

Pegasys plus Copegus:

Newly Published Data Reports Highest Overall Sustained Virological Response Ever - 63%



Alan Franciscus, Editor-in-Chief

The *Annals of Internal Medicine* recently published an article on the clinical trial data results from a large international multicenter phase III clinical trial in order to assess the safety and efficacy of 24 or 48 weeks of treatment with Pegasys plus Copegus at low or standard ribavirin dose.

The study was a randomized, double-blind trial that enrolled 1,311 hepatitis C positive patients from 99 international centers. The lead author of the study was S.J. Hadziyannis, MD, for the Pegasys International Study Group.

All patients were treated with Pegasys 180 µg /week and were randomized into four treatment arms:

- 24 weeks - Pegasys plus ribavirin 800 mg/daily.
- 24 weeks - Pegasys plus ribavirin 1000 or 1200 mg/daily.
- 48 weeks - Pegasys plus ribavirin 800 mg/daily.
- 48 weeks - Pegasys plus ribavirin 1000 or 1200 mg/daily.

The primary endpoint of this study was end of treatment response and sustained virological response at the end of treatment and during the 12 to 24 weeks of

follow-up.

It is well known that certain co-factors can influence treatment outcome: low viral load, minimal liver disease progression and infection with HCV genotypes 2 or 3 are all factors that predict a more favorable treatment outcome. This report will focus on the overall sustained virological response rate ((SVR) - undetectable HCV RNA or viral load achieved 24 weeks post treatment) - as well as on the SVR based on genotype, viral load and degree of HCV disease stage or progression. This is important since the majority of people in the United States are infected with genotype 1 with a high viral load, and these patients are considered the most difficult to treat with current HCV medications.

High viral load is defined as over 2,000,000 copies; low viral load is defined as under 2,000,000 copies.

RESULTS: GENOTYPE 1 - THE MOST DIFFICULT TO TREAT

The authors reported an overall 52% SVR for all genotype 1 patients, and the study confirmed that the optimal dose of ribavirin is 1000-12000 mg/daily with treatment duration of 48 weeks.



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The study also analyzed the treatment outcome by low viral load (65% SVR) and high viral load (47% SVR).

The authors further analyzed the SVR rates of patients according to the extent of fibrosis at baseline and found that patients without cirrhosis attained a 57% SVR versus 41% SVR for patients with cirrhosis or bridging fibrosis.

RESULTS: GENOTYPES 2 AND 3

As expected the SVR rates for people infected with HCV genotypes 2 and 3 were much higher than those attained by genotype 1 patients. The study also confirmed the results of previous Pegasys/Copegus studies that showed that a 24 week treatment duration and a ribavirin dose of 800 mg/daily produced the optimal sustained virological response rate for people with genotypes 2 and 3. The overall SVR for genotypes 2 and 3 was 84%. Results based on viral load were: 88% SVR for patients with genotypes 2 and 3, low viral load; and 82% SVR for patients

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HCV Genotype & Quasi-Species



Alan Franciscus, Editor-in-Chief

With respect to hepatitis C, the term genotype refers to different, but related strains of the hepatitis C virus. Approximately 200-400 years ago the virus began to develop variations in its genetic make-up. These variances have been classified into different genotypes. There are six major groups, or genotypes, numbered 1 to 6, although many experts believe that there may be as many as 11. Within each genotype are further divisions called subtypes (for example 1a and 1b) and quasi-species.

HCV constantly changes and mutates as it replicates—more than 1 trillion hepatitis C virions replicate each day. During the replication process, the hepatitis C virus will make 'bad' copies or errors in the genetic make-up of the newly replicated viruses. The process of constant mutation helps the virus evade the body's immune response—when the dominant quasi-species is eradicated, another quasi-species emerges. This requires the immune system to constantly identify and kill the newly emerged variants. This is why so many people develop chronic disease. Scientists believe there are literally millions of different HCV quasispecies in everyone infected with hepatitis C, which are unique to every individual. In addition, it has been suggested that quasi-species play a role in disease progression and treatment response, but this is still very controversial and more studies

are needed to fully appreciate the role of quasi-species.

