

## **EFFICACY AND SAFETY OF A ONCE-DAILY EXTENDED-RELEASE CIPROFLOXACIN TABLET FORMULATION FOR EMPIRICAL TREATMENT OF SYMPTOMATIC UNCOMPLICATED CYSTITIS IN KOREAN WOMEN.**

### Hypothesis / aims of study

Uncomplicated cystitis are among the most common bacterial infections in women. Despite of the frequent occurrence of uncomplicated cystitis, recently, there is an increase of resistant organisms among urinary tract pathogens to the first line antimicrobial agents. The mean rates of susceptibilities to ciprofloxacin and trimethoprim-sulfamethoxazole were 85.7% and 62.1% in multi-center study of antimicrobial susceptibility of uropathogens in Korea. The objective of this study was to compare the efficacy of a 3-day regimen of extended- release ciprofloxacin (ciprofloxacin ER) 500mg q.d. to that of trimethoprim-sulfamethoxazole (TMP/SMX) 800mg/160mg b.i.d in the empirical treatment of acute cystitis in Korean women.

### Study design, materials and methods

Randomized, single-blind treatment trial of 75 women with acute uncomplicated cystitis was done. Women were eligible for enrollment if they were healthy, above 18 year-old, and had dysuria, frequency, and/or urgency. Of seventy five, Sixty five women with clinical sign and symptoms of acute uncomplicated cystitis and findings of urine cultures with at least 10<sup>3</sup> CFU/ml were included in analysis. Women were randomly prescribed ciprofloxacin ER or TMP/SMX for 3 days. Patients were assessed at post-treatment 7th day for clinical and microbiological outcomes and safety, and at post-treatment 14th day with telephone interview for clinical symptoms and safety.

### Results

The 65 women eligible for the analyses (32 randomized to receive ciprofloxacin ER and 33 randomized to receive TMP/SMX). The most prevalent causative organism was Escherichia coli (83%), followed by Proteus (6%), coagulase negative Staphylococcus (6%), Pseudomonas (5%). The mean rates, in-vitro susceptibility to ciprofloxacin ER, TMP/SMX were 86.2% (56/65), 73.4% (48/65), respectively. Clinical cure rates were observed in 28 (87.5%) of 32 women treated with ciprofloxacin ER compared to 26 (78.8%) of 33 those with TMP/SMX. Microbiological cure at 7 days was observed in 25 (89.3%) of 28 women treated with ciprofloxacin ER compared with 18 (69.2%) of 26 women treated TMP/SMX. Re-treatment rates to ciprofloxacin ER, TMP/SMX were 12.5% (4/32), 21.2% (7/33), respectively. The mean interval to improve clinical symptoms after medication was 2.0 days in patients treated with ciprofloxacin ER compared to 2.9 days of those with TMP/SMX. Adverse events appeared 28.1%, 15.5% to ciprofloxacin ER, TMP/SMX, respectively, but two drugs were well tolerated.

### Interpretation of results

This study is the first comparison of a 3 day regimen of ciprofloxacin ER vs TMP/SMX for the empirical treatment of acute uncomplicated cystitis in Korean women. Although ciprofloxacin ER had a resistance (13.8%) to organisms, ciprofloxacin ER was superior to TMP/SMX in clinical and microbiological cure rates as well as the mean interval to improve clinical symptoms.

### Concluding message

The high prevalence of resistance and retreatment rates to TMP/SMX suggest this drug would not provide adequate initial therapy, and once-daily ciprofloxacin ER was safe, effective to twice-daily TMP/SMX in the treatment of symptomatic uncomplicated cystitis

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**CLINICAL TRIAL REGISTRATION:** This clinical trial has not yet been registered in a public clinical trials registry.

**HUMAN SUBJECTS:** This study was approved by the the ethics committee, inje university and followed the Declaration of Helsinki Informed consent was obtained from the patients.