to liver failure:

Atractylis Gummifera	Germander (mint family)
Azadirachza indica	Tussilago farfara (Peppermint)
Berberis vulgaris	Valeriana officinalis (Valerian, Asfetida, Hops, Gentian)
Calliepsis laureola	Viscum alba
Cassia angustifolia (Senna)	Mistletoe
Crotalaria	Margosa oil
Corydalis	Mate tea
Hedeoma pulegoides	Gordolobo yerba tea
Heliotropium	Pennyroyal (squawmint) oil
Larrea tridentata (Chaparral bush, Creosote bush, Greasewood)	Senecio
Lycopodium serratum (Jin Bu Huan)	Heliotropium
Mentha pulegoides	Chelidonium majus (greater celandine)
Sassafras albidum (Sassafras)	Kava, and "a variety of Chinese herbal mixtures (artemisia, hare's ear, chrysanthemum, plantago seed, gardinia, red peony root, etc.)".
Scuteileria (Skullcap), Stephania	
Symphytum officinale (Comfrey)	
Teucrium chamaedrys	

In my opinion, if you have a chronic liver disease, such as hepatitis C, you should avoid herbs that have not been tested in controlled studies, especially if you are being treated with interferon. Any substance, such as herbs or over-the-counter medications, may interact with drugs you are taking. Always discuss medicines and herbs with your physician.

*See inside for the latest  
news about HALT-C  
enrollment.*

# ISSUES OF INTEREST

Current topics from experts in the field

## MEASURING FUNCTION OF THE LIVER

By Gregory T. Everson, M.D.

University of Colorado School of Medicine

Many patients with chronic hepatitis C ask their physicians, "Is my liver really that bad? I don't hurt, I have no pain. How much liver do I have left?" Unfortunately, symptoms, physical examination and standard blood tests (bilirubin, albumin, AST, ALT, alkaline phosphatase, GGT) are unable to provide sufficient information for your doctor to answer this question. For this reason, the HALT C clinical centers at the University of Colorado, Medical College of Virginia, and University of California-Irvine are conducting a study of a battery of quantitative tests designed to directly measure liver function (QLFTs). The specific QLFTs under investigation are described below.

Patients participating in HALT-C have significant scarring of their liver and are at risk for progressive loss of liver function, liver failure, and complications of liver disease. Patients without fibrosis cannot participate in HALT-C, but are also unlikely to suffer loss of liver function or its clinical consequences. Despite the fact that patients enrolled in HALT-C have liver damage and scarring, symptoms, physical examination, and standard blood tests cannot distinguish between those patients who have diminished function and those who have normal or near normal function. Thus, patients enrolled in HALT C are an ideal group for the use of QLFTs to measure liver function.

Knowing how the liver works will help you understand why things go wrong when hepatitis C attacks it and scar tissue (fibrosis) forms. This knowledge will also help you understand the rationale behind the QLFTs. Remember, liver disease affects your blood, bile, lymph, immune system, and chemical functions of the body.

As the liver becomes progressively injured, scar tissue builds up, making it difficult for blood from the portal vein and hepatic artery to flow through the liver. The blood tends to back up into other abdominal vessels and the spleen. Abdominal vessels become engorged and new vessels form, called varices or venous collaterals. One QLFT clearance test and SPECT liver imaging measure portal blood flow to the liver and determine the degree of backup of blood into abdominal vessels and spleen.

Processing of medications may also be impaired if your liver is severely damaged, and your doctor may need to adjust the doses of your medications. When fibrosis and cirrhosis impair liver function, metabolism is slowed and the ability to clear the blood is reduced. Certain QLFTs measure liver metabolism.

Your liver acts as a chemical powerhouse—building the substances you need for life and neutralizing or safely dumping harmful material. In fact, your liver performs more than 500 complex chemical functions! For example, when you eat carbohydrates (potatoes, pasta, and other starches), your body breaks them down into glucose. You need glucose for energy, but because of your liver, you don't have to eat carbohydrates all day long. Instead, the liver stores glucose as glycogen. When you need a burst of energy, your liver turns glycogen back into glucose and sends it through the bloodstream to your body. Galactose elimination measures the ability of the liver to clear sugar from the blood and process it for storage.

**Table of Specific Quantitative Tests used in the HALT-C QLFT Study**

Test	Samples	Assay
Caffeine clearance	Saliva	HPLC
Antipyrine clearance	Saliva	HPLC
MEGX generation	Blood	HPLC
Methionine metabolism	Breath	Mass Spectrometer
Cholate shunt	Blood	GC/MS
Galactose elimination	Blood	Spectro-photometric
SPECT Liver Scan	Gamma Counter	Nuclear Medicine Imaging

### Potential Importance of the QLFT Study

**Predicting Prognosis.** As stated above, patients in the HALT C Trial have significant fibrosis but lack biochemical or clinical evidence of deterioration. Standard blood tests that are normal or near normal, do not accurately reflect hepatic function or reserve, and cannot predict which patients will deteriorate in long-term followup. In contrast, QLFTs assess function and reserve even in patients with normal standard tests, and, therefore, can stratify potential for risk in patients in the HALT- C study. One of our primary aims is to define the ability of each and every

*Continued on next page.*

**(Measuring Function of the Liver continued.)**

QLFT to predict which patients in the HALT-C Trial will develop clinical complications over the followup of 4.5 years.

