MedicalXpress

Study evaluates antibiotic option for treating bladder infection in women

February 7 2012

Short-term use of the antibiotic cefpodoxime for the treatment of women with uncomplicated cystitis (bladder infection) did not meet criteria for noninferiority for achieving clinical cure compared with ciprofloxacin, a drug in the fluoroquinolone class of antibiotics for which there have been concerns about overuse and a resulting increase in resistance rates, according to a study in the February 8 issue of *JAMA*. The criteria for noninferiority was if the efficacy of cefpodoxime had been shown to be within a pre-specified margin of 10 percent of the efficacy of ciprofloxacin.

Fluoroquinolones have high rates of efficacy and minimal adverse drug reactions when used in a 3-day regimen as recommended to treat uncomplicated cystitis. However, increasing rates of antimicrobial resistance among fluoroquinolones have been reported. To prevent further emergence of fluoroquinolone resistance, there are calls for restricting fluoroquinolones to those specific instances of uncomplicated cystitis when other first-line urinary tract infection (UTI) antimicrobials are not suitable, according to background information in the article. "Cefpodoxime, with its broad spectrum of antimicrobial activity, would provide a useful alternative to fluoroquinolones for the treatment of cystitis if demonstrated to be similar in efficacy to fluoroquinolones and without adverse ecological effects (such as the selection of drug-resistant organisms)."

Thomas M. Hooton, M.D., of the University of Miami, and colleagues conducted a clinical trial to assess whether cefpodoxime would have

clinically acceptable efficacy and tolerance compared with ciprofloxacin. The study, conducted from 2005 to 2009, included 300 women ages 18 to 55 years with acute uncomplicated cystitis. Outcomes were assessed at 5 to 9 days and 28 to 30 days after completion of therapy. Intent-to-treat and per-protocol analyses were performed; 15 women in the ciprofloxacin group (n = 150) and 17 women in the cefpodoxime group (n = 150) were lost to follow-up. Patients were randomized to 250 mg of ciprofloxacin orally twice daily for 3 days or 100 mg of cefpodoxime proxetil orally twice daily for 3 days. Overall clinical cure was defined as not requiring antimicrobial treatment during follow-up through the 30-day follow-up visit. The hypothesis that cefpodoxime would be noninferior to ciprofloxacin by a 10 percent margin was formulated prior to data collection.

The researchers found that the overall clinical cure rate with the intent-to-treat approach in which patients lost to follow-up were attributed as having clinical cure was 93 percent (139/150) for ciprofloxacin compared with 82 percent (123/150) for cefpodoxime. The test of noninferiority was not statistically significant. In an alternative intent-to-treat analysis in which patients who were lost to follow-up were considered to have not responded to treatment, the clinical cure rate was 83 percent (124/150) for ciprofloxacin compared with 71 percent (106/150) for cefpodoxime. Among women who reported no previous UTI in the past year before enrollment, the overall clinical cure rate was 96 percent for ciprofloxacin and 83 percent for cefpodoxime, a magnitude of difference that was not seen among women who reported 1 or more UTIs in the past year before enrollment.

The clinical cure rate at the first follow-up visit (average, 5 days after treatment) was 93 percent for ciprofloxacin compared with 88 percent for cefpodoxime. The microbiological cure rate at the first follow-up visit (average, 5 days after treatment) was 96 percent for ciprofloxacin compared with 81 percent for cefpodoxime. At first follow-up, 16

percent of women in the ciprofloxacin group compared with 40 percent of women in the cefpodoxime group had vaginal E coli colonization (the presence of organisms on some surface or in some bodily fluid that are not causing symptoms). The differential effect of the two drugs on vaginal E coli colonization may have played a role in the difference in clinical outcomes.

"Among women with uncomplicated cystitis, a 3-day regimen of cefpodoxime compared with ciprofloxacin did not meet criteria for noninferiority for achieving clinical cure," the authors write. They add that this finding, along with concerns about possible ecological adverse effects associated with other broad-spectrum β-lactams (a class of antimicrobials that includes cefpodoxime), do not support the use of cefpodoxime as a first-line fluoroquinolone-sparing antimicrobial for acute uncomplicated cystitis.

More information: *JAMA*. 2012;307[6]:583-589.

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