Genital Wart Treatment Options Expanding

BY PATRICE WENDLING
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CHICAGO — A topical ointment containing components derived from green tea leaves is the latest addition to the available therapies for genital warts, Dr. Thomas C. Wright Jr. said at a conference on vulvovaginal diseases.

The ointment was approved by the Food and Drug Administration in October 2006, based on pooled results of two randomized, double-blind phase III trials in patients who used the ointment three times daily for up to 16 weeks. Complete clearance was reported in 213 of 397 patients (54%) treated with Veregen, compared with 73 of 207 (35%) patients on placebo. Higher clearance rates were reported in Veregen-treated women (60%) than in men (47%).

Veregen Ointment 15% is a botanical drug product that is specifically indicated for the topical treatment of external genital and perianal warts in immunocompetent patients aged 18 years and older. It is expected to be available in the United States by prescription only, said Dr. Wright, professor of pathology, director of gynecologic and obstetric pathology, Columbia University, New York.

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The drug substance in Veregen Ointment is sinecatechins, which is a partially purified fraction of the water extract of green tea leaves from *Camellia sinensis* (L.) O. Kuntze, and is a mixture of catechins and other green tea components. Catechins are thought to enhance immune system function and are more abundant in green tea leaves than in black tea leaves.

However, of the 397 patients who were treated with Veregen, 12 (30%) reported a severe local reaction that probably was related to the drug, Dr. Wright said. The incidence of local adverse events leading to discontinuation or dose reduction was 5% (19 patients). The most common adverse events were erythema, pruritus, burning, pain or discomfort, and erosion or ulceration.

Veregen Ointment 15% has not been tested in immunosuppressed patients or in nursing mothers and is an FDA pregnancy category C drug, Dr. Wright said at the conference, which was sponsored by the American Society for Colposcopy and Cervical Pathology.

The ointment was developed by MediGene AG, a biotech company based in Martinsried, Germany, and it will be distributed in the United States by Doak Dermatologics.

MediGene has agreed to a phase IV trial, comparing the pharmacokinetics of catechins following topical administration of Veregen ointment 15% with that after oral administration of a green tea solution. The trial is expected to start in January 2008 and will include 40 patients with external genital and perianal warts.

Other new treatments for external genital warts include Histofreezer (OraSure Technologies Inc.), a prepackaged portable cryosurgery unit that consists of a handheld canister of cryogen and a variety of applicators. The product is indicated for use on nine different types of lesions, including external genital warts. Histofreezer costs about $4 per use and is easier to use than large cryosurgery tanks, Dr. Wright said, adding that he has not used the product.

It produces a level of freezing (–55° C) similar to that achieved with carbon dioxide or nitrous oxide cryotherapy and therefore should perform similarly, he said. Reported clearance rates are similar to those in the literature for other forms of cryotherapy.

Local ablative methods such as cryotherapy, fulguration, and trichloroacetic acid are best if there are just a few lesions, whereas if there are more lesions, it is better to treat them with self-applied modalities such as imiquimod, Dr. Wright said.

Lasers also are useful but should be reserved for patients who fail chemical or immune modulation therapy. Lasers often are required in immunocompromised patients and those with large amounts of disease, he said.

Dr. Wright disclosed no financial or advisory relationships with MediGene AG, Doak Dermatologics, or OraSure Technologies. ■