This variability (genotype, subtypes and quasi-species) of hepatitis C has made it difficult to treat and to develop a vaccine that will protect against all HCV strains, although recent advances in vaccine development have been encouraging.

GENOTYPE DISTRIBUTION

HCV genotypes and subtypes are distributed differently in different parts of the world, and certain genotypes predominate in certain areas. Genotypes 1-3 are widely distributed throughout the world. Subtype 1a is prevalent in North and South America, Europe, and Australia. Subtype 1b is common in North America and Europe, and is also found in parts of Asia. Genotype 2 is present in most developed countries, but is less common than genotype 1. Some studies suggest that different types of HCV may be associated with different transmission routes. Subtype 3a appears to be prevalent among injection drug users and it is believed that it was introduced into North America and the United Kingdom with the widespread use of heroin in the 1960s.

Scientists believe there are literally millions of different HCV quasi-species in everyone infected with hepatitis C, which are unique to every individual.

Genotype Distribution Worldwide

HCV Genotype	Distribution
1, 2, 3	Worldwide
4	Middle East, Africa
5	South Africa
6	Southeast Asia

Genotype Distribution in the USA

Genotype	% of Population	U.S. Population
1	~ 70 %	2,800,000
2	~ 15%	600,000
3	~ 12%	480,000
4	~ 2%	80,000
6	~ 1.5%	60,000

IMPORTANCE OF GENOTYPE INFORMATION

HCV Genotype information is important because of the role it plays in predicting HCV medical treatment response, treatment duration, and the dose of ribavirin. However, it should never be used as a reason to deny treatment.

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HealthWise:

A Matter of Perspective



Lucinda K. Porter, RN, CCRC

Patients provided much of the material used in this year's annual April Fool's article. When describing their experiences of treatment for chronic hepatitis C viral (HCV) infection, patients commonly use analogies. HCV can be challenging. It is interesting and sometimes amusing to see how patients portray their various encounters. Humor can be a powerful coping mechanism. Here are a few of my favorite images:

"I just tell myself that I am in a rented body. I will upgrade it when I am done with HCV therapy."

"It is like menopause, complete with irritability and hot flashes. I love watching men on treatment. I hope it gives them sympathy for perimenopausal women."

"It's like being at high altitudes, except the view isn't as good."

"My body has been snatched by aliens, except in this case, the aliens are interferon and ribavirin."

"Treatment is the easiest weight loss program I have ever been on. I don't even think of food."

"Every once in awhile, I lose my temper or say something inappropriate. It is amazing how words just pop out of my mouth that I never would have said before. At first I chastised myself about it. Now I just tell myself that I have interferon-induced Tourette's syndrome. Thank goodness it is temporary."

"HCV treatment feel's like a preview of old age."

In addition to these descriptions, patients sometimes reveal stories about themselves. It is not uncommon for patients to lose their cars or get into the wrong vehicle. One poor fellow thought he had taken his sunglasses off and realized that he had actually taken his dentures out. He did this in public. The only time I ever ran out of gas was during treatment. I had placed a post-it on my dash board, reminding me to do an errand. Unfortunately the note covered my gas gauge and I did not see the low fuel warning indicator. What can one do but laugh!

One poor fellow thought he had taken his sunglasses off and realized that he had actually taken his dentures out.

Support groups provide wonderful opportunities to swap amusing anecdotes. We laugh quite a bit at the group I attend. There is camaraderie in commiseration. It has been said that misery loves company. Perhaps this is because when we gather, we already have a shared experience that needs few explanations and leaves room for merriment. Although laughter is not a cure for HCV, it sure can

ease the burden.

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Tips on Receiving the Best Medical Care



Kara Wright, PA-C

All patients should be active participants in their own health-care. Although medical professionals are highly trained and skilled, they are not mind readers. By taking an active role, patients can ensure they receive the best care possible.

TIPS ON CHOOSING A DOCTOR

It is very important that you feel comfortable with your medical provider. You should feel confident that he or she is knowledgeable in his or her field and has experience in treating patients with conditions similar to yours.

