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HCV Advocate

A monthly newsletter of the Hepatitis C Support Project
www.hcvadvocate.org

Heavy Alcohol Use Quadruples Risks of Developing Cirrhosis in HCV Patients

By Joe Shaw
Contributing Editor

A new study has confirmed the dangers of heavy alcohol usage for people with hepatitis C. According to the study published in the January 16 issue of the *Annals of Internal Medicine*, for people with hepatitis C, "a history of heavy alcohol abuse was associated with a fourfold increased risk for cirrhosis."

"Heavy alcohol abuse greatly exacerbates the risk for cirrhosis among patients with HCV infection," wrote the researchers from the National Heart, Lung and Blood Institute Study Group. "This finding

emphasizes the need to counsel such patients about their drinking habits."

Researchers evaluated 1030 patients from liver clinics in university and government hospitals who had contracted HCV from blood transfusions, comparing them with people who had transfusions but didn't develop HCV.

The absolute risk for cirrhosis was 17% among patients with transfusion-associated HCV, while patients with HCV and a history of heavy alcohol abuse had 31 times the odds of developing cirrhosis than did non-HCV-infected people who were not heavy drinkers.

The researchers determined if a patient was a heavy drinker based on whether they had experienced a loss of friends, family, or a job because of drinking; admitting to ever having a problem with alcoholism; evidence of heavy drinking abstracted from medical records; or quantification of usual intake of more than 80 grams of alcohol per day during the years when the patient drank.

Eighty grams of alcohol would be equivalent to about five or six 12-ounce cans of beer; five or six 5-ounce glasses of wine; or five or six shots of hard liquor.

SOURCE: *Annals of Internal Medicine*
www.annals.org

FDA Approves Schering's Peg-Intron

By Joe Shaw
Contributing Editor

On January 22, Schering-Plough announced that the U.S. Food and Drug Administration (FDA) has approved their version of a pegylated interferon as a once-weekly monotherapy for the treatment of chronic hepatitis C. Schering's Peg-Intron becomes the first pegylated interferon approved for use in the U. S. and is expected to be available to patients nationwide in early February 2001.

Pegylated interferon is interferon linked to a polyethylene glycol (peg) molecule designed to allow interferon's anti-viral abilities to last

See Peg-Intron on page 5

In This Issue:

Hemochromatosis.....page 2
Pass the Guacamole.....page 3
Spontaneous Loss of HCV.....page 4

Watch Out For Hemochromatosis Risk Factors

By Lucinda K. Porter, RN

Hereditary hemochromatosis (HCC) is a genetic metabolic disorder in which a person absorbs excessive iron. HCC is one of the most common genetic disorders. As many as one in eight Americans may carry the HCC gene. People of Scotch, Irish, British, Dutch, German, French, Spanish, Italian, and Mediterranean descent are at higher risk for carrying the gene.

The symptoms of iron overload vary among individuals. Symptoms may include chronic fatigue, joint pain, abdominal pain, and weight loss. Depression, impotence, loss of libido and amenorrhea (unexpected stopping of menstrual cycle) are also symptoms of iron overload. Changes in skin color such as bronze, olive, or tan color without the benefit of sun exposure may be caused by iron overload.

Elevated liver enzymes and blood sugar levels can be due to excess iron. The symptoms associated with heart disease, diabetes, hypothyroidism, fibromalgia, and irritable bowel syndrome may lead a physician towards one of those diagnoses rather than that of iron overload, but all of these can be due to excess iron.

Women may be somewhat less likely to have symptoms because of regular blood loss due to menstruation. The risk equalizes for women after the cessation of regular periods due to changes such as menopause or hysterectomy.

The effects of iron overload can be devastating, contributing to diabetes, heart failure, arthritis, depression, cancer and liver disease.

Obviously, if you have another liver disease such as chronic hepatitis C virus infection, it would be especially important to have a thorough diagnostic review if you have HCC risk factors.

There are various ways of diagnosing HCC, but when an iron loading condition is suspected, the common most cost effective tests to detect elevated tissue iron may include serum ferritin, TIBC and iron saturation percentage (TIS%).

