

Update from DDW:

Part 1



Alan Franciscus, Editor-in-Chief

This year the Digestive Disease (DDW) Conference was held in New Orleans, LA. DDW covers any disease related to the gastrointestinal system, including hepatitis C. This report is the first in a series of reports on the HCV data presented at DDW. For more detailed coverage of over 70 updated posters and presentations, please visit our web site. Part 1 will focus on HCV medical treatments.

EXPERIMENTAL THERAPIES

Unfortunately, there was little news at the conference on new therapies with the exception of some encouraging data on NM286 and a promising herbal combination.

NM286

NM286 is a new investigational polymerase inhibitor (NS-5 region) that shows great promise for treating HCV. This Phase I/II study evaluated the pharmacokinetics, tolerance and antiviral activity against HCV. A total of 82 patients were enrolled. The patient population included 87% of patients who were previous interferon based non-responders, and all participants were genotype 1. This was a dose escalating trial with 5 groups receiving either once a day dosing of NM286 in the range of 50-800 mg/day, twice daily dosing of 400 mg, or a placebo drug.

The results of the trials presented demonstrated a consistent, dose-related reduction of HCV RNA (viral load). The drug was well-tolerated with no serious side effects and no patients had to discontinue therapy due to side effects.

Future clinical trials are estimated to begin in the latter half of 2004 and will more closely examine the side effect profile as well as the combination of NM283 and pegylated interferon.

Mistletoe-Green Tomato Combo

Researchers presented the data from a trial using a combination of herbs—mistletoe extract, green tomato extract and Hepatodoron (*Fragaria vesca* and *Tritis vinifer*).

Eighty-five patients were enrolled, but 7 patients withdrew from the study (unrelated to treatment). Treatment included mistletoe inject-

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ed (sq) along with with Hepatodoron tablets for 14 days. After 14 days Solanum lycopersicum Herba D3-4 tablets were added to the combination therapy. Patients were treated from 12 to 24 months.

Sustained virological response (SVR) rates after one year of treatment was reported at 18% for 1 year of treatment and 56% after 2 years of treatment. Eighty percent of patients (regardless of treatment outcome) reported improved quality of life. No serious side effects were observed.

The advantage of this type of therapy is the lower cost—\$5000/yr vs. treatment with interferon plus ribavirin at \$28,000/yr. Another benefit of this treatment was the absence of side effects.

It should be noted that the mistletoe extract is a sq injection which requires FDA approval before it can be sold in this country, so it would have to go through vigorous clinical trials before it could be marketed. It was

Fine tuning of treatment in special populations and retreatment of prior treatment relapsers and nonresponders is an area of continuing research.

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The Media and Bad Science: or, How to Read an Abstract



Alan Franciscus, Editor-in-Chief

At this year's EASL conference, the media picked up on a press release that was issued comparing the two pegylated interferons. The media reports were based on a very small clinical trial that studied the viral kinetics of the two pegylated interferons. Unfortunately, the way the articles written by the media would have it, it would have been easy for the reader to conclude that one pegylated interferon was superior to the other one. However, anyone who took the time to closely examine the data would have been able to conclude that the information released by the media was basically gibberish.

Below are some highlights of the actual study overlooked or ignored by the media:

- The trial was **not** designed to compare the two pegylated interferons. This is very important because certain variables or parameters would have had to have been included in the study design in order for the results to be accurate and reliable.
- The patient population of the study was not randomized to prevent bias. This means that the patients were not selected based on a strict protocol, itself part of the study design. Rather, they were consecutive pa-

tients (patients seen at a clinic as they presented themselves to the clinic). Nor were they randomized—randomization means that the patients are randomly assigned (usually by a computer program) to different treatment groups.

- The patient population was not large enough to power the results. It is very important that a large number of patients are enrolled into a clinical trial so that the information learned from the trial can be translated into information that can be applied to a larger group of patients.
- The patient population and characteristics in the two groups were not evenly balanced by genotype, weight, BMI, and the amount of damage to the liver—all factors that can greatly influence treatment response rates.
- The results that were reported were end of treatment response rates (ETR), **NOT** sustained virological response rates (SVR). Many people with end of treatment response relapse within six months after stopping HCV medications.

Even the lead investigator of the study, Dr. Lilliana Chemello refuted the claims made by the

media: “As it is not a randomized and comparative clinical trial (RCT) between the two drugs—it is not possible to take any definitive scientific evidence or any definitive conclusion of superior efficacy between the two peginterferons.”

