

## Herbal & Dietary Supplements

SAN DIEGO -- Patients taking herbal and dietary supplements may be at risk for liver injury severe enough to warrant an organ transplant, researchers said here.

In a review of national data, supplements accounted for 18% of liver injuries in the U.S., Jose Serrano, MD, of the National Institutes of Health, reported during a press briefing at Digestive Disease Week.

"The number of cases in our network has increased over the years," Serrano said during the briefing. "There were no deaths, but 7% of patients needed a liver transplant. These are not trivial consequences."

It's estimated that as much as 40% of the U.S. population uses herbal or dietary supplements, but their potential side effects, including hepatotoxicity, are not well defined.

The researchers looked at data from the Drug Induced Liver Injury Network, which evaluated patient information from eight sites across the U.S. from 2003 to 2011.

Of 679 cases of liver injury, 93 were attributed to herbal or dietary supplements, Serrano said, adding that these patients tended to be younger than those who have similar liver injuries due to other medications. The majority of these patients were white.

Among patients that had used supplements, 33% used them for body building, 26% for weight loss, and the remaining 31% used a variety of other types of supplements.

Serrano said the symptoms of liver injury caused by supplements weren't different from those caused by other medications. But one factor that distinguished liver injury from body building supplements over the others was itching, which occurred in 86% of patients.

Those who had liver injury resulting from either body building or weight-loss supplements also tended to have a longer latency time between exposure and injury compared with liver injury from other medications or the miscellaneous category of dietary supplements.

Weight-loss products also appeared to be associated with a more hepatocellular pattern of injury, while body building supplements (usually anabolic steroids) had a more mixed pattern with increments on total bilirubin, Serrano said.

Most of the patients (66%) had to be hospitalized, and 11% developed alterations in liver function that persisted for at least 6 months, he added. The median serum alanine-aminotransferase (ALT) at presentation was 533 U/L, the alkaline phosphatase was 166 U/L, and the total bilirubin was 7 mg/dL.

The R-value, which represents liver injury pattern, was in the hepatocellular range (>5%) in 65% of the patients with a median ALT of 1,275 U/L. The range for normal ALT is generally between 7 and 56 units U/L.

Symptoms included:

- Jaundice (78% of patients)
- Nausea (60%)
- Itching (58%)
- Abdominal pain (47%)

The majority of patients (60%) used only one type of supplement, while 23% used two or more supplements, and 16% used at least one supplement concurrently with prescription drugs.

While the most common injury pattern seen was hepatocellular, the distribution of overall causality scores was not significantly different across injury patterns ( $P=0.30$ ), the authors stated.

The biggest risk to patients that use supplements is not reporting supplement use to a healthcare professional, noted Donald Jensen, MD, of the University of Chicago and DDW press conference moderator.

"Patients need to be label readers," Jensen told MedPage Today. "They can't just assume that everything out there is safe. There are things out there that can be potentially damaging."

He added that patients think supplements "are food or that they're very safe. And there are some herbal medicines that probably are safe and may even do some benefit for people. I don't want to throw everything in the trash can. But, on the other hand, there are enough [supplements] that are damaging."

He said that future research on supplements should focus on potential patient interactions with herbal supplements, noting that not all patients have negative interactions with them.

"I don't think we're going to stop people from taking herbal medicines," he said. "I'd like to see the FDA regulate the toxic ones better, but otherwise I think the important next step is some scientific understanding of why some people get damaged and others don't."