Ideally tests should be done after fasting - nothing

by mouth 8 hours prior to blood work. Avoid iron and Vitamin C supplementation three days prior to tests. Since Vitamin C binds with iron it is wise to reduce consumption of Vitamin C rich juices during this same three-day period of time.

Many physicians do not make these specific recommendations, but if you know that you are going to have these lab tests performed, it would be wise to take these extra steps.

The recommended treatment for iron overload is therapeutic phlebotomy or blood extraction. Preventive measures are essential. These include avoiding excess iron, especially iron supplements.

Iron-free multiple vitamins are readily available. Those with iron overload should avoid the use of iron cookware. Vitamin C supplements should also be avoided. Abstinence from alcohol and raw seafood/shellfish are also recommended.

For additional information, contact:

American Hemochromatosis Society (888) 565-4766 <http://www.americanhs.org>

Iron Disorders Institute <http://irondisorders.org>

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

Chinese Herbs Recalled

Lotus Herbs of La Puente, CA and FineMost Corp./QualiHerb of Cerritos, CA., are recalling eight brands of Chinese herbs:

Lotus:

Mu Tong, lot # SL04461, exp. Date - 12/2004

Fang Ji, lot # SW12261, exp. Date - 12/2004

QualiHerbs:

Ba Zheng San, or Dianthus formula, item #. 20209

Fang Ji Huang Qi Tang, or Stephania and Astragalus combination, item #. 20711

Chuan Mu Tong, or Clematis armandi, item # 10424 A.

See Recall on page 9

Pass the Guacamole!

Avocados May Help Protect the Liver

By Alan Franciscus
Editor

New research from Japan indicates that the common avocado (*Persea americana*) may help to protect the liver from damage.

The researchers fed rats avocados and 22 different fruits and gave them D-galactosamine, a substance that causes liver damage in an effort to find fruits that would help protect the liver.

The rats that were given avocado obtained the least amount of liver damage from the D-galactosamine. The researchers are now analyzing the compounds in avocado and other fruits to determine if there are chemicals in the fruit that can explain the protective effect. They hope to be able to isolate the chemicals in these fruits to use for future drugs.

Now, let's keep in mind that this study was on RATS and not humans and little conclusions can be drawn at this time.

However, eating fresh fruits have long been known to supply many vitamins, minerals and other nutrients necessary for good health. Additionally, it is always best to obtain nutrients in the form of fruits and vegetables rather than from nutritional supplements.

Avocado is native to Central America and was eaten by the Aztec, Mayan and Inca peoples. Avocados are a cholesterol-free, sodium-free, low saturated fat food with only 5.0 grams of fat per serving-1/5 of a medium avocado. The fat found in an avocado is monounsaturated, believed by some scientists to protect against heart disease and certain kinds of cancer. Avocados are nutrient dense in potassium, folate, dietary fiber, vitamin C, vitamin E, riboflavin and vitamin B6.

Other fruits that the researchers believe will help protect the liver include:

Watermelon is native to the Kalahari Desert and was first harvested over 5,000 years ago in Egypt. The watermelon is mostly water but is an excellent source of Vitamin A and C, potassium, micronutrients and

water-soluble fiber.

Grapefruit originated in Jamaica and is a good source for vitamin C, inositol, Folic Acid and fiber.

Lychee is a native to low elevations of the provinces of Kwangtung and Fukien in Southern China. Lychee's are very high in Vitamin C and supply adequate amounts of dietary fiber and iron.

Figs are one of the earliest fruits cultivated by man and are native to areas from Asiatic Turkey to northern India. Today, the United States, Turkey, Greece and Spain are the primary producing nations of dried figs. Figs are good sources for calcium, iron and fiber.

Kiwi Fruit, common name for a southeast-Asian vine, also called Chinese gooseberry and yangtao. Kiwi is considered one of the most nutritionally dense of all the major fruits— with lots of vitamin C, and Lutein, which is believed to reduce the risk of cancer and heart disease as well as other diseases. Kiwi also contains both soluble and insoluble fiber, copper, potassium, Folate, Magnesium, and Vitamin E.