The best advice is always to check the sources. Unfortunately, in this case, the abstract that was issued did not contain the information about the results reported by the media.

Even though the press release and subsequent articles generated a lot of buzz in the community, it was very interesting that many patients with HCV who read the articles saw any benefit from, or made important treatment decisions based on, this data.

Below is a starting place and some simple pointers for reading and understanding an abstract. It is by no means a definitive guide. Additional resources are listed at the end of the article.

A SIMPLE GUIDE TO READING AN ABSTRACT

Reading and interpreting an abstract can be very challenging because there are many variables to consider. By definition an abstract is just a very brief synopsis or brief review of a study. The most reliable and comprehensive information comes from research articles published in prestigious

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HealthWise:

Herbs and Hepatitis C - Part 2 of a 3 Part Series



Lucinda K. Porter, RN, CCRC

Last month's column provided an overview on the subject of herbs and hepatitis C virus (HCV) infection. This month I suggest some guidelines and tools that can be used for making informed choices about the use of herbs.

When choosing an herb, start with the label. Herbs can vary in strength and purity, so it may be wise to take a standardized and certified form. Certification and standardization is voluntary. The goal of the United States Pharmacopeia (USP) is to set industry standards for drugs and dietary supplements in the U.S. The label of a supplement that displays the USP seal is worth considering. A product that is certified by NSF International (formerly the National Sanitation Foundation) is another indicator that the manufacturer complies with particular standards. A seal of approval from ConsumerLab.com (CL) also carries some distinction. Another standard is that of the world's leading authority on herbs, the German Commission E. This agency is the German equivalent of the Food and Drug Administration (FDA). The American Herbal Pharmacopoeia is also developing standardization guidelines for the American marketplace. ConsumerLab.com has provided a much-needed service by testing popular supplements. This company has discovered that many products do not contain the levels of key ingredients that are on the products' labels. A product that passes their inspection may carry the triangular label with the ConsumerLab.com quality of approval. The use of this service does have a fee associated with it. Companies that belong to the

Be skeptical. Claims made by the product manufacturers or vendor may differ vastly from independent evidence-based research.

American Herbal Products Association and submit to this organization's code of ethics are another good choice.

SUGGESTED GUIDELINES FOR HERBAL USE

- Assess your overall health. If you smoke, drink alcohol, and have other unhealthy habits, do not expect herbs to offset the potential damage these habits can cause. Adopting healthy habits will provide far more benefit than any herb can possibly give.
- Discuss herb and supplement use with your healthcare provider. Identify all the herbs and supplements you take, even if you think your doctor might disapprove. Drugs and supplements can interact with each other as well as with other health conditions.
- Apply the same commonsense approach and standards to herbs as you would to any drug. If you are reluctant to take any prescription or over-the-counter drug, be equally as reluctant to take an herb.
- Be informed and be sure your information is current.
- Before you take an herb or supplement, find out if it is compatible with other drugs or supplements you are taking. Verify that the supplement is not contraindicated for any other condition you may have (see *A Warning about Milk*

Thistle and Drug Interactions in Part 3).

- Take extra precautions if you have a history of allergies. Botanical products can cause allergic reactions.
- Follow the label's dosage recommendations. More is not better.
- Know your source. Herbs may be contaminated. Before ingesting anything, ask yourself what you know about what you are about to take.

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HCV Treatment for Nonresponders



Liz Highleyman

With recent improvements in therapy for hepatitis C, there is a growing interest in the management of patients who have not responded to previous treatment. Nonresponders are patients who do not achieve a sustained virological response (SVR) six months after the end of therapy. They fall into three groups: those who experience little or no decrease in HCV viral load (complete nonresponders); those who achieve a significant reduction in viral load at least 1-2 logs but do not clear the virus completely (partial responders); and those who achieve an early virological response (EVR) or end-of-treatment response (ETR) followed by a viral load rebound (relapsers). About half of patients with HCV genotype 1 receiving the current best treatment do not achieve an SVR.

Three basic retreatment strategies are being studied for nonresponders. The first involves administering the current standard of care, pegylated interferon plus ribavirin, to patients who previously received suboptimal therapy with standard interferon alone (monotherapy), standard interferon plus ribavirin, or pegylated interferon monotherapy. The second strategy is to administer pegylated interferon plus ribavirin at higher doses or for longer periods. The third involves treatment with new drugs instead of, or in addition to, pegylated interferon and ribavirin.

