Ulcerative cutaneous lesions and contraindications to chloroquine.

Clofazimine may be indicated as a therapeutic option for patients with exclusively cutaneous lesions and contraindications to chloroquine.

The compound clofazimine was as effective as chloroquine diphosphate in controlling active cutaneous lesions in patients with systemic lupus erythematosus who participated in a small randomized study.

The trial, which involved 33 patients, is the first randomized, controlled, double-blind study comparing the two drugs, as well as the first study of this indication for clofazimine, a ruminophenazine compound that is stored for months in the fat and in the reticuloendothelial system in SLE patients, reported Elaine Lira Medeiros Bezerra, M.D., of the Universidade Federal do Rio Grande do Norte in Natal, Brazil, and her associates.

Clofazimine may be “indicated as a therapeutic option for lupus patients with exclusively cutaneous lesions and with contraindications to chloroquine,” they said (Arthritis Rheum. 2005;52:3073-8).

Although not statistically significant, most of the patients who were excluded from the study because of the development of an SLE flare were taking chloroquine, a finding that requires further investigation, they explained.

It’s possible that clofazimine itself may have been the cause of the lupus flares, or that the difference in the frequency of flares between the two drug groups “might have been due to the known effect of chloroquine diphosphate in reducing lupus activity,” they said.

Of 33 patients enrolled in the study, 16 were randomized to receive 100 mg of clofazimine once a day for 6 months, and 17 were assigned to receive 250 mg of chloroquine once a day for 6 months. The drugs were placed into identical capsules.

The treatment groups were similar demographically and clinically. Patients in both groups received a broad-spectrum sunscreen twice a day, and prednisone doses were kept stable. The patients’ lesions were evaluated by two blinded observers at baseline and throughout the study.

Based on an intent-to-treat analysis, 12 clofazimine-treated patients (75%) and 14 chloroquine-treated patients (82%) had complete or near-complete remission of their skin lesions, Dr. Bezerra and her associates reported.

Side effects—mainly skin and gastrointestinal events—were frequent but were “mild and tolerable,” they said.

Five clofazimine-treated patients were withdrawn after they developed a serious flare; all improved after treatment.

Another patient died about 4 months into the study after presenting with fever, seizures, and asymmetric paraparesis; the autopsy revealed infarction at the right choroid plexus and cerebral and cerebellar hemispheres, associated with a subarachnoid hemorrhage, the investigators reported.

One patient in the chloroquine group developed necrotizing vasculitis in the upper limbs and was withdrawn in the second month, they said.

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