Cherries were considered a delicacy for Greek, Roman and Chinese Noblemen for centuries. Cherries were brought to America by ship in the 1600's and today, the U.S. cherry industry produces over 650 million pounds of cherries each year. Cherries are high in melatonin and anti-oxidants and are a good source for vitamin A, vitamin C, calcium, iron, phosphorus and potassium.

Japanese Plums have been growing in their native areas for several thousand years and were introduced into the New World in the late 1800s. Plums are high in riboflavin (B2), vitamin C, and calcium.

Papaya or the edible 'tropical papaya' (called by the English and their colonial descendants 'paw paw') is a fruit native to the tropical lowlands of eastern Central America. One serving of papaya will meet about 20% of an adult daily folate needs, and provides about 75% of an adult's daily requirement of vitamin C.

Source: News from ACS



Spontaneous Loss of HCV

The changing landscape of HCV chronic infection rates

By Alan Franciscus
Editor

It is currently held that 15% of people infected with HCV clear the virus on their own. This conclusion was drawn from various studies from the mid-1990s, and relies heavily on data from the National Health and Nutrition Examination Survey (NHANES III), a nationally representative probability sample of US residents conducted from 1988-1994. Data analysis of this survey has led to recommendations from various US medical organizations that verifying HCV infection with a viral load testing may be unnecessary.

However, recent reported or published studies have shown that the rate of clearance may be much higher than previously believed, which could have drastic consequences for HCV+ individuals and medical providers.

The majority of the data that suggest the rate of HCV infection clearance rate is approximately 15% was drawn from mainly two studies - (1) Alter MJ, Margolis H S, Krawczynski K., et al. The natural history of community-acquired hepatitis C in the United States (New England Journal of Medicine - 1992); (2) Alter H J, Conry-Cantilean C, Melpolder J, et al. Hepatitis C in asymptomatic blood donors. Hepatology 1997.

These conclusions were drawn from retrospective

studies - a clinical study in which patients or their records are investigated after the patients have experienced the disease or condition.

These studies are generally performed in large medical centers, and attract people with existing disease, which may very likely affect the clinical results. These types of studies lead to 'referral bias' and can lead to flawed results.

The reported HCV spontaneous recovery rate of 15% was drawn from studies that used retrospective methods and there are limitations to these analyses. More people will seek testing and are more likely to have active HCV if they have symptoms of disease. This is especially true of people with HCV since most people do not have symptoms.

The ideal method to obtain these figures is to conduct epidemiological studies that provide confidential testing in various medical settings around the country.

Data from newer studies that employ more rigorous, lengthy and therefore more expensive methodology-known as a prospective and cohort study approach— indicate that the spontaneous recovery rate for HCV may be much higher—26-45%— than that reported from retrospective analyses.

Definitions

Prospective studies - a clinical or epidemiological investigation of patients or health subjects with respect to the medical, social, and environmental

See Spontaneous on page 6

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The HCV Advocate offers information about various forms of intervention in order to serve our membership at large. By providing information about any form of medication, treatment, therapy or diet we are neither promoting nor recommending use, but simply offering information in the belief that the best decision is an educated one.

Hepatitis C Support Project - A Tides Center Project

Peg-Intron Approved

Continued from page 1

over a longer time period, and allowing a patient to inject this treatment once weekly instead of the thrice-weekly injections used with regular interferons. A once-weekly dose will allow patients to better tolerate the side effects of interferon therapy.

The Peg-Intron regimen approved in January is injected once weekly for a year by the patient, on the same day each week. Preliminary studies also show that pegylated interferons in combination with ribavirin have a greater success than the current standard "combo therapy" of regular interferon and ribavirin. The FDA has not yet approved pegylated interferon and ribavirin as a combination therapy.

The safety and efficacy of Peg-Intron has been demonstrated in a randomized, controlled clinical studies involving 1,219 adult patients with chronic hepatitis C who were not previously treated with alpha interferon. Patients were treated for 48 weeks. In the study, patients receiving Peg-Intron achieved a 24 percent treatment response rate of sustained virologic response and normal liver enzymes compared to a 12 percent treatment response rate in patients receiving regular interferon only.

