Botanical Found Cost Effective for Genital Warts

BY BRUCE JANCIN

WAIKOLOA, HAWAII — Sinecatechins ointment 15%—the first botanical approved by the Food and Drug Administration for prescription use—outperformed imiquimod cream 5% for treatment of external genital warts in a cost-effectiveness analysis.

The analysis by Paul C. Langley, Ph.D., of the University of Minnesota, Minneapolis, utilized pharmacoeconomic modeling based upon data from the two pivotal phase III, double-blind, vehicle-controlled, randomized trials of sinecatechins ointment 15% (Veregen), along with a systematic review of the published imiquimod (Aldara) literature, Dr. Brian Berman explained at the annual Hawaii dermatology seminar sponsored by Skin Disease Education Foundation.

As first-line therapy, the botanical was the clear winner with a sustained clearance rate of 51.9%, compared with 40.6% with imiquimod.

The average treatment cost was lower, too, at $774 compared with $930. The cost per successful outcome was $1,492 with sinecatechins ointment and $2,289 with imiquimod (J. Med. Econ. 2010;13:1-7).

Factoring in the additional cost of second-line ablative therapy for patients who didn't respond to the initial topical regimen, the average cost of treatment climbed to $943 in the sinecatechins arm and $1,138 in the imiquimod group.

"Take this cost-effectiveness analysis with a grain of salt. I find cost-effectiveness analyses are usually paid for by the product that does well, as was the case here," observed Dr. Berman, professor of dermatology at the University of Miami.

A disadvantage of the sinecatechins is that they need to be applied three times daily, while imiquimod calls for application three times per week.

Sinecatechins ointment 15% is a green tea extract, the chief antioxidant component of which is epigallocatechin gallate.

The systemic exposure following repeated application of the ointment is less than that resulting from drinking 400 mL of green tea.

The botanical is approved as prescription therapy for both external genital and perianal warts.

Dr. Berman highlighted several key findings from the pivotal clinical trials of the botanical, which included more than 1,000 patients.

For one, sinecatechins ointment was significantly more effective in women than in men.

Complete clearance of all warts by week 16—those present at baseline as well as all warts arising during the 16 weeks of treatment—occurred in 60.4% of women and 47.3% of men, Dr. Berman said.

The recurrence rate was remarkably low: just 6.8% during 12 weeks of follow-up after completing the 16 weeks on sinecatechins.

"Most studies of other agents have 20%-50% recurrence rates," the dermatologist noted.

Also noteworthy was the fact that the recurrence rate in the control group was even lower, at 5.9%.

"It turns out there's an irritant in the vehicle.

"Whether that has something to do with the low recurrence rate is not clear," Dr. Berman said.

A disadvantage of the sinecatechins ointment is that it needs to be applied three times daily, while imiquimod calls for application three times per week, he said. ■

Disclosures: *Dr. Berman disclosed that he is a consultant to and on the speakers bureaus for 3M, Graceway Pharmaceuticals, and PharmaDerm, which markets Veregen. SDEF and this news organization are owned by Elsevier.*