HCV ADVOCATE

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HealthWise

NIH Conference on Complementary and Alternative Medicine in Chronic Liver Disease

Lucinda K. Porter, RN
LporterRN@Rocketmail.com

An important and unique meeting relevant to those with chronic hepatitis C (HCV) infection, entitled “Complementary and Alternative Medicine in Chronic Liver Disease”, was held this August at the National Institutes of Health (NIH) Conference Center in Bethesda, Maryland. The sponsors included the National Institute of Diabetes and Digestive and Kidney Diseases NIDDK, the National Center for Complementary and Alternative Medicine, NCCAM, the Office of Dietary Supplements, the NIH,

continued on page 2 -

INSIDE THIS ISSUE

HCV ADVOCATE

Alan Franciscus – Founder / Editor
Russell Keimer – Co-editor
Hepatitis C Support Project - A Tides Center Project
P.O. Box 427037
San Francisco, CA 94142-7037
Helpline: (415) 834-4100
Email: SFHEPCAT@MSN.COM

Treatment Advocate

Joe Shaw

There's a lot of important stuff out there since the last column, so I won't waste too much of your time. Let's just get to it. By the way, I only have three interferon shots left! I will give a full reporting next month.

Low selenium intake may raise risk of liver cancer - Individuals infected with the hepatitis B virus are at increased risk for liver cancer, and a similar risk has been suggested for hepatitis C. In a report published this week, researchers in Taiwan suggest that low blood levels of the element selenium may be linked to the increased risk of liver cancer in patients infected with these viruses.

The association was most striking among cigarette smokers and among subjects with low plasma levels of (antioxidants such as) retinol or various carotenoids," report Dr. Ming-Whei Yu and colleagues at National Taiwan University, Taipei, in the August 15th issue of the American Journal of Epidemiology.

According to previous studies, selenium boosts immune system function and helps inhibit cancerous cell changes in liver cells exposed to known carcinogens.

The Taiwan team examined the blood selenium levels of over 7,000 men chronically infected with hepatitis B, hepatitis C, or both during the years 1988 to 1992. Sixty-nine subjects developed liver cancer during the study period.

Yu and his colleagues report that selenium levels were "significantly lower" in those who developed liver cancer compared with those who did not develop cancer.

According to the investigators, a previous study has suggested that vitamin E and selenium supplements taken in combination resulted in a 13% reduction in cancer mortality in a population with high rates of esophageal and stomach cancer. The effectiveness of this nutrient 'combo' in fighting liver cancer ``merits further study," the authors conclude. Recommended daily dietary allowances (RDAs) for selenium are 70 micrograms for men and 55 micrograms for women. Foods rich in

continued on page 3 -

HealthWise - continued from page 1-

and the American Association of Naturopathic Physicians. Hepatitis Foundation International's presence was evident with Thelma Thiel's recent appointment to the Advisory Council of the National Institute of Allergies and Infectious Diseases. The American Liver Foundation also sent representatives and distributed a position paper supporting future research in complementary and alternative medicine (CAM) for liver diseases.

To those who value both holistic and allopathic (or standard "Western") medicine, this was an historic event. Practitioners from varied disciplines gathered to share their experiences. These included allopathic physicians (MDs), naturopathic physicians (NDs), PhDs from a variety of disciplines, and pharmacists. There were representatives from the NIH, the Food and Drug Administration (FDA), the Center for Disease Control and Prevention (CDC), the botanical industry, and university research centers. Prestigious speakers hailed from nearly every continent. One evening was devoted to hearing from patients with liver disease. The significance of this event was the exchange of ideas, research, and shared interests around a common theme: CAM and chronic liver disease.

The aims of the workshop were: 1) to assess current knowledge on the treatment of chronic liver diseases with CAM, focusing on the available scientific evidence regarding efficacy and safety; and 2) to identify and prioritize needs that will more fully define the potential for efficacy and safety of CAM for treatment or amelioration of liver diseases[1] It is impossible to adequately describe key points from all of the details of this conference. Hopefully, by outlining some of the presentations, I can convey a general sense of how the workshop goals were met.

