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## Medscape Medical News

# Steroid Improves Compliance for Melasma Triple Therapy

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Aug. 5, 2002 -- A triple-combination product for the treatment of moderate-to-severe melasma shows a clinical success rate double that of previously used compounds. The once-daily regimen containing hydroquinone, a depigmenting agent (4.0%), tretinoin, a retinoid (0.05%), and fluocinolone acetonide (Tri-Luma), a low-potency steroid (0.01%), has a favorable safety profile and is well tolerated by patients. Tri-Luma received US Food and Drug Administration marketing approval earlier this year.

"Tri-Luma is a welcome addition to the dermatology marketplace," Pearl Grimes, MD, associate clinical professor of dermatology at the University of California at Los Angeles, tells WebMD. "As a therapeutic material for melasma, it requires no extemporaneous compounding."

Tri-Luma is the first triple therapy indicated for the short-term treatment of moderate-to-severe melasma of the face in the presence of measures for sun avoidance, including the use of sunscreen.

Melasma is a common disorder of macular hyperpigmentation, mostly affecting women of childbearing age. It is exacerbated by sun exposure, pregnancy, oral contraceptives, and certain antiepilepsy drugs. Although all races are affected, melasma is prominent among Hispanics and Asians. Melasma is a chronic disease; long-term therapeutic success relies on sun avoidance and rigorous use of sunscreens. Intense or chronic exposure to the sun worsens the condition and precipitates recurrence.

Most treatments thus far have included hydroquinone and tretinoin, says Maritza Perez, MD, who presented data on the treatment at a sponsored session of the American Academy of Dermatology's Academy 2002 conference on Aug. 1 in New York. Two studies sponsored by Galderma Pharmaceuticals, the maker of Tri-Luma, showed a success rate of 13% to 38% at eight weeks compared with a 4% to 15% success rate in patients receiving only hydroquinone and tretinoin. Perez attributes the success to "an increased compliance rate based on the decreased side effects, due to the incorporation of a low-potency steroid in the medication."

In the two studies, 641 patients aged 21 to 75 years were enrolled, with skin phototypes I to IV and moderate-to-severe melasma of the face. Tri-Luma was compared with the three possible combinations of two of the three active ingredients. Patients were instructed to apply a thin layer of study medication to affected areas nightly, while taking precautions against the sun. Patients were evaluated at baseline and at weeks 1, 2, 4, and 8 of treatment. Primary efficacy was based on the proportion of patients who had an investigators' assessment of treatment success, defined as the clearing of melasma at eight weeks.

The medications compared with Tri-Luma included hydroquinone 4% (HQ), tretinoin 0.05% (RA), and fluocinolone acetonide 0.01% (FA) in various combinations. Success rates for Tri-Luma varied between 13% and 38% in the two studies. This compares favorably with the efficacies of HQ+RA (4%-15%), FA+RA (0%-4%), and FA+HQ (1%-4%). Based on melasma severity at the beginning of the trial, 161 patients were assessed for improvement at day 56 of treatment. Sixty-one percent of patients using Tri-Luma experienced symptom improvement from "moderate" to "mild" or "cleared," and 68% showed improvement from "severe" to "mild" or "cleared" over the eight-week treatment period.

Adverse reactions were mild to moderate in severity. Most commonly seen were erythema (41%), desquamation (38%), burning (18%), dryness (14%), and pruritis (11%). Patients using the cream showed a similar pattern of adverse events after eight weeks or six months, indicating a lack of cumulative toxicity.

"We have had tremendous success with outpatients on Tri-Luma", says Helen Torok, MD, in a news release. Torok, a board-certified dermatologist in private practice, served as a clinical investigator in trials of Tri-Luma. "We have seen a rather dramatic improvement in just the first 2 weeks of therapy. Combination therapy has been a desirable but somewhat problematic and unpredictable approach in the past. Triple drug therapy like Tri-Luma is of definite benefit. Ultimate success, however, rests with the commitment of the patient and physician to a long-term regimen of sunscreen use, sun avoidance, and overall good skin care."

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*Reviewed by Gary D. Vogin, MD*

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