The side effects associated with Peg-Intron were

"flu-like" symptoms, which occurred in approximately 50 percent of patients; injection site irritation or inflammation, seen in 47 percent of patients; and depression, seen in 29 percent of patients.

Source: PR Newswire

New Ribavirin-like Drug to Start Clinical Trials

ICN Pharmaceuticals, Inc., has submitted an Investigational New Drug Application (IND) to the U.S. Food and Drug Administration (FDA) to begin clinical testing of ICN's new drug-levovirin, a nucleoside analog compound similar to ICN's ribavirin that is approved in combination with interferon to treat HCV.

Like ribavirin, levovirin has been found to have an immunomodulatory function in vitro (test tube) and in vivo (in a living body). Levovirin has demonstrated to be safe in animal studies. If the IND is approved by the FDA, ICN is will test their new drug in healthy volunteers (phase 1). Once safety and tolerability is established in healthy subjects, ICN hopes to test their new drug in HCV-infected individuals and evidentially in combination with interferon.

Source: Reuters

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Spontaneous Loss of HCV

Continued from page 4

factors encountered from the time of the beginning of the study until the investigation is terminated usually over a long period of time.

Cohort studies - The study of a group of individuals with some characteristics in common and traced through life as it enters successive time and age periods.

Studies employing these methodologies may give a better picture of the true nature of how many people actually clear HCV without treatment.

A large concurrent-prospective study, that followed up on an original study conducted by Seeff et al. (1992), combined the mortality (death) and morbidity (the number of sick persons or cases of

disease) from a large 20-year follow-up study and found that only 75% of the group that tested HCV antibody positive by ELISA, RIBA, or other, tested HCV positive by HCV RNA. **Twenty-five percent cleared the virus on their own.**

Even more striking are the results from two other studies - Kenny-Walsh et al. and Vogt et al.

Kenny-Walsh et al. (1999) studied the results of Irish women that were inadvertently given the HCV-contaminated Rh immune globulin following child-birth (Rh immune globulin, known as "Rhesus-D" or "Anti-D" in the US, is commonly used to prevent Rh factor incompatibility between the maternal and fetal blood supply.) After a 17-year follow-up, Kenny-Walsh and colleagues reported that only 55% of the 704 patients found to be positive with HCV anti-

bodies were positive for HCV by HCV RNA - that is, tested positive for virus. **Forty-five percent cleared the virus on their own.**

Vogt et al. (1992) studied 458 German children who had undergone cardiac surgery and received blood transfusions, and found that 67 patients had anti-bodies to HCV, but that only 55% test positive for HCV by HCV RNA viral load. **Forty-five percent cleared the virus on their own.**

Another study conducted by the National Health and Nutrition Examination Survey (NHANES III) reported that only 74% of 21,241 people surveyed who acquired HCV tested positive for the virus. **Twenty-six percent cleared the virus on their own.**

It is clear that emerging data

is changing the way we look at HCV infection and subsequent testing and medical care. By conservative estimates, 20-25% of people initially infected with HCV clear the virus on their own. Repeated testing for HCV by a sensitive viral load test is the only possible option for identifying individuals with active infection.

Sources: Recovery, Persistence, and Sequelae in Hepatitis C Infection: A Perspective on Long-term Outcome - Harvey J. Alter, MD and Leonard B. Seef, MD

Sem Liver Disease 20 (1): 17-35, 2000 and Medscape <http://www.medscape.com>

"Spontaneous" Loss of Hepatitis C Virus Based on Anti-HCV Seropositivity in Absence of HCV-RNA

Author(Ref.)	Country	%Loss	Comments
Alter et al.	USA	26%	NHANES III
Kenny-Walsh et al.	Ireland	45%	Women receiving immune globulin
Seeff et al.	USA	26%	Transfusion hepatitis
Vogt et al.	Germany	45%	Children

Source: Hepatitis C - edited by J. Jake Liang & Jay H. Hoofnagle

A Review of Clinical Data - Interferon Non-Responders Retreated with Interferon and Ribavirin

By Alan Franciscus
Editor

The majority of patients with hepatitis C do not respond to interferon monotherapy. It is generally recommended that these individuals be retreated with the combination of interferon and ribavirin.