Leonard Seeff, M.D. of NIDDK eloquently opened the proceedings. He set the stage by stating, "given the extraordinary widespread use of 'alternative' remedies, the intense faith displayed by many users, and by the fact that current 'conventional' treatment is not yet a panacea, it is incumbent on the medical scientific community to give proper consideration to the views and anxieties expressed by the public on this issue." Seeff emphasized the need to use a scientific approach to confront this problem and reviewed the goals of the workshop.

The next speaker was Richard Nahin from NCCAM. He offered an encouraging perspective, supported by the fact that in a relatively short time, the Office of Alternative Medicine (OAM) has been elevated to a National Center (NCCAM) along with a substantial increase in its budget.[2]

A common theme in many of the subsequent presentations elucidated the complexities of studying the use of botanicals for medical treatment. This was well summarized by Edward Alstat, RPH, ND of the Eclectic Institute. He provided a picture of an echinacea plant (Echinacea purpurea) as well as a bottle of echinacea supplement. He stated that the plant is not identical to the products found on the shelves. Using an analogy, he reminded us that a grape is not the same as a raisin, or wine, or grape juice, or a grape leaf. If one were making muffins, one would not substitute wine for raisins. Consequently, one needs to understand what is useful and for what purpose. For instance, milk thistle is a well-known botanical substance often used for treatment of liver diseases. When using this plant, does one used the whole plant, the roots, the stem, or the flower? Should it be fresh, dried, raw, or cooked? When the plant is harvested, as well as where it is grown, also may alter its potency.

Given these limitations, it makes it difficult to study botanicals in a

continued on page 4

Treatment Advocate - continued from page 1 -

selenium include fish (particularly tuna), asparagus, Brazil nuts, meat, poultry, and bread.
SOURCE: American Journal of Epidemiology 1999;150:367-374.

2.7 Million Americans May Have Hepatitis C - At least 2.7 million Americans carry the hepatitis C virus, making it the most common blood-borne infection in the United States, a study found. The study from the Centers for Disease Control and Prevention in Atlanta represents the first look at the prevalence of hepatitis C in the United States. The estimate was published in the New England Journal of Medicine. ``This is what we consider a conservative estimate," said Dr. Harold S. Margolis of the CDC. ``This is everyday Mr. and Mrs. American who live in a household. This doesn't include the homeless and the prison population. The number could be higher."

Editor's note: The homeless and the prison population account for a very large proportion of people infected with HCV. As an example it is estimated that there are 63,500 people in the California Prisons that are infected with HCV.

Ocular complications with high-dose interferon alpha in chronic active hepatitis -
PURPOSE: Interferon alpha, which is used to treat various systemic disorders, has many reversible side-effects involving various organ systems. In this study, chronic active hepatitis patients undergoing interferon alpha therapy were followed with regard to the ocular side-effects.
METHODS: Thirty-six patients with chronic active hepatitis undergoing subcutaneous interferon alpha therapy for 1 year were enrolled. Complete ocular examination and photographic documentation were performed at baseline of the therapy and monthly thereafter.
RESULTS: Trichomegaly was noted in 2 (6%) patients. Fifteen patients (42%) were found to have retinopathy with cotton wool spot formation and splinter haemorrhages.
CONCLUSIONS: These findings emphasise the need to monitor these retinal complications, which may result in loss of vision in patients receiving interferon alpha therapy.