Try to gather information from many sources and in many forms—the more sources of information, the better—including: friends/family, your health benefits officer at work, fellow employees, and health plan network lists. Be sure to investigate the doctor's qualifications by reviewing the following:

- Education and Training: College (four years); Medical School (four years); Residency Training (up to seven years); Fellowship Training (up to seven years); and Continuing Education (lifetime).
- Quality Measurements: Board Certification; Years in Practice; Disciplinary Actions by State Medical Boards and Medicare.
- Customer Satisfaction: Personal Attributes such as Doctor Gender and Age; Referrals from Colleagues/Friends.

- Doctor Affiliations: Health Plans; Quality of Affiliated Hospitals.

Most of this information can be obtained by contacting the state board of medical examiners either by phone or on the internet.

20 TIPS TO HELP PREVENT MEDICAL ERRORS

The most important way you can help to prevent errors is to be an active member of your health care team. That means taking part in every decision about your health care. Research shows that patients who are more involved with their care tend to get better results.

Medicines

- Make sure that your doctors—and every member of the health care team—are aware of each medicine you are taking. This includes prescription and over-the-counter medicines, and even dietary supplements such as vitamins and herbs.
- Make sure your doctor knows about any allergies and adverse reactions you have had to medicines. This could keep you from receiving a medicine that can harm you.
- When your doctor writes you a prescription, make sure you can read it. If you can't read your doctor's handwriting, your pharmacist might not be able to either.
- Ask for information about your medicines in terms you can understand—both when they are

prescribed and when you receive them. What is the medicine for? How am I supposed to take it, and for how long? What side effects are likely? What do I do if they occur? Is this medicine safe to take with other medicines or dietary supplements I am taking? Are there foods, drinks or activities should I avoid while taking this medicine?

- When you pick up your medicine from the pharmacy, ask: "Is this the medicine that my doctor prescribed?" A study by the Massachusetts College of Pharmacy and Allied Health Sciences found that 88% of medication errors involved the wrong drug or the wrong dose.

- If you have any questions about the directions on your medicine labels, ask. Medicine labels can be hard to understand. For example, ask if "four doses daily" means taking a dose every 6 hours around the clock or just during regular waking hours.

- Ask your pharmacist for the best device to measure your liquid medicine. Also ask questions if you're not sure how to use it. Research shows that many people do not understand the right way to measure liquid medicines. For example, people use household teaspoons, which often do not hold a true teaspoon of liquid. Special devices like marked syringes help people to measure the right dose. Being told how to use the devices helps even more.

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Review:

The Official Patient's Sourcebook on Hepatitis B

By James N. Parker, M.D. and Philip M. Parker, Ph.D.



Christine Kukka

I had high expectations for this book. There's the promising title: "Official Patient's Sourcebook . . .," there's the book's hefty girth, and then there's the undisputed need for a comprehensive, easy-to-understand guidebook to one of the world's most deadly and complex viral infections.

Today, 6 percent of the world's population has chronic hepatitis B. To put this in perspective, 2.8 percent of the world is infected with hepatitis C, and less than 1 percent is infected with HIV. In China, home to 1.3 billion people, 60 percent have been infected with the hepatitis B virus (HBV) and 10 percent are chronically infected with hepatitis B.

Closer to home, one in 20 Americans has been infected with HBV, and 1.2 million (equivalent to the population of Maine) are chronically infected with hepatitis B.

Despite its widespread infection rate, pediatricians and general practitioners have trouble understanding hepatitis B, and even health care providers struggle to interpret hepatitis B viral tests. Most doctors still think of hepatitis B as a sexually-transmitted disease and assume if you don't sleep around, you won't get infected.

This attitude prevails despite the fact that about half of those who are chronically infected in the United States were born to HBV-infected mothers and infected at birth

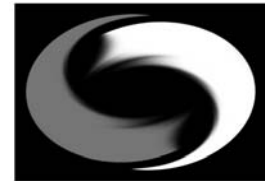
because they weren't immediately immunized, and their mothers weren't screened for HBV during pregnancy.

And if the viral make-up and natural history of this infection doesn't confuse you, the available treatments, and when they should be prescribed, will. You need an algorithm and a degree in medicine to understand the unique features of viral load, antigen status and liver enzyme readings that together dictate when treatment is needed.