CURRENT STANDARD OF CARE

Research indicates that about 20% of patients who did not respond to the older standard interferon can achieve an SVR with pegylated interferon plus ribavirin. For example, in the April 2004 issue of *Gastroenterology*, Mitchell Shiffman and colleagues reported the first results from the Hepatitis C Antiviral Long-Term Treatment Against Cirrhosis (HALT-C) trial. The study evaluated 604 patients who did not respond to previous treatment with standard interferon, with or without ribavirin. Subjects were retreated with pegylated interferon (Pegasys) 180 µg per week plus ribavirin. Those who achieved an EVR (undetectable HCV viral load at 20 weeks) continued treatment for 48 weeks. At the end of treatment, 32% of patients had an undetectable viral load; at the end of follow-up (72 weeks), 18% achieved an SVR. Among those who achieved an EVR at 12 weeks, 34% went on to achieve an SVR, but only three patients (1%) who did not achieve an EVR later achieved an SVR. SVR rates were 14% for patients with HCV genotype 1, 65% for genotype 2, and 54% for genotype 3. African Americans and patients over age 60 had lower SVR rates. The researchers concluded that "[s]elected nonresponders to previous interferon-based therapy can achieve SVR following retreatment with [Pegasys] and ribavirin."

The likelihood of successful retreatment is highest when patients who originally received standard interferon monotherapy are retreated with pegylated interferon plus ribavirin. It is uncommon for patients to respond to retreatment with the same suboptimal regimen. In both HALT-C and ACTG 5071 (a study of patients coinfecting with HCV and HIV), patients who started at lower doses of ribavirin in an effort to reduce toxicity were less likely to achieve an SVR, confirming that ribavirin helps prevent relapse.

It is also possible that individuals who did not respond well to Peg-Intron, the first approved pegylated interferon, may do better with Pegasys. At the May 2004 Digestive Disease Week (DDW) conference, N. Zeng and colleagues from Johns Hopkins reported on the use of Pegasys plus ribavirin in 15 genotype 1 patients who failed to respond to Peg-Intron plus ribavirin. At 24 weeks, 40% (six subjects) had undetectable HCV viral load. One-third of the continued nonresponders (3 out of 9) and just one of the responders were African American. SVR rates are not yet available, and patients will continue to be followed. A currently enrolling study called REPEAT will also look at retreatment with Pegasys plus ribavirin in Peg-Intron nonresponders. (For details and study sites, see

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HERBS

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- Choose herbs and supplements that are standardized.
- Buy products that submit to voluntary self-regulation.
- Natural does not equal healthy or safe. Snake venom is natural but not healthy.
- Do not be swayed by bargain prices. Herbs are not all equal.
- Check the expiration date on the container.
- Do not rely on the health food store staff for health care information. Although they may be helpful, remember that salespeople are usually not licensed to practice medicine. Do not treat your condition on the advice of a salesperson.
- Be skeptical. Claims made by the product manufacturer or seller may vastly differ from independent evidence-based research.
- Do not be swayed by personal testimonies. Although individuals may benefit from botanical use, the notion that "one size fits all" does not apply in medicine.
- Do not be influenced by the latest supplement to make headlines. Dietary supplements can be compared to cars. When new models are introduced, sometimes it takes time before problems develop. A product that really has value will be around for awhile.
- Herbs and supplements should not be given to children or taken by pregnant or nursing women without a physician's approval. Older adults and those with various health conditions should also exercise extra caution before taking non-prescribed supplements. Herbs should never be used with decompensated cirrhosis.
- Some herbs prolong bleeding times or interfere with anesthetics.

Stop all herb use at least a week prior to any surgery or procedure that uses anesthesia. Tell your attending physician and anesthesiologist about any herbs you are using, particularly if the procedure occurs before you have sufficient time to observe this "wash-out" period.

- Report any suspected adverse reactions to an herb or supplement to the FDA's monitoring program, Medwatch. Call 800-322-1088 or www.fda.gov/medwatch.

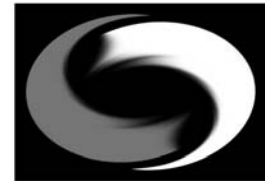
Next month's column will focus on some specific herbs, warnings, and resources.