However, it has been unclear how many of these patients benefit from retreatment with combination therapy.

Now, researchers have analyzed pooled data from 9 randomized controlled trials and report on the efficacy of combination therapy for interferon nonresponders.

In the January issue of *Hepatology*, Cheng et al. reviewed data from 9 clinical trials (789 patients) on the efficacy of combination therapy treatment for interferon non-responders.

Nonresponders were defined as patients who were treated with interferon (3 mu, 3 times a week) for at least 3 months and did not attain normal alanine transaminase (ALT) level (biochemical) or undetectable HCV RNA level (viral load - virologic) during treatment. The majority of these patients were genotype 1 - the hardest genotype to treat.

Retreatment was defined as an interferon dose of at least 9 MU/week, a ribavirin dose of at least 800mg/day, treated for at least 24 weeks.

Sustained response was defined as sustained biochemical and sustained virologic response.

The end of treatment sustained response rate was 13%. It was also noted that patients retreated with combination therapy for a 48-week period increased the sustained response rate to 21.3%.

The authors recommended retreatment for 48 weeks, which is consistent with treatment recommendation for genotype 1. Unfortunately, the data did not analyze the potential of retreatment to improve liver histology (overall liver health).

Hopefully, retreatment with pegylated interferon or the combination of pegylated interferon and ribavirin will provide more benefits to interferon and interferon and ribavirin nonresponders.

Source: *Hepatology*, Jan 2001

New HCV Prison Website(s) & HIV/HCV Co-Infection Online List

Two new websites are being launched to bring about more awareness on HCV in prisons.

www.hcvprisonnews.org will be launched on February 01, 2001. A coalition of various HCV and HIV groups aim to bring about more awareness of HCV and HIV/HCV co-infection in prisons. Information on HCV and HIV/HCV in prisons will be featured along with prison newsletters and various links. Hepatitis C Awareness Project will also launch their website during February, which will include a section for the Hepatitis C Prison Coalition. More information will be available soon.

On-Line HIV/HCV Co-infection list:

A new on-line list for people affected by HIV and HCV co-infection was launched in January. For more information please email: sfhepcat@pacbell.net or go directly to:

www.egroups.com/group/HepCandHIVSupport

HAART Treatment May Reduce HCV in HIV/HCV Co-infected Patients

A recent study from the Nagoya University School of Medicine in Nagoya Japan reported that 2 hemophiliac patients co-infected with HIV and HCV eliminated HCV while undergoing highly antiretroviral therapy (HAART).

Researchers studied 130 male hemophiliac patients with HIV. These subjects were divided into 4 groups according to their HIV and HCV status. Researchers found that HAART increased CD4+ cell counts and HIV-RNA load declined as expected. However, HAART was associated with a decline in HCV RNA, a rise in B-cell counts, and decline in serum IgM levels in the HIV/HCV co-infected group. Two HIV/HCV co-infected individuals cleared HCV.

The authors findings contradict previous data that HAART has little impact on HCV. They also concluded that co-infected patients should be treated with HAART for their HIV and combination therapy for HCV.

Source: *Blood* 2000 Dec 15;96 (13) 4293-9

News Briefs

Hepatitis C and Lupus - Is There a Connection?

Scientists from the University of Barcelona in Spain studied 134 patients with systemic lupuserythematosus (SLE) in an effort to find a connection between hepatitis C (HCV) and SLE. Their study results found that HCV infection was present in 11% of SLE patients compared to 1% of the healthy control subjects.

This study represented the largest group of SLE patients ever analyzed for HCV infection and suggested that there may be a possible link between HCV infection and SLE. The authors also noted that the usual clinical symptoms of SLE are different in HCV infected individuals. The authors suggested that individuals with SLE should be tested for HCV especially those individuals without typical SLE symptoms.

SLE is an autoimmune disease that can range from mild to severe. An estimated 500,000 Americans have been diagnosed with SLE. Ninety percent of individuals with SLE are women that were diagnosed during their childbearing ages, which lead some scientists to believe that hormones might play a role in this disease.