Interferon retreatment in chronic hepatitis C: which patients to choose, and what schedule to use -
OBJECTIVE: To evaluate the results of a large cohort of non-responder or relapsing responder patients with chronic hepatitis C retreated with various schedules of interferon (IFN).
METHODS: Our study included 276 patients (158 non-responders and 118 relapsing responders) who underwent IFN retreatments. Among the non-responder group, 158 patients underwent further courses of IFN. In particular, 108 patients underwent one course of IFN retreatment, 40 patients underwent two courses, eight patients underwent three courses, and two patients underwent four courses. Regarding the relapsing responder group, the 118 patients were retreated with the same dosage for varying periods. In particular, 50 patients were treated for 6 months, 43 patients for 12 months, and 25 for 24 months.
RESULTS: Long-term biochemical (normal ALT levels) and virological (HCV-RNA negative) response was obtained in 2.6% of non-responder retreated patients, and in 33.9% of relapsing responder retreated patients. Evaluation of response on the basis of the duration of treatment showed that 48%, 19% and 16% of relapsing responder patients retreated for 24, 12 and 6 months, respectively, obtained long-term biochemical and virological response.
CONCLUSION: Non-responder patient retreatment is inefficient especially in cirrhotic and/or genotype 1 b patients. IFN retreatment is warranted in relapsing responder patients. In particular, 24-month therapy induces significant long-term biochemical and virological response. *SOURCE: European Journal of Gastroenterology and Hepatology 1999 Jun;11(6):649-53*

Watch Out for Oysters! A Melbourne, Ky., man is in critical condition with an infection that might be linked to eating raw oysters from a local restaurant. The bacterial infection - vibrio vulnificus - is often found in shellfish. According to the U.S. Food and Drug Administration, the illness can be fatal to persons with underlying health problems such as hepatitis or other liver disease, diabetes, cancer, or stomach problems. Persons who use steroids for asthma or arthritis are also at risk. The FDA recommends these persons eat only fully cooked oysters. SOURCE: Cincinnati Post

Drugs That May Cause Liver Dysfunction or Damage -
The liver is the principal organ that is capable of converting drugs into forms that can be readily eliminated from the body. Given the diversity in use today and the complex burden they impose upon the liver, it is not surprising that a broad spectrum of adverse drugs effects on liver functions and structures has been documented. The reactions range from mild and transient changes in the results of liver function tests to complete liver failure with death of the host. Many drugs may affect the liver adversely in more than one way, as cited below in several listings. The use of the following drugs requires careful monitoring of their effects on the liver during the entire course of treatment.

continued on page 6 -

Healthwise - continued from page 2 -

research setting. In order to design a reliable study, a product needs to be consistent and reproducible. Since botanicals are not subject to the same regulations as pharmaceuticals[3] it is difficult for a researcher to obtain a reliable botanical product. Using milk thistle once again as an example, if an investigator cannot prove that milk thistle is effective in treatment of HCV infection, is this negative result due to milk thistle in general, or to the particular plant that was studied. The same herb found in Australia may be ten times more potent than the same herb grown in the U.S. Processing of botanicals also raises a number of problems. The way in which a plant is handled can cause contamination, which can render toxic a potentially beneficial botanical.

A number of presenters stated that many plants are not being used in traditional ways. Rossanne Philen, MD from the CDC, illustrated this point using the example of tobacco. Native Americans have used tobacco in healing rituals for centuries, but never by smoking twenty peace pipes a day. Another example is the use of chaparral. This potentially carcinogenic and hepatotoxic herb has been used in folk medicine for many generations. In its traditional form, it is made into a tea that has an unpalatable taste, making it impossible to drink very much. However, the same herb can by bought in high concentrations and the taste disguised by its manufacture in capsules. This non-traditional form of chapparal alters its dosage and again, turns a potential remedy to a potential poison.

Although there was an exchange of information regarding the use of specific botanicals for liver disease, the primary focus was on generalities. There were presentations on silymarin (milk thistle)[4] glycyrrhizin (licorice root extract)[5] and various botanicals used in Asian medical practices (Traditional Chinese, Kampo, Ayruvedic, etc.). No cures were offered, but hope and good preliminary research was a suitable substitute. Clearly, the aims of the workshop were to lay the groundwork for the future.