And did I mention the various hepatitis B viral mutations that are able to replicate without one of the viral antigens, or are able to resist the antiviral punch of lamivudine, the most commonly used antiviral treatment?

Hence, a patient's source book is exactly what HBV-infected individuals and their family members need to help manage their health care. Unfortunately, the "Patient's Sourcebook . . ." doesn't deliver.

While it touts itself as an authoritative directory for the Internet age, the doctor who edits the book isn't even a gastroenterologist or a hepatologist. He edits many of the ICON Health Publications' "Official Patient Sourcebooks," that address a variety of maladies from appendicitis and



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Acute Hepatitis C



Liz Highleyman

Acute hepatitis C refers to the initial period after infection; if the hepatitis C virus (HCV) remains in the body longer than six months, it is considered chronic. HCV has an incubation period of 2-26 weeks, and the onset of illness occurs an average of 6-7 weeks after exposure.

Most people with acute hepatitis C do not show symptoms (study results vary, but as many as 80% may be asymptomatic). Those that do may experience a flu-like feeling, nausea, fatigue, weakness, loss of appetite, abdominal pain, or muscle aches—the same symptoms as chronic hepatitis C. Some develop jaundice (yellowing of the skin and whites of the eyes) and elevated liver enzymes (particularly ALT). Symptoms usually subside after about 4-8 weeks. In a small number of cases, acute viral hepatitis can cause fulminant liver failure—which can lead to encephalopathy, coma, and death—but this is rare with hepatitis C.

It has traditionally been thought that hepatitis C becomes chronic about 85% of the time, but more recent research indicates that the proportion is closer to 75%. (For comparison, hepatitis B becomes chronic only about 5% of the time.) Spontaneous resolution is associated with a strong HCV-specific cell-mediated immune response. If the immune system fails to control HCV during acute infection, the virus can take up permanent residence in liver cells, and HCV-

specific immune responses may be lost.

Acute hepatitis C is difficult to detect because it is often asymptomatic and because symptoms, if they do occur, mimic other illnesses such as the flu. It usually takes about 3-8 weeks for the body to produce antibodies against HCV, so antibody tests performed during the acute phase may not return a positive result. However, HCV genetic material (RNA) can be detected in the blood as early as a few days after infection.

Experts do not agree about whether people with acute hepatitis C should be treated. To date, studies have not been comparable and sample sizes have been small, producing varying results. But most research indicates that early treatment with interferon can eliminate HCV and prevent chronic hepatitis C. For example, R. Myers and colleagues conducted a meta-analysis for the *Cochrane Review* of randomized trials comparing interferon to placebo or no treatment during acute infection. They concluded that “[i]nterferon alfa is effective in improving biochemical outcomes and achieving sustained virologic clearance.”

In the November 15, 2001 issue of the *New England Journal of Medicine*, Elmar Jaeckel and colleagues from Germany reported results of a prospective trial that treated 44 patients presumed to have acute hepatitis (known or suspected HCV exposure, docu-

mented seroconversion, and/or sudden ALT increases). All had detectable HCV viral load and elevated ALT; 68% had jaundice. All received 5 million units of standard interferon daily for four weeks, then three times weekly for an additional 20 weeks. The average time from presumed infection to the initiation of treatment was 89 days. At the end of a 24-week post-treatment follow-up period, 43 of the 44 (98%) had undetectable HCV viral load and normal ALT (including one who discontinued therapy after 12 weeks due to adverse side effects). This trial did not include a placebo or control group, and some subjects no doubt would have spontaneously cleared HCV without treatment, but such a high response rate is unlikely to be due to chance alone.

Interferon also appears to prevent chronic hepatitis C in coinfecting patients. Jürgen Rockstroh and colleagues from Bonn reported at the 9th European AIDS Conference in October 2003 that among eight HCV/HIV coinfecting patients with acute hepatitis C (six symptomatic, four with jaundice, all with elevated ALT) treated with standard interferon monotherapy, pegylated interferon monotherapy, or pegylated interferon/ribavirin for 24 weeks, six (75%) achieved sustained HCV clearance.

