

Anuwat Keerasuntonpong, M.D.

Single-Day, Patient-Initiated Famciclovir Therapy for Recurrent Genital Herpes: A Randomized, Double Blind, Placebo-Controlled Trial

Fred Y. Aoki, Stephen Tyring, Francisco Diaz-Mitoma, Gerd Gross, Joseph Gao, and Kamal Hamed. *Clinical Infectious Diseases* 2006;42:8-13.

Purpose: To assess the efficacy and safety of a patient-initiated, single-day regimen of famciclovir therapy, compared with placebo, in immunocompetent adult patients with recurrent genital herpes.

Methods: Multicenter, multinational, randomized, double blind, parallel-group, placebo-controlled study compared single-day, patient-initiated oral famciclovir 1,000 mg twice for one day with placebo for the treatment of recurrent episode of genital herpes. Of the 329 patients, 163 received twice-daily 1,000-mg dose of famciclovir, and 166 received placebo. Patients were instructed to initiate therapy within 6 hours after onset of prodromal symptoms or genital herpes lesions.

Results: Famciclovir reduced the time to healing of nonaborted lesions (those that progressed beyond the papule stage) ($p < 0.001$). Median time for healing of nonaborted lesions was 4.3 vs 6.1 days for famciclovir and placebo groups respectively. Median time for all nonaborted and aborted lesions was 3.5 vs 5.0 days for famciclovir and placebo groups respectively. The proportion of patients with aborted lesions was larger in the famciclovir group than in the placebo group (23.3% vs 12.7%; $p = .003$). Median time to resolution

of all symptoms in the famciclovir group was 3.3 days vs 5.4 days in placebo group. Adverse events in the famciclovir group were infrequent overall; most were of mild-to-moderate severity and were similar to adverse events in the placebo group. The most commonly reported adverse effects were headache, nausea, diarrhea, abdominal pain and dizziness.

Conclusion: A single-day regimen of patient-initiated famciclovir treatment was well tolerated and safe. The healing of recurrent genital herpes lesions in the treated group occurred about 2 days faster than with placebo. A single-day famciclovir treatment stopped the development or progression of lesions beyond the papule stage. Furthermore, patients in famciclovir group reported a significant reduced time to resolution of all symptoms as well as time to resolution of symptom individually (ie., burning, tingling, itching, tenderness, and pain) compared with the placebo group. A single-day regimen of 1,000-mg famciclovir has the potential for improving patient compliance and satisfaction with therapy due to its convenience.

Discussion

Currently, traditional therapy for a recurrent episode of genital herpes for immunocompetent adults has consisted of (1) acyclovir (400 mg) three times a day for 5 days (2) acyclovir (800 mg) three times a day for 2 days (3) famciclovir (125 mg) two times a day for 5 days and (4) valacyclovir (500 mg) two times a day for 3 days. And also patient-initiated therapy has been shown to be more effective than physician-initiated therapy for recurrent genital herpes due to earlier

treatment from previous study. This study demonstrated that famciclovir given in 1,000 mg twice for one day was effective for the treatment of recurrent episode of genital herpes. The results showed a significant improvement in the time to resolution of lesion healing and symptoms as well as significant increasing the proportion of patients with aborted lesions while the adverse drug reactions were mild to moderate and

similar to the placebo groups. A single-day regimen of famciclovir reduced the number of doses, compared with standard antiviral therapy for recurrent episode of genital herpes, thus increasing patient compliance along with reducing the cost. However, whether or not this regimen will be effective in immunocompromised patients need further studies.