In the context of the meeting, here are some guidelines for those who are considering using botanicals. Use botanicals cautiously. Bruce Bacon, a hepatologist and Professor of Internal Medicine at Saint Louis University School of Medicine, pointed out that some herbs can help liver diseases and some can cause liver diseases. Apply a rigorous set of standards to everything you ingest. If you are the type of person who likes to read the fine print about a pharmaceutical agent, then do the same research before taking a botanical.[6] Keep in mind that pharmaceutical products have been tested under extremely regulated circumstances. Before a drug is brought to market, it has to pass rigorous testing in laboratory animals, and in humans. The FDA, local Institutional Review Boards, as well as individual investigators oversee all aspects of these studies. All adverse events along with information about drug - drug interactions, are reported. Botanicals, however, are generally not pre-tested and reporting of adverse events is not mandatory.

With these facts in mind, here are some additional questions to ask before using botanicals:

1. Has the substance been used as a common supplement for your particular condition?
2. What are the known side effects of the particular substance?[7]
3. What is the proper dose and how should the botanical be taken?
4. Is the substance known to interact with other medications, foods, or other botanicals?
5. Has the product been standardized?[8]
6. Has the product been tested in a clinical setting?
7. Under what conditions should one stop using the botanical?

In addition to the above, consider working with someone who is trained to work with botanical substances.

Continued on page 5-

Healthwise - continued from page 4 -

There are many reputable CAM practitioners in this country, some of whom are associated with colleges and universities.[9]

One final note: botanicals are rarely sold in childproof containers. Herbs can be potent substances and need to be stored safely out of reach of children. Do not give botanical substances to children without first seeking professional advice. Pregnant and nursing mothers need to be extra cautious before taking a botanical substance without a doctor's instructions. "Natural" does not mean safe. Many poisons are natural. Cultivate an informed, consistent approach before taking any drug or supplement. Use common sense and seek expert advice on all of your medical care.

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[1] NCCAM 1999 budget is $49 million.
[2]The FDA does not regulate the products used by CAM practitioners. The FDA does regulate the labeling and manufacturing of the products used in these practices.
[3]May act as a mild laxative.
[4]Glycyrrhizin and licorice are known to lower potassium levels, raise blood pressure, and cause cardiac problems. Consult with your physician before using this as well as all botanical supplementation.
[5] Since botanicals are not regulated with the same standards as prescribed and OTC drugs, information may be scanty. A resource list is provided at the end of this article.
[6]ide effects can be reported to MedWatch at 800-FDA-1088
[7]Standardization is voluntary in the U.S. Some guidelines for choosing a botanical supplement are to buy brands that meet the standards of the German Commission E, the U.S. Pharmacopeia, or the American Botanical Council
[8] Some examples are Harvard University, Stanford University, and University of Arizona. If you work with a non-M.D. practitioner, choose someone who has earned credentials from a state-accredited school.

Resources:
The American Pharmaceutical Association Practical Guide to Natural Medicines by Andrea Pierce
The Green Pharmacy by James A. Duke
Herbs of Choice by Varro E. Tyler
The Honest Herbal by Varro Tyler
PDR for Herbal Medications
FDA: vm.cfsan.fda.gov/~dms/supplmnt.html or MedWatch 800-FDA-1099**.** www.fda.gov/medwatch
National Institutes of Health http://www.nal.usda.gov/fnic/ibids
U.S. Pharmacopeia. 800-822-8772. www.usp.org
American Botanical Council. 512-926-4900. www.herbalgram.org
www.theherbalists.com Website of Douglas Schar, DipPhyt.MCPP – editor of *The British Journal of Phytotherapy*

Hepatitis C Trial - Journal of the American Medical Association (09/15/99) Vol. 282, No. 11, P. 1028-

Stephenson, Joan A $28 million trial of antiviral drugs for the treatment of chronic hepatitis C virus (HCV) infection is being sponsored by the National Institutes of Diabetes and Digestive and Kidney Diseases. The eight-year study will be conducted at nine centers throughout the United States. Researchers hope to determine whether long-term antiviral treatment can help delay or prevent liver disease in HCV patients. The study is also intended to help identify predicting or correlating factor of HCV-associated liver disease.

