Green Tea Ointment May Clear Genital Warts

BY MICHELE G. SULLIVAN
Mid-Atlantic Bureau

ST. LOUIS — An investigational ointment containing extract of green tea successfully clears genital warts in about 60% of patients, Karl Beutner, M.D., said at the annual meeting of the Society for Investigative Dermatology.

The ointment, polyphenon E, is being developed by MediGene AG, Martinsried, Germany. The active ingredient is 80% tea polyphenols.

The main catechin in the extract is (−)-epigallocatechin gallate (EGCG), which has been shown to induce apoptosis in human carcinoma cell lines.

“It’s a strong antioxidant that inhibits a number of different enzymes,” said Dr. Beutner, chief medical officer at Dow Pharmaceutical Sciences, Petaluma, Calif., and associate clinical professor of dermatology at the University of California, San Francisco. “Unpublished reports indicate that it induces a pro-Th1 cytokine profile not dissimilar to that of imiquimod.”

The three-armed, placebo-controlled trial randomized 502 patients with active treatment of 10% or 15% concentration, or the vehicle, which contains isopropyl myristate. Patients had an average of eight anogenital warts (2-30), which covered an average area of 95 mm².

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“The primary end point was clearance of all warts—the baseline warts and any warts that developed during treatment,” Dr. Beutner said. “This is an important distinction because other trials report the response in terms of only clearing the baseline warts. This was a stringent end point. They had to be cleared of all warts,” he said.

At the end of 16 weeks of treatment, about 59% of patients in both active groups had complete clearance of their baseline warts, compared with about 34% of vehicle patients. Complete clearance of all warts occurred in 56% of the 10% group, 57% of the 15% group, and about 34% of the vehicle group. Average time to response was 11 weeks.

About 80% of those in both active groups had more than 50% clearance. Less than 10% of those in either active group failed to respond. Women responded better than men, with about 65% of women and 50% of men in both active groups achieving complete clearance.

During the 12-week follow-up period, 8.8% of those in the vehicle group experienced recurrence of baseline warts, compared with 6.5% of the group receiving the 15% formulation and 5.9% of the group receiving the 10% formulation. No new warts appeared in the vehicle group; however, new warts did appear in 8% of the group receiving the 10% formulation and in 9.7% of the group receiving the 15% formulation.

About 87% of the active patients and 72% of the vehicle patients experienced at least one adverse event; events peaked at 2 weeks and then declined throughout the trial. Most were mild to moderate and included erythema, erosion, exudation/edema, and induration. Only 1% of the patients discontinued use because of an adverse event. About 20% of the vehicle patients also experienced a mild to moderate local reaction.

The only serious adverse events related to the study drug were two cases of vulvovaginitis, which were judged to be unrelated to the study drug.

“Antivirals may help reduce transmission rates,” Dr. Gilbert said. Dr. Gilbert is a member of the speakers’ bureau for GlaxoSmithKline Inc., which manufactures Valtrex and provided 50% of the funding for the study.

High-Dose Valacyclovir Reduced Shedding of Oral Herpes Virus

NEW ORLEANS — Treatment with once-daily, high-dose valacyclovir significantly decreases the duration and quantity of oral herpes simplex virus-1 shedding associated with recurrent herpes labialis, according to data from a randomized study.

Oral shedding, either associated with known outbreaks of herpes labialis or, perhaps more importantly, during asymptomatic periods, is the presumed mode of transmission of herpes simplex virus-1 (HSV-1), Stan C. Gilbert, M.D., said in a poster presentation at the annual meeting of the American Academy of Dermatology.

HSV-1 causes gingivostomatitis in infants and children and recurrent cold sores in most people. It also has become the primary cause of genital herpes in the majority of cases among young adults.

Current herpes labialis (RHL) affects up to 40% of HSV-1-seropositive adults.

Research has shown oral shedding associated with episodes of RHL lasting from 1 to 8 days. But the studies are rare and have relied mostly on viral cultures, according to Dr. Gilbert, of the University of Washington, Seattle.

His study randomized 64 adults with a history of three or more RHL episodes a year to four 500-mg valacyclovir (Valtrex) caplets taken at the first sign of an outbreak or placebo. The dosing was repeated 12 hours later. Polymerase chain reaction (PCR) swabs were collected every 12 hours starting at the first sign of outbreak and continuing for 10 days. Both groups had a history of cold sores for an average of 28 years and an average of four cold sores in the previous 12 months.

Patients receiving valacyclovir experienced fewer days of shedding than did the placebo group (1.8 vs. 4 days). A comparison of the log HSV-1 DNA copies detected by PCR over time, using the average area under the curve (AUC), showed significantly less shedding from the valacyclovir-treated patients than from the placebo-treated patients (average AUC 1.1 vs. 2.2).

The study’s findings are important because information about the natural history of oral HSV-1 shedding and the impact of antivirals may help reduce transmission rates, Dr. Gilbert said. Dr. Gilbert is a member of the speakers’ bureau for GlaxoSmithKline Inc., which manufactures Valtrex and provided 50% of the funding for the study.

—Patrice Wendling

Only 10% of Teens Retested After Chlamydia Treatment

BY TIMOTHY F. KIRN
Sacramento Bureau

LOS ANGELES — Physicians most likely to follow up with adolescent patients they treat for a chlamydia infection, as recommendations state they should, according to a study conducted with the records from five Northern California pediatric clinics.

Only 10% of 122 patients testing positive for a Chlamydia trachomatis infection at the clinics received appropriate retreating, and many also did not appear to have been counseled about safer sex, did not notify their partners, or were not tested for other STIs, Loris Hwang, M.D., and her colleagues said in a poster presentation at the annual meeting of the Society for Adolescent Medicine.

Antibiotic resistance is not considered a problem with chlamydia, so treatment generally is successful and a follow-up visit is not necessary to test for cure. Rather, the reason for follow-up is because those who get infected tend to return to the same “sexual networks” where they got the infection in the first place, said Dr. Hwang of the University of California, San Francisco.

Because the study was conducted at clinics that were all part of the Kaiser Permanente system, an HMO where patients are treated for all their health care needs, the results may not be generalizable to other clinical settings.

The study randomized 602 patients with acute infection to active treatment of 10%-15% concentrations, or the vehicle, which contains isopropyl myristate. Patients had an average of eight anogenital warts (2-30), which covered an average area of 95 mm².

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“Eighty-three percent of the study’s adolescents did not come back for a treatment visit, and then another with in 12 months,” said Dr. Hwang.

At the end of 16 weeks of treatment, 30% of patients in both active groups had complete clearance of their baseline warts, compared with about 34% of vehicle patients. Complete clearance of all warts occurred in 56% of the 10% group, 57% of the 15% group, and about 34% of the vehicle group. Average time to response was 11 weeks.

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