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NONRESPONDERS

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www.clinicaltrials.gov/ct/gui/show/NCT00039871.)

LONGER OR HIGHER-DOSE THERAPY

The usual course of therapy for HCV is 48 weeks for patients with genotype 1 HCV and 24 weeks for those with genotypes 2 or 3. While most genotype 2 or 3 patients do well with a 24-week course, some studies suggest that 72 weeks may work better for those with genotype 1. This may be especially true for HCV/HIV coinfecting patients, who appear to respond more slowly to HCV therapy. The benefits of higher doses are less clear, however. C. Bapin reported at the April 2004 European Association for the Study of the Liver (EASL) conference that 24% of previous standard interferon monotherapy or standard interferon plus ribavirin nonresponders achieved a SVR after 48 weeks of retreatment with Peg-Intron plus ribavirin. However, subjects who started with an initial Peg-Intron dose of 2 µg/kg per week for the first 12 weeks did not respond better than those who received the usual 1.5 µg/kg per week dose for the entire 48 weeks.

OTHER DRUGS

One therapy under study for treating nonresponders is consensus interferon-alpha (Infergen), a recombinant product that combines the features of several natural alpha interferons. At the recent DDW meeting, Steve Kaiser reported on a study of high-dose Infergen in previous nonresponders. In this study, 50 subjects (about half with genotype 1) who did not respond to pegylated interferon plus ribavirin were retreated with either 9 µg

Infergen daily for 16 weeks or high-dose (27 µg) daily Infergen induction therapy for 4 weeks followed by 18 µg daily for 12 weeks. All patients then received continued therapy with 9 µg daily Infergen plus ribavirin for an additional 34-56 weeks. Twenty-four weeks into the combination therapy phase, 46% of subjects who started with 9 µg Infergen and 52% of those who started with 27 µg achieved an undetectable HCV viral load. ETR rates were 42% and 48%, respectively, and SVR rates were 23% and 27%. "[Consensus interferon] daily dosing/induction therapy together with subsequent [ribavirin] combination therapy thus shows sustained viral response rates in about one quarter of previous peginterferon combination therapy nonresponders," the researchers concluded.

Another drug being studied in nonresponders is interferon-gamma-1b (Actimmune), now in Phase II trials. In a pilot study presented at the DDW conference, Carroll Leevy reported that after 24 weeks, 47% of previous Peg-Intron plus ribavirin nonresponders achieved an undetectable HCV viral load when retreated with a combination of Infergen 15 µg daily plus Actimmune 50 µg twice weekly plus ribavirin. SVR results are not yet available, and the study is continuing. Although both Kaiser and Leevy reported that treatment was generally well-tolerated in their studies, some physicians are skeptical about using high daily doses of Infergen and/or Actimmune due to potential toxicity. Further research is needed to determine whether less frequent or lower doses would produce similar results.

FUTURE PROSPECTS

Failure to achieve a sustained virological response can be discouraging. But research indicates that patients may experience a histological response, improved liver tissue health, or a reduced rate of fibrosis progression even if they do not completely clear HCV. This is most likely in partial responders who experience some decrease in viral load. Even in the absence of SVR, treatment may help prevent progression to decompensated cirrhosis and lower the risk of hepatocellular carcinoma (liver cancer). For this reason, some experts believe nonresponders may benefit from interferon maintenance therapy. Due to its toxicity, long-term therapy with full-dose interferon is an unattractive prospect. But even low-dose maintenance therapy may be useful. This is now being evaluated in a few large trials including HALT-C.

Given the side effects, inconvenience, and cost of HCV therapy, the decision whether to retreat can be difficult. The current National Institutes of Health (NIH) consensus guidelines recommend that retreatment should be considered especially for patients with advanced liver fibrosis or cirrhosis, who stand to benefit the most from therapy. Improvements in HCV therapy are rapidly emerging, and it is probable that future therapeutic advances including drugs from entirely new classes such as protease inhibitors will offer improved prospects for successful retreatment of patients who have not previously responded to therapy.



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also noted that the potency depends of the type of tree that is used to harvest the mistletoe.

There was concern raised by some physicians that this combination has a potential to cause liver damage especially in people with decompensated cirrhosis. Larger patient populations are needed, and different populations, to be able to learn the exact mechanism of action of the drug and how it reacts in the body.

In another small study of 8 patients on the effect of the above herbal treatment on fibrosis, the authors found that the herbal combination was able to inhibit and reduce fibrosis in the patients. Further studies are needed to confirm the preliminary results.