**Measuring Effect of Treatment.** The primary goal of HALT C is to determine whether long-term maintenance therapy with pegylated interferon alfa-2a (Pegasys) will slow or prevent disease progression. QLFTs will be performed in each participant every two years. The change in QLFTs will be compared between patients randomized to maintenance treatment and those randomized to no therapy. Another of our primary aims is to determine whether QLFTs are useful in this long-term clinical trial of treatment of chronic hepatitis C with pegylated interferon alfa-2a (Pegasys) to measure benefit.

**HALT-C ENROLLMENT NEWS**



As of December 31, 2001 a total of 602 patients have been entered into the Lead-in Phase of the HALT-C Trial. Of these patients, 207 entered the Randomized Phase of the trial. The chart at the bottom

of the page shows enrollment numbers over the past 12 months.

**PATIENT'S CORNER**

**TIPS FROM FELLOW PATIENTS!**

- ✓ Pay attention to your energy level. You need extra rest, especially the day after your injection. I clear my calendar every Wednesday so I can get extra rest. VNG
- ✓ When I am suffering from body aches and pains I use copious amounts of Baththerapy Bath Salts in a hot bath. The aches are lessened, and I don't have to take any pain medication. VNG
- ✓ Drink lots and lots of water. MAT

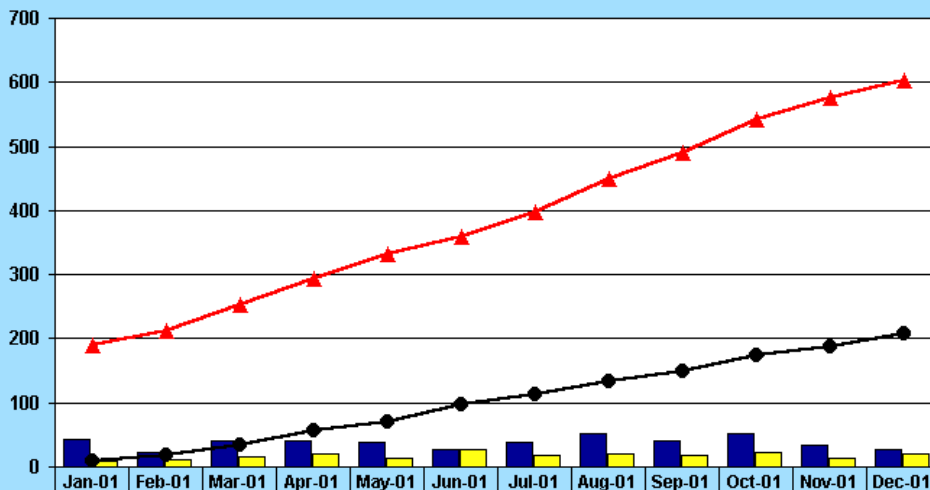


*Thanks to the patients at University of Colorado for these great tips!*

**HALT-C Enrollment Chart**

Jan. - Dec. 2001

■ Pts. Enrolled by month  
■ Pts. Randomized by month  
▲ Total pts. enrolled  
● Total pts. randomized



	Jan-01	Feb-01	Mar-01	Apr-01	May-01	Jun-01	Jul-01	Aug-01	Sep-01	Oct-01	Nov-01	Dec-01
Pts. Enrolled by month	44	22	41	41	39	26	38	53	41	52	33	26
Pts. Randomized by month	8	11	16	21	14	26	17	20	17	23	14	20
Total pts. enrolled	190	212	253	294	333	359	397	450	491	543	576	602
Total pts. randomized	8	19	35	56	70	96	113	133	150	173	187	207

**MEET THE STAFF FROM...  
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**Coming next Issue:  
The staff from Massachusetts General  
Hospital, Boston, MA**

**About the University of Colorado  
Health Sciences Center**

Located in the residential heart of Denver, the University of Colorado Health Sciences Center encompasses the Schools of Medicine, Nursing, Dentistry and Pharmacy and the Graduate School. Its widely renowned cluster of health sciences institutions includes two teaching hospitals, University of Colorado Hospital and Colorado Psychiatric Health, the NCI-designated University of Colorado Cancer Center and a constellation of research and treatment institutions listed among the most prestigious in the country.



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The HALT-C News is a publication of New England Research Institutes and is published 4 times a year.

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