Given that treatment during the acute phase can seemingly prevent chronic hepatitis C in most indi-

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ACUTE HEPATITIS

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viduals—and the fact that treatment for chronic hepatitis C still leaves much to be desired—Dr. Jaeckel thinks everyone identified during this stage should receive therapy: “Since the current treatment for chronic HCV infection eliminates the virus in only about half of cases, we suggest that all patients with acute hepatitis C should be treated.”

But others question whether the drawbacks of giving an expensive drug that can cause side effects and have a negative impact on quality of life outweigh the benefits, considering that about one-quarter never would have developed chronic hepatitis C anyway.

Unfortunately, experts do not know how to determine in advance who will spontaneously clear HCV and who will develop chronic hepatitis C. But there are some predictors. Women and younger people are more likely to spontaneously clear HCV. S. Hwang and colleagues found that people with HCV genotype 1b and a longer incubation period (more than six weeks) were more likely to develop chronic infection. S. Villano and colleagues found that people with lower peak viral loads were more likely to spontaneously clear HCV. And H. Hofer and colleagues found that people whose HCV viral load decreased rapidly in the first weeks after infection were more likely to completely clear the virus.

Another important predictor of spontaneous HCV clearance is the presence of symptoms, which appear to signal a more vigorous immune response. Several studies have shown that people who have clinical symptoms, jaundice, and/or elevated ALT are more likely to

clear HCV on their own. In a study by J.T. Gerlach and colleagues, 52% of symptomatic patients with acute hepatitis C cleared the virus without treatment, while all asymptomatic patients developed chronic infection. In Dr. Jaeckel’s study, 68% had jaundice and all had elevated ALT, raising the possibility that his impressive response rate might have been lower if the study had included more asymptomatic patients.

This, of course, presents a major challenge: those who are most likely to benefit from early treatment for acute hepatitis C—the majority with asymptomatic infection—are precisely those who are least likely to be identified during this stage. An exception is individuals with a known exposure to HCV (for example, health-care workers who sustain a needle-stick injury), raising the possibility of post-exposure prophylaxis.

Many questions remain about how best to treat people with acute hepatitis C, including duration, drugs, and dose. Dr. Jaeckel’s study found that 24 weeks of therapy (shorter than the usual 48-week course for chronic genotype 1 HCV) produced a sustained response rate of close to 100%, regardless of genotype. Might a shorter course of therapy also work well? Could using pegylated interferon or adding ribavirin lead to even higher clearance rates? And for individuals with genotypes 2 or 3, is it better to wait, since they have a good chance (as high as 80-90%) of responding to pegylated interferon/ribavirin therapy if they do become chronically infected?

Perhaps the most crucial unresolved question concerns timing. Based on his study, Dr. Hofer concluded that, “[interferon] therapy appears only [to be]

needed in patients who fail to clear the virus within 35 days after onset of symptoms.” In Dr. Jaeckel’s study, the delay was even longer, 30-112 days (average 89). Might it be better to wait three months to see if spontaneous resolution occurs before starting therapy? Or is it unethical to wait, given that most people could be cured with immediate treatment? Given what we know now, says Dr. Hoofnagle, “arguments can be made for either the wait-and-see or the immediate-therapy approach.”

Much remains to be learned about treating acute hepatitis C. In the meantime, the most recent (2002) hepatitis C consensus guidelines from the National Institutes of Health advise that “delays in treatment for two to three months seem reasonable to identify cases that spontaneously resolve.” Likewise, Dr. Hoofnagle concludes, “therapy can be delayed until the diagnosis is confirmed and the risks and benefits adequately discussed with the patient.”

References:

Hoofnagle, J. Therapy for Acute Hepatitis C. *New England J Med* 345: 1495-1497. November 15, 2001.

Jaeckel E et al. Treatment of acute hepatitis C with interferon alfa 2-b. *New England J Med* 345: 1452-1457. November 15, 2001.

Myers R et al. Interferon for acute hepatitis C. *Cochrane Review*. In: *The Cochrane Library*, Issue 1. Chichester, UK: John Wiley & Sons. 2004.