IDN-6556

Oral IDN-6556 is a caspase inhibitor that is believed to slow apoptosis (programmed cell death). In this multicenter, double-blind, placebo-controlled dose ranging study, 80 patients were treated with doses ranging from 5 mg BID to 100 mg BID for 14 days with a 21 day follow-up period. It was found that the drug was well-tolerated and significantly lowered ALT levels. HCV RNA (viral load) levels did not increase nor did IDN-6556 inhibit HCV RNA clearance. There is concern, however, that there might be a potential of increasing the risk of cancer. Further studies of additional dose levels in HCV patients with HBV, PBC and NASH are planned.

HCV Treatment

Current therapies work for approximately 50% of people. Fine tuning of treatment in special popu-

lations and retreatment of prior treatment relapsers and nonresponders is an area of continuing research.

Pegasys

Howell and colleagues studied treatment with Pegasys plus Copegus (ribavirin) in Blacks and Caucasians. All Black patients had not been previously treated. The primary endpoint of this study was to examine the safety, tolerability and efficacy in Blacks.

All patients received Pegasys (180 ìg) once a week plus Copegus (1000 to 1200 mg/day). All patients were treated for 48 weeks with an additional 24 weeks of posttreatment follow-up.

The results reported were for the Black patients only. Using intent to treat analysis, 26% of patients achieved a sustained virological response (SVR). No unexpected seri-

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BAD SCIENCE

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medical journals that are carefully reviewed by peer medical editors.

GENERAL TIPS FOR READING AND UNDERSTANDING AN ABSTRACT:

An abstract is usually divided into seven sections. A good tip is to read the entire abstract quickly then go back and review it in detail. Some people just read the conclusion section. This is not a good idea because the conclusion can be misleading.

1) Title:

A very brief (one brief sentence) description of the study.

2) Authors:

All the authors will be listed and sometimes the affiliations of the authors will also be listed. Look for reputable authors and medical institutions. The author and affiliation carry a lot of weight.

3) Introduction or background:

A brief history of what is known about the topic under study and why the study is important.

4) Aim:

This is one of the most important sections because it spells out the original intent or design of the study. The aim should include definite end points that are carefully planned and executed. Look for *prospective* studies that are designed in advance with set clinical outcomes. *Retrospective* studies are studies that look back over time at a previous study or population. They are important for compiling information for future studies, but they can also be ma-

nipulated and do not carry much weight in evidence based medicine.

5) Patients/Methods:

This section will give you information on patient characteristics, drug dosing and other valuable information.

Important points to ask yourself when reviewing this section:

a. How many patients were enrolled in the study? Larger studies carry more weight.

b. Outcomes vary widely depending on many factors. What were the patient characteristics? Were they evenly matched by age, gender, race, genotype, viral load, degree of liver damage, biochemical markers and other important patient information?

c. Was the clinical trial randomized and blinded to prevent bias? The gold standard of clinical research on humans is the blinded, randomized control trial. In this type of trial, patients are randomly selected. Randomization means that patients are randomly assigned—usually by a computer program—to a particular study group to receive the test drug, a standard of care drug or a placebo.

d. How did the researchers test their hypothesis and what tools did they use? Are they using sensitive diagnostic tools?

e. Was the study designed to compare one drug against another drug, or against the current standard of care? Was the dose of medication appropriate in both groups?

6) Results:

This section reports on the outcome of the study. It should break the information down by overall results and then by patient characteristic and medication dose. The results should also report the statistical significance, which is an indicator of how well the drug will work under the same circumstances in a different setting. This is usually reported as a p-value. P-value of < 0.05 is considered statistically significant. $P = 0.05$ means that there is a 95% chance the drug will work and a 5% chance that it will not.

7) Conclusion:

This can be a slippery slope since it is a fine balance between the reality and what the author has concluded. Refer back to the results and compare the results with the author's conclusions.

The more you practice reading an abstract the more you will be able to understand the information presented. Always use your critical mind when trying to interpret scientific data or any other source of information. And don't be afraid to ask questions—most medical professionals welcome questions and the involvement of patients in their medical care and management.