Treatment Advocate - continued from page 3 -

Drugs that may cause ACUTE DOSE-DEPENDENT LIVER DAMAGE (resembling acute viral hepatitis)
acetaminophen salicylates (doses over 2 grams daily)

Drugs that may cause ACUTE DOSE-INDEPENDENT LIVER DAMAGE
(resembling acute viral hepatitis)

acebutolol
indomethacin
phenylbutazone
allopurinol
isoniazid
phenytoin
atenolol
ketoconazole
piroxicam
carbamazepine
labetalol
probenecid
cimetidine
maprotiline
pyrazinamide
dantrolene
metoprolol
quinidine
diclofenac
mianserin
quinine
diltiazem
naproxen
ranitidine
enflurane
para-aminosalicylic acid
sulfonamides
ethambutol
penicillins
sulindac
ethionamide
phenelzine
tricyclic antidepressants:
halothane
phenindione
valproic acid
ibuprofen
phenobarbital
verapamil

Drugs that may cause ACUTE FATTY INFILTRATION OF THE LIVER
adrenocortical steroids
phenothiazines
sulfonamides
antithyroid drugs
phenytoin
tetracyclines
isoniazid
salicylates
valproic acid
methotrexate

Drugs that may cause active chronic hepatitis
acetaminophen (chronic dantrolene methyldopa use, large doses) isoniazid nitrofurantoin

Drugs that may cause liver cirrhosis or fibrosis (scarring)
methotrexate
nicotinic acid

Drugs that may cause LIVER TUMORS (benign and malignant)
anabolic steroids
oral contraceptives
thorotrast
danazol
testosterone
SOURCE: The Essential Guide to Prescription Drugs, 1994 Edition, by James W. Long and James J. Rybacki. ISBN 0-06-273211-0

Studies Uncover Major Variations In How Hepatitis C Progresses - How a person acquires the hepatitis C virus makes a significant difference to the disease's progression, researchers reported yesterday at Gastro 99 - the Pan American congress of Digestive Diseases conference being held in Vancouver, B.C.

Researchers from Canada and France say that whether the person contracts the deadly virus from blood transfusions, intravenous drug use, needle stick injuries (in the case of healthcare workers) or from organ transplants will have a profound impact on whether they develop a more virulent form of the disease. This will ultimately affect whether they suffer, total liver failure and perhaps develop liver cancer.

For those who had the disease less than five years, 18 percent of blood transfusion patients had cirrhosis of the liver, indicating total liver failure, whereas less than two percent of drug users did. For blood transfusion recipients who had the virus for between 5-9 years, one-quarter had cirrhosis of the liver as compared with just six percent of drug users. Dr. Ma said that part of this discrepancy might be explained by the fact that those who had received blood transfusions were also 20 years older, on average, than the drug users. Nonetheless, he said the difference in natural history of the disease was remarkable.

All of this compares with the incidence of liver failure in a group of Irish women who all contracted the disease through a tainted immunoglobulin preparation and in whom only four percent had severe inflammation

continued on page 7 -

Treatment Advocate - continued from page 6 -

and two percent had cirrhosis after 17 years of infection. The difference in the severity of the disease may even extend to non-intravenous drug use. Those who have used cocaine more than 10 times will develop this disease faster and in a more severe form than those who use cocaine less than 10 times, or never.

Meanwhile, Dr. Thierry Poynard, a professor of medicine at l'Hopital Pitie Salpetriere, Paris, said HCV represents a "menage-a-trois" between the host, the virus and the fibrosis that develops from the disease.

The various stages of fibrotic development in the liver are rated on a scale from F0 to F4, leading to liver hemorrhage, hepatic insufficiency and ultimately cancer of the liver. "Fibrosis is predictive for the outcome of liver failure in people with HCV in the same way that a CD-4 count is for people with HIV," Dr. Poynard explained.