National Institutes of Health Consensus Development Conference Statement. Management of Hepatitis C. 2002. http://consensus.nih.gov/cons/116/091202116cdc_statement.htm.



GENOTYPE

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PREDICTION OF TREATMENT RESPONSE

Genotype information is important because it can be used as a predictor of a positive treatment outcome or response. The sustained virological response rates for pegylated interferon plus ribavirin are much higher in genotypes 2 and 3 compared with genotype 1.

Other predictors of treatment response include:

- Age of Patient—younger patients respond more favorably.
- Sex of Patient—women are more likely to respond to therapy than men.
- Histology (health of the liver)—people with minimal damage respond better to treatment.
- Viral Load—the lower the viral load (less than 2,000,000 IU/mL) the more likely one is to respond to medications.
- Weight—heavier weight is associated with lower treatment response rates.

GENOTYPE AND TREATMENT RESPONSE

Genotype 1 is considered the most difficult to treat with current HCV medications. However, treatment response rates with the newer forms of pegylated interferon plus ribavirin have been remarkably high, with up to a 52% sustained virological response rate (SVR—undetectable viral load six months post treatment). Genotypes 2 and 3 respond even better to current medications—up to 80%.

GENOTYPE AND TREATMENT DURATION

Genotype is also a factor in the period of time required to treat with current HCV medications. Generally, genotype 1 is treated for 48 weeks and genotypes 2 and 3 are treated for 24 weeks. However, there are studies underway to determine the optimal treatment duration based on certain factors. For instance, some experts believe that people with genotype 1, high viral load should be treated for 72 weeks instead of 48 weeks to maximize treatment response rates. There are also studies evaluating treating people with genotypes 2 and 3 for 12 weeks.

GENOTYPE AND HCV MEDICATION DOSAGE

Genotype information is also important for establishing the appropriate dose of ribavirin. For instance, people with genotypes 2 and 3 are given 800 mg a day of ribavirin, whereas the ribavirin dose for people with genotype 1 is dosed by body weight (1000 or 1200 mg/daily).

MIXED GENOTYPES

A person can become infected with more than one genotype. Data is almost non-existent on infection with more than one genotype, but some experts believe it may affect treatment response and HCV disease progression.

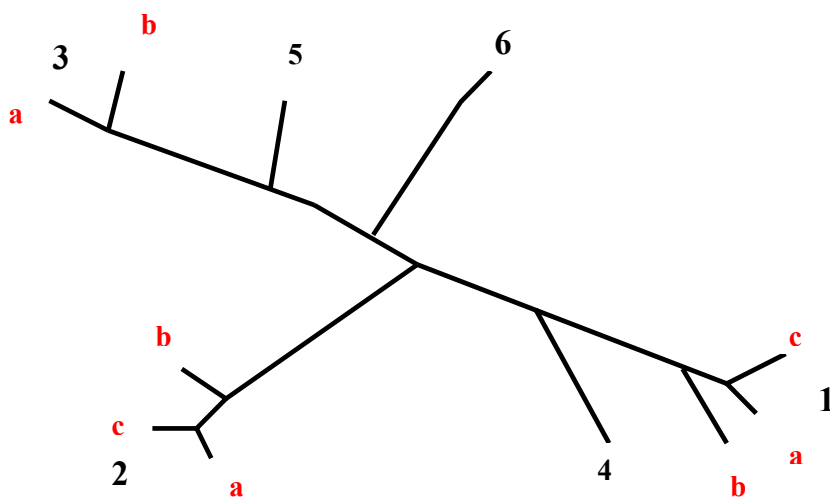
STEATOSIS AND GENOTYPE

Steatosis (fatty infiltrates of the liver) is a well-recognized feature of hepatitis C infection. Steatosis can contribute to HCV disease progression although the exact mechanism is not completely understood. People with HCV genotype 3 are more likely to develop steatosis and it is believed that HCV genotype 3 is an independent risk factor and may actually play a direct role in the development of steatosis. It has been reported that when genotype 3 individuals are successfully treated that steatosis will generally improve, and that for many steatosis will disappear.

