

CLINICAL CAPSULES

Liver Toxicity Reported With Ketek

The Food and Drug Administration is recommending that physicians monitor patients taking telithromycin (Ketek) for signs and symptoms of liver problems in response to reports of liver toxicity in three patients taking the drug.

Telithromycin is the first of the ketolide class of antibiotics to be approved, and is indicated for adults for the treatment of serious bacterial infections, such as community-acquired pneumonia, acute bacterial sinusitis, and acute exacerbation of chronic bronchitis. The drug is mar-

keted by Aventis Pharmaceuticals Inc.

All three patients developed jaundice and abnormal liver function. One patient recovered, one required a transplant, and one died. The patients previously had been healthy and were not using other prescription drugs.

Examination of the livers of two of the patients revealed massive tissue death. The cases were reported online as an early-release article in the *Annals of Internal Medicine* (www.acponline.org/journals/annals/hepatotoxicity.htm).

The FDA recommends that telithro-

mycin should be stopped in patients who develop signs or symptoms of liver problems. Patients who have been prescribed the drug and who are not experiencing side effects such as jaundice should continue taking their medicine as prescribed. Patients who notice any yellowing of their eyes or skin, or other problems such as blurry vision, should call their health care provider immediately.

Telithromycin should be used only for infections caused by a susceptible microorganism. These include *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*, *Staphylococcus aureus*, *Chlamydia pneumoniae*, and *Mycoplasma*

pneumoniae. The FDA is continuing to investigate the issue of liver problems in association with the use of telithromycin in order to determine if labeling changes or other actions are warranted.

Infections Prolong Hospitalization

Elderly patients who developed surgical site infections after undergoing orthopedic surgery had significantly longer hospital stays, Dr. Jeanne Lee wrote in a poster at the annual Interscience Conference on Antimicrobial Agents and Chemotherapy. Surgical site infection was a significant independent predictor of prolonged hospital stay according to both bivariate and multivariate analyses in the outcomes study, conducted by Dr. Lee and her colleagues at Duke University in Durham, N.C.

The study was conducted in eight hospitals between 1991 and 2002. The most common procedures were hip arthroplasty in 74 patients (22%), fracture repair in 55 patients (16%), and knee arthroplasty in 40 patients (12%). *Staphylococcus aureus* was the dominant pathogen, associated with 95 infections (56%), and 55% of these pathogens were methicillin resistant.

The mean length of stay was 13 days among 169 infected patients, compared with 4 days among 171 uninfected controls. The patients' mean age was 75 years; 66% were women, and 83% were white.

Other predictors of prolonged hospital stay included an inability to bathe independently, undergoing procedures of longer duration, postoperative glucose greater than 200 mg/dL, and having procedures on the same day as hospitalization.

Severe Diabetic Skin Infections

Diabetic patients with severe skin infections had greater improvement when treated with meropenem than with imipenem-cilastatin, Dr. John M. Embil reported in a poster presented at the annual Interscience Conference on Antimicrobial Agents and Chemotherapy.

Skin and skin-structure infections are a perpetual problem for diabetic patients, and may require surgical intervention if left untreated, wrote Dr. Embil of the University of Manitoba, Winnipeg, Canada.

The international, randomized, double-blind study included 1,037 hospitalized patients with complicated skin infections, 398 of whom were diabetic.

The clinical cure rate was 86% among the 204 diabetic patients who received a 500-mg intravenous dose of meropenem every 8 hours, compared with 72% among the 194 diabetic patients who received the same dosing regimen of imipenem-cilastatin. The cure rate among the nondiabetic patients treated with meropenem (87%) was similar to the rate in those treated with imipenem-cilastatin (89%).

Overall, meropenem was associated with slightly higher cure rates for all groups of pathogens—aerobic gram-negative, aerobic gram-positive, anaerobic, and polymicrobial—compared with imipenem-cilastatin, but the differences were not statistically significant. More than 40% of the pathogens were gram-negative aerobic or anaerobic organisms, and 29% of the *Staphylococcus aureus* isolates showed methicillin resistance. A similar spectrum of pathogens appeared in both diabetic and nondiabetic patients.

—Heidi Splete and Kerri Wachter

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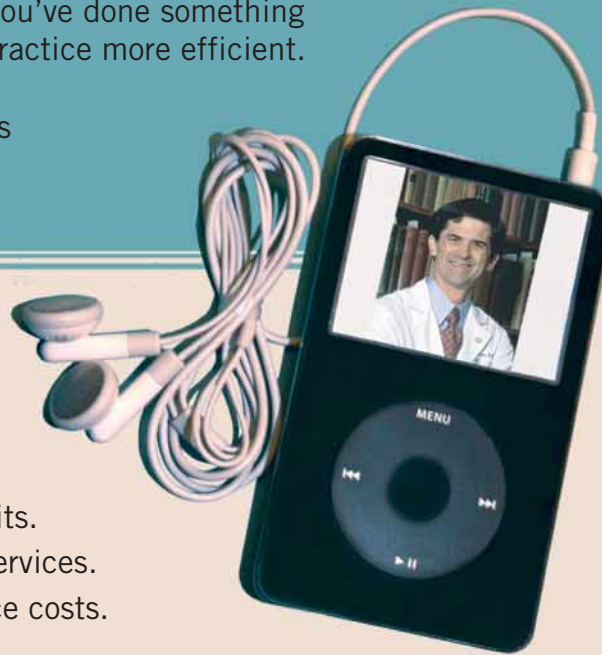
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