Medication Duo Scores Big Against *P. acnes*

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GOTHENBURG, SWEDEN – Multimodal therapy with adapalene 0.1% and benzoyl peroxide 2.5% in a fixed-dose combination gel plus oral doxycycline proved safe, effective, and well tolerated for severe acne vulgaris in a large, double-blind, multicenter randomized trial.

Indeed, the combination therapy's favorable safety profile makes it a compelling first-line treatment for all but the most severe, recalcitrant cases of nodular acne, where oral isotretinoin, despite its problematic safety profile, remains the treatment of choice because of its unequalled efficacy, Dr. Alma Cruz said at the meeting.

The mechanism of benefit for adapalene 0.1%–benzoyl peroxide 2.5% fixed-dose combination gel (Epiduo) plus oral doxycycline in patients with severe acne appears to involve, at least in part, the combination therapy's ability to achieve a rapid and sustained reduction in *Propionibacterium acnes* as documented in the trial by serial fluorescent photography, according to Dr. Cruz, a dermatologist in Carolina, P.R.

At week 4 in the 12-week trial, patients in the combination therapy arm had a mean 60% reduction from baseline in *P. acnes* compared with a 22% decrease in the vehicle plus doxycycline group.

At weeks 8 and 12, the combination therapy group had 73% and 74% reductions from baseline in *P. acnes*, compared with reductions of 16% and 14% in controls.

The reduction in *P. acnes* correlated with clinical efficacy. At week 2, one-third of the ultimate reduction in total lesion count in the combination treatment arm had already been achieved, with a mean 21% reduction from baseline, compared with a 13% decrease in controls.

At week 12, patients on Epiduo plus doxycycline had a mean 64% decrease from baseline in total acne lesions, compared with a 41% reduction in controls. The combined therapy outperformed doxycycline plus vehicle in treating both inflammatory and noninflammatory lesions.

The treatment success rate as defined by a rating of clear or almost clear on the investigator's global assessment scale was 9.9% and 31.5% at weeks 8 and 12 in the combined therapy group, versus 2.6% and 8.4% in the controls.

The trial involved 459 patients with severe acne who were randomized to once-daily application of Epiduo in the evening plus 100 mg/day of doxycycline hyclate for 12 weeks, or to vehicle plus doxycycline.

The overall safety and tolerability of the combination therapy was similar to that of the vehicle plus doxycycline. Just under 10% of patients in both study arms reported gastrointestinal complaints believed to be due to the doxycycline.

A week-12 patient satisfaction survey showed 76% of patients in the combined therapy arm were satisfied or very satisfied overall with their treatment, compared with 50% of the controls. Sixty-seven percent of patients in the combination therapy group indicated they felt a lot better or much better about themselves since starting their therapy, as did 48% of the controls. ■

VITALS

Major Finding: At weeks 8 and 12, the combination therapy group had 73% and 74% reductions from baseline in *Propionibacterium acnes*, compared with reductions of 16% and 14% in controls.

Data Source: A large, double-blind multicenter trial involving 459 patients with severe acne who were randomized to once-daily application of Epiduo in the evening plus 100 mg/day of doxycycline hyclate for 12 weeks, or to vehicle plus doxycycline.

Disclosures: Dr. Cruz said he had received a research grant from Galderma Laboratories, which funded the clinical trial.

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