GENOTYPE AND HCV DISEASE PROGRESSION

With regard to genotype and HCV disease progression, early limited data suggested that genotype 1b was associated with a more severe disease progression than in genotypes 1a or 2, but further studies have not been able to confirm this observation.

Genetic Diversity of Hepatitis C - Genotypes



BOOK REVIEW

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gas to peptic ulcers and Whipple disease.

These books all follow a similar formula; this one offers a brief, simplistic paragraph describing hepatitis B: "Hepatitis B is a liver disease. Hepatitis makes your liver swell and stops it from working right. You need a healthy liver...." After the cursory description of the infection, symptoms and transmission modes (all of which gets only two pages), it proceeds to provide more than 200 pages of summaries or abstracts (plus their web addresses) from scientific journals that relate to hepatitis B.

Even when the book lists organizations that focus on hepatitis B support, resources and treatment, it leaves out critically important ones, including the Hepatitis B

Foundation and the only available on-line adult support group for adults and families infected with hepatitis B, found at www.hblist.org.

While copying and pasting hepatitis B-related abstracts may make for quick copy production, it does little to truly help adults and families touched by hepatitis B. What is needed is a simple, seamless reference tool that can help patients understand how HBV is transmitted, how it is prevented, how and when it should be treated, and how to interpret viral tests, liver function tests and liver biopsies.

In addition to missing some good resources, any "yellow page" directory to the Internet is going to have a limited shelf life. Abstracts come and go; as time passes and new findings emerge, journal editors take these abstract reports of outdated scientific studies off-line.

Many of the abstracts listed in this book date back to the early 1990s, an era that can be considered pre-historic when it comes to hepatitis research.

Nothing moves at a faster clip these days than advances in treatment of hepatitis B and C. A report on lamivudine or conventional interferon conducted two years ago has little value today as researchers navigate a brave and promising new world of pegylated interferons and new antivirals.

In short, this sourcebook delivers a simplistic primer on hepatitis B, and then plunges the reader into highly-technical abstracts, with nothing to bridge the huge gap between "entry level" patients and medical researchers and practitioners. There is nothing to empower or inform patients so they can become savvy healthcare consumers and partners

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MEDICAL CARE

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- Ask for written information about the side effects your medicine could cause. If you know what might happen, you will be better prepared if it does—or if something unexpected happens instead. This way, you can report the problem right away and get help before it gets worse. Written information about medicines can help patients recognize problem side effects and then give that information to their doctor or pharmacist.

- At least once each year, bring all of your medicines and supplements with you to your doctor. "Brown bagging" your medicines can help you and your doctor talk about them and find out if there are any problems. It can also help your doctor keep your records up to date, which can increase the quality of your care.

Hospital Stays

- If you have a choice, choose a hospital at which many patients undergo the procedure or surgery you need. Research shows that patients tend to have better results when they are treated in hospitals that have a great deal of experience with their condition.

- If you are in a hospital, consider asking all health care workers who have direct contact with you whether they have washed their hands. Handwashing is an important way to prevent the spread of infections in hospitals, yet it is not done regularly or thoroughly enough. A recent study found that when patients checked whether health care workers washed their hands, the workers washed their hands more often and used more soap.

- When you are being discharged from the hospital, ask your doctor to explain the treatment plan you will use at home. This includes learning about your medicines and finding out when you can get back to your regular activities. Research shows that at discharge time, doctors think their patients understand more than they really do about what they should or should not do when they return home.

Surgery

- If you are having surgery, make sure that you, your doctor, and your surgeon all agree and are clear on exactly what will be done. Doing surgery at the wrong site (for example, operating on the left knee instead of the right) is rare. But even once is too often. Wrong-site surgery is 100% preventable.

OTHER STEPS YOU CAN TAKE

- Speak up if you have questions or concerns. You have a right to question anyone who is involved with your care.

- Make sure that someone, such as your personal doctor, is in charge of your care. This is especially important if you have many health problems or are in a hospital.

- Make sure that all health professionals involved in your care have important health information about you. Do not assume that everyone knows everything they need to.

- Ask a family member or friend to be there with you and to be your advocate (someone who can help get things done and speak up for you if you can't). Even if you think you don't need help now, you might need it later.

