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The full report is titled "Brief Communication: Severe Hepatotoxicity of Telithromycin: Three Case Reports and Literature Review." It is in the 21 March 2006 issue of *Annals of Internal Medicine* (volume 144, pages 415-420). The authors are K.D. Clay, J.S. Hanson, S.D. Pope, R.W. Rissmiller, P.P. Purdum III, and P.M. Banks.

Telithromycin: A Possible Cause of Severe Liver Damage?

What is the problem and what is known about it so far?

Drugs are a common cause of liver damage. Companies that test new drugs often check liver enzyme levels to see if a new drug causes liver damage. Telithromycin, a new antibiotic, was approved in 2004 for the treatment of sinus and respiratory infections. In testing before approval, telithromycin caused liver enzyme elevations in very few people. It was as safe and effective as other antibiotics.

Why did the researchers do this particular study?

The researchers observed severe liver damage in young, healthy people taking telithromycin. They wanted to see if telithromycin caused the damage. They also wanted to review other reports of liver damage before and since the drug was approved for use.

Who was studied?

3 patients who started taking telithromycin just before they developed severe liver damage.

How was the study done?

The authors reviewed the patients' medical information and reports of telithromycin and liver damage in the medical literature and in reports to the U.S. Food and Drug Administration. They asked the maker of the drug to provide information from drug testing.

What did the researchers find?

A healthy 46-year-old man developed jaundice and liver enzyme elevations soon after starting telithromycin therapy. He improved after the drug was withdrawn. A 51-year-old healthy woman developed jaundice and enzyme elevations the week after starting telithromycin. Her condition worsened, and she required liver transplantation to survive. Examination of her liver suggested drug-related liver failure. A 26-year-old man who drank alcohol regularly developed jaundice, fever, and gastrointestinal bleeding the week after starting telithromycin therapy. His condition quickly worsened, and he died. Examination of his liver also suggested drug-related liver failure. In a review of available information, the authors found that telithromycin was a known cause of mild liver enzyme elevations. However, there was no evidence that telithromycin caused mild elevations more often than other antibiotics. There were also no reported cases of elevations or liver damage as serious as those in the 3 patients.

What were the limitations of the study?

The authors cannot prove that telithromycin caused the episodes of liver damage they observed. Alcohol, other drugs, and unknown factors may have contributed.

What are the implications of the study?

Telithromycin is a possible cause of severe liver damage. The drug should probably be taken with caution until it is proven to be safe.

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