The most important factors that predict how long a person with HCV will survive, or how quickly their liver will deteriorate, are their age (People who contract the virus over the age of 30 will develop fibrosis and cirrhosis 27 times faster than those who are under 30); alcohol consumption (drinking more than 200 ml per day is associated with greater risk); and their gender (since women with HCV experience a more benign form of the disease due to the protective benefit from estrogen).

The researchers disagreed as to the role viral load played in disease progress. Dr. Ma said the viral load was dependent on the mode of transmission, so those who had needle-stick injuries or those who used intravenous drugs less than 10 times would not have as high a viral load as those who had had blood transfusions and organ transplants. Dr. Poynard disagreed, saying that neither the viral load nor the genotype of the virus appear to have a bearing on how quickly they progress to fibrosis.
SOURCE: Doctor's Guide to Medical News

HCV Treatment for African-Americans -
African-Americans did not respond well to interferon treatment for HCV in this study. The reasons why have not yet been well evaluated. Their end-of-treatment response and sustained response was 5% and 2%, respectively. However, in a second study they used 5 MIU daily for induction and then reverted to 3MIU TIW and had an increase in responders. The poor response to interferon treatment of African-American patients with chronic hepatitis C can be overcome by a more intensive regimen of interferon but the withdrawal rate increases with this approach.

NATAP HIV/HCV Radio Show on WOR Radio 710 AM in NYC, 11 PM Sunday Available on the Internet
Every Sunday night from 11 PM to 12 Midnight Jules will host ``Living Well With HIV," a talk interview show on current HIV and hepatitis treatment issues. Jules is the writer and publisher of the well recognized NATAP Reports newsletter and the NATAP web site, URL address http://:www.natap.org. Jules is both HIV and hepatitis C positive and is currently undergoing treatment for both. He brings his personal knowledge and experience to the discussions. Each week the show is devoted entirely to a new topic and a guest experienced in the field comes on to talk with Jules about the most current developments and advances in HIV or hepatitis. If you are out of the WOR listening range, you can hear the audio live by tuning into the WOR web site and clicking the listen button. If you don't have Real Audio, its available for free on the WOR site (http://www.WOR710.com).
SOURCE: NATAP

NEW JERSEY LAW MANDATES HEPATITIS C REPORTING -
A new state law in New Jersey says doctors and hospitals must report all cases of Hepatitis C, along with the names of those infected, to the state Department of Health and Senior Services. This information will help New Jersey determine the best way to approach new cases, which can take up to 30 years to develop, sponsors of the law said.

New Jersey is also the only state in the Philadelphia region which requires reporting of the names of people with HIV that has not yet progressed to an AIDS diagnosis. Doctors say people should not believe there is an outbreak of hepatitis C.

The new law seeks to identify existing cases, most of which involve baby boomers who were infected 20 to 30 years ago. In fact, there have been fewer new cases of the disease because of better blood-testing methods, health officials said. "We don't feel it's an epidemic," said David Feit, associate at the new Hepatitis Center at Hackensack University Medical Center.

The law, passed last year, provides guidelines on how to screen patients for the disease. Assemblyman Francis J. Blee (R., Atlantic), who cosponsored the bill, said because there was no law requiring reports of the disease, numbers from federal agencies may not be accurate. "I would expect 50 to 100 percent more than the current estimate suggests," Feit said.

Previously, only acute cases were reported to the federal Centers for Disease Control and Prevention and state health agencies. But more people are chronically ill with the disease - about 90 percent. About 450 of the 144,000 people with hepatitis C in New Jersey die each year. Nationally, 2.7 million Americans are infected with the virus and up to 10,000 die each year, according to the Centers for Disease Control. "This law will allow us to obtain better numbers," said Tom Breslin, spokesman of the New Jersey Department of Health and Senior Services. (Associated Press)