

New Treatments Available for Hepatitis B

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Not every person with chronic hepatitis B requires treatment. All infected individuals should, however, be monitored regularly by a doctor knowledgeable about the disease. Simple blood tests can help doctors assess liver health and monitor viral activity in order to determine if and when medication is appropriate. The purpose of treatment is to slow or prevent liver damage caused by hepatitis B.

The not-so-distant past
Just a decade ago, there were no treatments available for hepatitis B. Other than making some liver-friendly lifestyle changes (abstaining from alcohol, for instance), an infected individual could only hope for the best.



The first hepatitis B treatment, Intron A, was developed by New-Jersey-based Schering-Plough and approved by the Food and Drug Administration (FDA) in 1991. Intron A utilizes alpha interferons, a man-made version of a protein that the body produces naturally to fight off disease. The drug, administered via injections several times a week over a period of six months to a year, proved very effective at reducing the amount of virus in the body, but tolerability remained an issue.

Almost all patients reported some type of adverse reaction, the most common being flu-like symptoms (nausea, vomiting, fatigue, fever, headache) and depression. For more than 20 percent of patients, the side effects were severe enough to interfere with normal daily activities and warranted stopping treatment.

In 2005, Roche Holding AG, also out of New Jersey, introduced a second alpha interferon called Pegasys onto the market. Also administered via injection, but only once a week for six months to a year, the drug reflected the industry's shift toward convenience for patients. Pegasys was easier to take and equally as effective as Intron A, but it also shared its predecessor's side effects.

Though both drugs remain available, Intron A and Pegasys are largely used outside of the United States. American doctors now prefer oral treatments for both their convenience and tolerability.

The Promise of the Present

All five of the oral treatments currently available work much the same way. They all reduce the ability of the hepatitis B virus to replicate and infect new liver cells, and in many cases lower the amount of virus in the body.

The first oral treatment, Epivir-HBV, was introduced in 1998 by GlaxoSmithKline out of the U.K. The drug contains lamivudine, which, in higher doses, is used to treat HIV. In most cases, side effects are minor (nausea, diarrhea, muscle aches, etc.) and temporary.

Hepsera (Gilead Sciences, Inc.), Baraclude (Bristol-Myers Squibb Co.) and Tyzeka (Idenix Pharmaceuticals/Novartis Pharmaceuticals, Inc.) followed in 2002, 2005 and 2006, respectively. Like Epivir-HBV, they are taken once a day. Side effects are also usually mild and similar to Epivir-HBV.

The latest oral treatment to hit the market is Viread, the second HIV medication discovered to also be effective in treating patients with chronic hepatitis B. Viread, which was approved for the treatment of hepatitis B in August 2008, is produced by Gilead Sciences, Inc., based in Foster City, Calif. Like the other oral treatments, it is taken once a day, and side effects are usually mild.

Single-drug “monotherapy” has proven effective for most patients, though concerns about drug resistance are prompting researchers to try to develop new drugs with longer efficacy, and to look at the possibility of combining existing drugs to decrease resistance.

Setting the Bar for Treatment

“There wasn’t much we could offer before [these drugs],” says Dr. Kevin Man, a gastroenterologist at St. Mary’s Medical Center in San Francisco. “All we could do is tell patients, ‘Don’t smoke, don’t drink, eat right and come in for monitoring and to get screened for liver cancer.’”

As medications come online and data emerge showing that hepatitis B is not the passive virus it was once believed to be, more and more emphasis is being put on identifying infected individuals as early as possible.

With the tools to minimize or prevent hepatitis-B-related liver damage at doctors’ disposal, federal health officials and healthcare advocates are pushing for doctors to routinely screen patients already identified to be at-risk for hepatitis B, such as members of immigrant communities who are disproportionately impacted by the disease. An estimated one out of every ten Asian and Pacific Islander Americans is infected with chronic hepatitis B.

Once infected individuals are identified, doctors, who once had no choice but to follow the disease’s lead, can determine an appropriate proactive course of action. Whether

that course of action includes medication or simply regular monitoring, doctors have the power to keep the virus at bay. But it all starts with screening.

