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A COMBINED SOLUTION OF 2% 4-HYDROXYANISOLE AND 0.01% TRETINOIN IN THE TREATMENT OF SOLAR LENTIGENES: A CLINICAL STUDY ON EFFICACY AND SAFETY

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Objective: To assess the efficacy and safety of 4HA/tretinoin (2% 4-Hydroxyanisole/ 0.01%tretinoin) vs 2% 4-hydroxyanisole, 0.01% tretinoin, 3% hydroquinone and vehicle in the treatment of solar lentigenes.

Methods: This was a randomized, parallel-group, double-blind study. Subjects were randomized to one of the 4 products. Assessments of the clinical success and overall cosmetic effect on lesions were conducted throughout the study. Safety parameters included local and systemic safety and lab analysis at all visits.

Results: A total of 221 subjects were enrolled, 194 completed the 40 weeks period. A significantly higher proportion (p,,T 0.05) of patients achieved clinical success with 4HA/tretinoin in comparison with 3% hydroquinone as measured by both the Physician's Global Assessment (60% vs 38%) and Lesional Pigmentation (70% vs 50%) on the forearm at the end of treatment (week 24). The proportion of patients with clinical success on the face in the 4HA/tretinoin group was consistently higher than that in the 3% HQ group (72% vs 58%). Some treatment effects remained at the end of the treatment-free follow-up (week 40), with trends in favor of 4HA/tretinoin over HQ being apparent for the face. For all treatment groups, skin-related adverse events were mild or moderate and transient. Laboratory results did not show any treatment-related changes.

Conclusions: This study has demonstrated that 4HA/tretinoin solution is a highly effective and well-tolerated treatment for solar lentigines. The combination of 4HA and tretinoin provides a good alternative to 3% hydroquinone; it is superior to hydroquinone with clinical response being apparent within 16 weeks.

Disclosure not available at press time.

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AN 8 MONTH EFFICACY AND SAFETY EVALUATION OF A TRIPLE COMBINATION AGENT IN THE TREATMENT OF MELASMA

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Objective: To compare the efficacy and safety of the Triple Combination Agent (TCA; 0.01% Fluocinolone Acetonide + 4% Hydroquinone + 0.05% Tretinoin) compared to any double combination of the active components in the treatment of melasma.

Methods: This was a multicenter, active controlled, comparative study with a daily treatment for 8 weeks. The patients who cleared during this period where treated with TCA, 3 × times a week the first month, 2 × week a second month and 1 × week the third month. Clinical efficacy and safety were evaluated at regular intervals.

Results: In total 377 subjects were included in the trial and 300 completed the blinded period of the study. The proportion of patients who completely cleared by week 8 were 28.6%, 5.5%, 1.1% and 3.4% for TR-HQ-FL cream, TR + HQ cream, TR + FL cream and FL + HQ respectively ($p < 0.001$). Proportions of patients who completely cleared or almost cleared at week 8 were respectively in above averages: 74.5%, 45%, 12% and 52.3%. Under TR-HQ-FL cream treatment 42% patients were cleared or about cleared at week 4. In the tapered dosing phase several patients re-pigmented as early as 2 weeks of once daily 3× week dosing. The observed side effects were erythema, skin peeling which are irritation potential inherent in tretinoin.

Conclusions: The fixed triple combination cream of tretinoin, hydroquinone and fluocinolone is a safe and effective new drug in the treatment of melasma.

Disclosure not available at press time.

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A TRIPLE COMBINATION AGENT IN THE TREATMENT OF MELASMA

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Objective: To obtain long-term safety information on Triple Combination Agent (TCA; 0.01% Fluocinolone Acetonide + 4% Hydroquinone + 0.05% Tretinoin). Although efficacy was not a primary objective, investigator evaluations were performed.

Methods: A multicenter, open-label study over 12-months. Patients were treated once daily with TCA and evaluated monthly until resolution or lack of response was demonstrated. If there was resolution, treatment was stopped except for sunscreen. Patients were then followed every 2 months and retreated as needed. Patients who required continued treatment restarted once daily with TCA. They were followed up every month until resolution or lack of response. If at such time there was a lack of response, treatment was stopped except for sunscreen use. They were then followed every 2 months. Efficacy and safety evaluations were conducted at baseline and monthly intervals until treatment was completed. Routine laboratory analyses were performed in selected centers.

Results: In total 228 subjects were included. Most of the patients had 1 or 2 treatment courses lasting between 173-177 days. TCA demonstrated a good a safety profile. The majority of TCA related adverse events reported were of mild intensity and included erythema and desquamation. Local AEs tended to increase with the number of courses and with increased number of TCA treatment up to 6 months and then stabilized. This is not unexpected since tretinoin is associated with these side effects. TCA was not associated with any SAEs or clinically meaningful laboratory changes. No case of skin atrophy or rosacea and very few cases of telangiectasia occurred during the study. The physicians' assessment of melasma severity demonstrated that after 12 months of treatment, 94% of the patients had mild and cleared lesions. Both physicians' and patients' global assessments concurred that patients had cleared or nearly cleared melasma after treatment. Very little evidence of worsening of lesions was observed from baseline to Month 12 (0.46% vs. 0.66%, respectively).

Conclusions: This study confirmed the longterm safety and efficacy of the combination of 0.01% Fluocinolone Acetonide + 4% Hydroquinone + 0.05% Tretinoin in the treatment of melasma on the face.

Disclosure not available at press time.

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GENERALIZED VITILIGO WITH THE POSSIBILITY OF MISDIAGNOSIS AS PIGMENTARY DISEASES: CASE REPORT

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A 31-years-old male presented with facial skin lesions that had been existed for 17 years. A rice sized hyperpigemented macules were observed under both eyes. Firstly, it was suspected of pigmentary disease such as freckles or lentigines. However, after closer observation of the lesions on the neck and inquires, the hyperpigmented areas were not the lesions but actually normal skin and the circumferential skin that had been seem normal was actually the lesion. Thus, he was finally diagnosed as vitiligo. A 62-years-old female presented with 20 years of facial skin lesions. She was suspected of pigmentary disease due to her pea sized hyperpigmented macules on both cheeks and periocular area. However, wood's lamp examination showed that what seemed to be normal area turned out to be vitiligo lesion and the hyperpigmented area was actually normal.

Hence, when vitiligo is widely dispersed on the face or in universal or generalized form, normal skin may appear as pigmentary disease. Thus, observers require to pay more attention to the patients with more thorough inquiries and careful examinations such as wood's lamps.

Disclosure not available at press time.