- Know that "more" is not always better. Find out why a test or

treatment is needed and how it can help you. You could be better off without it.

- If you have a test, don't assume that no news is good news. Ask about the results.

- Learn about your condition and treatments by asking your doctor and nurse and by using other reliable sources. For example, treatment recommendations based on the latest scientific evidence are available from the National Guidelines Clearinghouse. Ask your doctor if your treatment is based on the latest evidence.

You should be the most important participant in your healthcare. Ask as many questions as you need in order to feel comfortable with the care provided. Be confident and be sure you understand what is happening. After all, it is your body.



Medical Writers' Circle is a publication of the Hepatitis C Support Project. It consists of a series of articles written by medical professionals about the management and treatment of hepatitis C. The articles are available for printing at the Hepatitis C Support Project website.

PEGASYS

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with a high viral load.

The analysis by histology found that 87% of those patients without cirrhosis or bridging fibrosis achieved an SVR, as opposed to 75% for those patients with bridging fibrosis or cirrhosis.

SAFETY

The reported adverse events (side effects) were mild to moderate in severity and were typical of those reported in previous clinical trials of Pegasys plus Copegus.

CONCLUSION

The authors of this study concluded that the study demonstrated that treatment with Pegasys plus Copegus may be individualized by genotype.

KEY POINTS

Sustained virological response (SVR) rates:

- Overall SVR was 63%, which is the highest response rate ever reported in a hepatitis C treatment clinical trial.
- Genotype 1 = 52% SVR.
- Genotype 1, high viral load = 47% SVR.
- Genotype 1, low viral load = 65% SVR.
- Genotypes 2 and 3 = 84% SVR.
- Genotypes 2 and 3, high viral load = 82% SVR.
- Genotypes 2 and 3, low viral load = 88% SVR.

Treatment Duration and ribavirin dosage:

- Genotype 1 - 48 weeks with ribavirin dose of 1000-1200 mg/day.
- Genotype 2 & 3 - 24 weeks with ribavirin dose of 800 mg/day.



BOOK REVIEW

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with their doctors in the management of their health. There is nothing to help them understand privacy and civil rights protections afforded them by federal law, or to understand when and how to disclose their HBV infection to others.

Patients are far better off with William Green's book, "The First Year - Hepatitis B: An Essential Guide for the Newly Diagnosed," if they're looking for an in-depth, easy-to-understand sourcebook to this devastating infection. The HCV Advocate Web site also features fact sheets on HBV detailed by topic. Anyone who can type "hepatitis B" into Google or any other search engine will harvest far more up-to-date and pertinent information than is offered in this lengthy book.



HCSP's comprehensive overview of hepatitis C - 'A Guide to Understanding Hepatitis C' is now available in the following languages:

- English
- French
- Spanish
- Chinese
- Russian
- Tagalog
- Vietnamese

Printer ready copies are available on the Hepatitis C Support Project's Web site - www.hcvadvocate.org. If you do not have access to a computer, please fax your request to 877-203-3580 or write us at PO Box 427037, San Francisco, CA 94142-7037.

Include your shipping information—sorry only U.S. orders.

FOR MORE INFORMATION ABOUT HCV, CONTACT THE FOLLOWING ORGANIZATIONS:

Hepatitis Foundation International

1-800-891-0707
www.hepfi.org

American Liver Foundation

1-800-223-0179
www.liverfoundation.org

L.O.L.A. (Latino Organization for Liver Awareness)

1-888-367-5652
www.lola-national.org

Hep C Connection

1-800-522-4372
www.hepc-connection.org

Centers for Disease Control

(Division of Viral Hepatitis)
1-888-4HEPCDC (1-888-443-232)

HIV/HCV Nightline

800-273-2437

HCV PHARMACEUTICAL RESOURCES:

Roche Patient Assistance Program – Pegassist

877-734-2797

Schering-Plough Commitment to Care

1-800-521-7157

Fisher's Pharmacy

1-888-347-3416

INFORMATION ABOUT SOCIAL SECURITY

1-800-772-1213

Americans for Disability Protections:

1-800-949-4232

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