“When we go out and speak with doctors, whether it’s one-on-one or in a conference setting, we really encourage them to do screenings,” says Dr. Christopher Ng, director of medical sciences with Gilead Sciences, Inc.’s Hepatitis Team. The team meets regularly with doctors to update them on new recommendations, treatment guidelines and treatment options. “We can’t emphasize the importance of screening enough.”

Even the Centers for Disease Control and Prevention (CDC) recently revised its guidelines to re-emphasize screening, particularly of at-risk individuals. For the first time, the guidelines also address long-term treatment of infected individuals.

“There’s a greater understanding now of the risks associated with chronic infection,” explains Dr. Gillian Zeldin, gastroenterologist and director of medical affairs, infectious disease and transplant immunology with Novartis Pharmaceuticals. “We treat risk now. And we recognize that even people who have [a smaller amount] of virus in their blood have risks. Their risks are lower, but they are not normal risks. So the old tipping point doesn’t apply any more.”

The New Tipping Point

Whereas liver function, as determined by standard blood tests, was once the only measure used by doctors to assess hepatitis B status, the growing consensus among the medical community now is that viral load is a much better marker. That is, by running another test to determine how much of the hepatitis B virus is in the blood, some doctors believe they can predict the virus’s next move and act accordingly.

“Liver disease is caused by the immune system’s response to the virus,” explains Dr. Stewart Cooper, director of California Pacific Medical Center’s Liver Disease Management & Transplant Program. “So the risk of liver disease has a proportional relationship to the amount of virus in your blood.”

This idea has yet to be fully embraced by the medical community. But more and more doctors are now basing their decisions regarding treatment on viral load.

“Among the doctors I work with [at Saint Mary’s], viral load is the number one thing we look at,” Dr. Man says. “We keep a close eye on it, and we use it to determine whether or not treatment is appropriate. For patients on drug therapy, viral load is how we can tell if a drug is working or not.”

Just last month, the FDA approved a new test that will further help doctors determine the effectiveness of treatment.

The COBAS TaqMan HBV Test, which was developed by Roche Holdings AG, is administered before and after therapy begins and allows doctors to examine a given drug's effect on the virus's genetic structure.

Clearing the Hurdles

While the long-term outlook appears promising for patients with chronic hepatitis B, there remains a major hurdle to clear in the short run.

The revised CDC guidelines prescribe a more aggressive approach to battling hepatitis B. But the responsibility falls entirely on doctors, many of whom continue to rely on information that is outdated and, in some cases, just plain wrong.

"I see people every week who got wrong information [about hepatitis B] from their doctor," Dr. Cooper states. "This is a poorly understood disease."

Because there was little that could be done for patients with chronic hepatitis B until just a few years ago, the disease was largely ignored by doctors. Forced to choose between a disease for which there was no quick fix and serious, but treatable ailments, such as high blood pressure, busy doctors often opted for the latter. Now, the success of available treatments depends largely on re-educating the medical community, from nurse practitioners working in small, neighborhood clinics to hospital administrators, about the availability and effectiveness of treatments.

The new CDC guidelines are great, says Dr. Samuel So, founder of the Asian Liver Center at Stanford University. But he says the guidelines are likely to be ignored by doctors, most of whom see dozens of patients each day and barely have time for a bathroom break, much less to read through the many recommendations issued by the CDC each month.

Even more confusing, says Dr. Ng, is the fact that doctors often receive conflicting recommendations from multiple agencies.

"It's very confusing," he states. "So my team does a lot of disease education. We go through all of the data and all of the guidelines, and we try to summarize it for the doctors to make sure they really understand."

Ng concludes: "You'd be surprised how many of the doctors still aren't familiar with the guidelines [for hepatitis B]. That seems to be improving, though. It takes meeting with a doctor several times and going over the information with them each time to really make it stick. That's our approach, and it seems to be working. People are beginning to pay more attention to hepatitis B."