Common symptoms of SLE include - arthritic pain, fever, skin rashes, fatigue, nausea, weight loss, and loss of appetite. SLE is a chronic illness that is unpredictable— 20-30% of cases are mild, but the majority of patients experience cycles or flare-up periods that usually occur 2-3 times a year and can be quite disabling. Vital organs can be severely affected, which can result in death.

No definitive test is available to diagnosis SLE. Instead, a physician will diagnosis SLE based on symptoms such as the characteristic rash across the cheek, other skin and organ lesions, arthritis, photosensitivity, evidence of kidney or neurologic disease. Additionally, blood tests such as the test for Anti-nuclear Antibodies (ANA), other antibody tests, and skin biopsy of skin lesions are used to rule out or confirm diagnosis.

There is no cure for SLE. Treatment usually consists of steroids and nonsteroidal anti-inflammatory

drugs (NSAIDs). However, in a new experimental stem transplant treatment is raising hopes of a possible cure or an effective treatment to manage the disease. In a study conducted by Northwestern University in Chicago, 7 patients were successfully treated and the researchers are hopeful that a cure might be in sight. The stem cell procedure is considered risky and should only be considered for patients with the most severe disease and at risk for death. The results of this study were encouraging and larger scaled studies are planned.

Source: Reuters & WebMD Medical News

SciClone Pharmaceuticals Begins Phase 3 Clinical Trials with Zadaxin Plus Peg

SciClone Pharmaceuticals announced that it would initiate Phase 3 clinical trials of Zadaxin and Pegasys (Roche's pegylated interferon) in the U.S with a projected 1,000 patients. This study will test individuals that did not respond to interferon or the combination of interferon and ribavirin.

The phase 3-study design will consist of two 500-patient, multicenter, randomized, double-blinded studies. Trial subjects will be HCV patients that did not have a virological response to previous treatment with interferon or the combination of interferon and ribavirin.

Treatment will consist of two treatment arms - Zadaxin plus Pegasys (pegylated interferon) and placebo plus Pegasys for a 12 month period. The primary efficacy endpoints will be measured six months after the end of treatment and consist of a sustained virological response (SVR) and an improvement in histological activity index (HAI) by biopsy that will show HCV inflammation and scarring. Secondary endpoints will be sustained biochemical response - normalization of ALT's.

Zadaxin is a synthetic peptide that enhances the immune response. Pegasys is Roche's pegylated interferon, a time-release interferon.

Source: PRNewswire

Support Groups

Northern California

San Rafael

Barry Howe (415) 453-3622

Redwood City

For Info Call: (650) 367-5998

San Francisco

Rose Christensen (415) 333-2411
Info Meetings/Hep C 101 - (415) 978-2400

San Mateo

Debra Magnum (650) 581-3339

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Sunnyvale

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Support Groups

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Recall

Continued from page 2

Wei Ling Xian, or Clematis, item # 12401
Han Fan Ji, or Stephania tetrandra, item # 10731
Ma Dou Ling, or Aristolochia, item # 11052

These products were contaminated with aristolochic acid, a substance has been linked to kidney cancer and kidney failure. Products were sold nationwide, including by acupuncturists and chiropractors.

Products should be returned to the place of purchase for a refund. Contact Lotus at 877-665-6884 (Lotus) or 800-533-5907 (QualiHerb) for more information.

Source: SafetyAlerts

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415/978-2400

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Clinical Trials

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University of San Francisco Medical Center
Scott Shimotsu Clinical Project Assistant (415) 514-2370
VA Hospital-UCSF
(415) 750-2105
California Pacific Medical Center
Linda Brooks (415) 202-1504 or (415) 202-1506
San Francisco General Hospital
Athiana (415) 206-3725
Stanford University Hospital
Stanford Liver Research Clinic (650) 724-7057
Quest Medical Research
Dr. Jay Lalezari (HIV/HCV Co-infection trials)
(415) 353-0800
East Bay Liver Clinic
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Dr. John J. Jolley - San Rafael
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