Recommended links:

Prostatitis Organization
<http://prostatitis.org/index.html>

SciDev.Net
www.scidev.net

Harcourt College
<http://www.harcourtcollege.com/student/scipaper1.html>



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ous adverse event was observed. More Black patients required Pegasys dose reductions due to neutropenia (37% vs. 18% for white patients), but only one patient developed treatment related infection. The high prevalence of neutropenia in Black patients treated in this trial is believed to be related to the documented higher rate of neutropenia in the general Black population. The authors concluded that therapy with Pegasys plus Copegus was effective, well-tolerated and that patients with genotype 1 should be treated for 48 weeks.

In another study on Pegasys plus Copegus from the HALT-C trial, preliminary data (48 wks) in HCV patients (55 patients including 15 patients who were previous Peg-Intron plus Rebetol [ribavirin] non-responders) was reported. Patient characteristics were evenly matched by age, race, genotype, and viral load. Thirty-three percent of the patients treated achieved an end-of-treatment response. The 24 week posttreatment SVR will be reported when available.

Infergen

Dr. Leevy reported on the preliminary results of a study in which 32 patients were treated with Infergen 15 mcg daily and interferon gamma-1b (50 mcg SQ TIW) for 48 weeks. Patients in this trial were initially treated with Pegasys plus Copegus, but if they did not achieve an undetectable or at least a 2 log drop of HCV RNA (viral load) at week 12 they were switched to Infergen plus gamma interferon therapy. At the end of 24 weeks of therapy 47% of patients were HCV RNA negative. Twenty-five percent of patients treated required Filgrastim due to reductions in Neutrophil counts. The authors concluded that treatment with

Infergen and gamma interferon was well-tolerated and that the preliminary data looked encouraging. The SVR rates will be reported 24 weeks post completion of therapy. In addition, the author stated that a larger patient study is now being started as well as a phase II study to find the most effective dose of the drugs.

An additional presentation was given by Dr. Kaiser on the end-of-treatment response rate of the combination of Infergen and ribavirin using induction and dose escalation in 60 patients. In this randomized open label study, prior Peg-Intron plus ribavirin and Pegasys plus ribavirin non-responders were treated:

- Group A – Induction phase (4 weeks) Infergen 27 mcg daily followed by 18 mcg Infergen daily plus ribavirin (11mg daily) for 12 weeks then 9 mcg daily for another 32-72 weeks.*
- Group B – induction phase (4 weeks) 9 mcg daily followed by 9 mcg Infergen plus ribavirin (11 mg/kg) for 12 weeks with an additional 9 mcg/kg plus ribavirin (11 mg/kg) for 12-72 weeks.*

** Treatment duration varied from patient to patient. Once a patient tested negative for HCV RNA, treatment was continued for an additional 6 months.*

The SVR rates for 23 patients were available at the time of the presentation. In these patients the SVR rate was 23% (group B) and 27% (group A). The SVR rates for all of the trial participants will be released when all the patients complete the 24 week follow-up period.

Peg-Intron

A small study examining twice weekly administration of Peg-Intron plus ribavirin was reported. Sixty-five patients (38 men/27 women, age range 20-65) were enrolled. The pa-

tients were divided into two treatment arms with both receiving a mean dose of 11 mcg/Kg/week of ribavirin:

- Group A – Twenty-two patients (7 genotype 2, 15 genotype 1) received Peg-Intron (1.5 mcg/Kg) once a week.
- Group B – Forty-three (17 genotype 2, 26 genotype 1) received Peg-Intron (2.4 mcg/Kg/) twice weekly.
- There were no significant differences reported in the patient characteristics.

The SVR for genotype 1 patients was reported. Genotype 1 SVR for group B was 46% vs. 13% for group A. Patient discontinuation rates were higher for group A compared to those in group B.

The authors concluded that twice weekly dosing of Peg-Intron was more effective in genotype 1 naïve patients.

In another presentation on Peg-Intron, researchers studied the effect of retreatment with Peg-Intron in previous non-responders and relapsers to standard interferon plus ribavirin. One hundred and ninety-six patients were randomized to receive either 0.50 or 1.5 mcg/kg/wk peginterferon and the same dose of ribavirin. Patient characteristics were not noted. Sustained virological response rates were 30% for the patients enrolled in the higher treatment group compared to 6% for those in the lower treatment group. As expected more patients that relapsed on a prior course of interferon plus ribavirin therapy achieved an SVR compared to the non-responders. The authors concluded that treatment with Peg-Intron plus ribavirin was a reasonable option for prior relapsers and non-responders to interferon plus ribavirin therapy.



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