

TREATMENT OF MODERATE OR MARKED MELASMA WITH A 4% HYDROQUINONE SKIN CARE SYSTEM PLUS 0.1% TRETINOIN CREAM: A COMPARISON BETWEEN ASIAN AND CAUCASIAN PATIENTS

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INTRODUCTION

Hyperpigmentation is a major concern in patients with skin of color, so melasma treatment must be well tolerated to minimize this risk. Treating melasma using a 4% hydroquinone skin care system plus tretinoin cream is known to be effective and well tolerated in Caucasians and African Americans,^{1,3} but it has not been studied specifically in Asians. To address this, a study has been performed comparing the efficacy and tolerability of this treatment in Asians and Caucasians.

METHODS

Main inclusion criteria

- Moderate or marked melasma (covering 26% to 50% of face)
- At least moderate intensity of pigmentation on the most severe area of melasma (deemed the target lesion)
- Cutaneous melanosis stable over preceding 3 months
- Fitzpatrick skin type III, IV, or V
- 18-65 years old

Treatment regimen

- All patients were instructed to use the 4% hydroquinone skin care system and 0.1% tretinoin cream on their face every day for 12 weeks and, optionally, could continue in an extension to receive an additional 12 weeks of treatment.
- The hydroquinone system involved applying the following proprietary products:
 - Foaming gel cleanser (twice daily)
 - Toner (twice daily)
 - 4% hydroquinone (twice daily)
 - Exfoliant (each morning)
 - Sunscreen SPF 35 (each morning).
- Tretinoin 0.1% cream was applied each evening mixed 1:1 with 4% hydroquinone.
- Moisturizer use was allowed as needed for dryness.

Outcome measures

- The investigator evaluated overall melasma severity, target lesion pigmentation intensity, erythema, dryness, peeling, and burning/stinging.
- Patients evaluated the following indicators of quality of life (as “very much”, “a lot”, “a little”, or “not at all”):⁴
 - How embarrassed or self-conscious they had been because of their skin

- How much their skin discoloration had made them feel unattractive to others
- How much effort they had put into hiding their skin discoloration from others
- How much others had focused on their skin discoloration rather than on what they were saying or doing
- How much their skin had affected any of their social and leisure activities.

- Patients also evaluated the following compared with a pre-treatment photograph taken at the baseline visit:
 - Ease of applying the study treatment (rated as “very easy”, “easy”, “average”, “difficult”, or “very difficult”)
 - Smoothness of skin (rated as “much smoother”, “smoother”, “no difference”, “rougher”, or “much rougher”)
 - Impression of the study treatment (rated as “highly favorable”, “favorable”, “neutral”, “unfavorable”, or “highly unfavorable”)
 - Effectiveness of treatment compared with other medications (rated as “much more effective”, “more effective”, “same”, “less effective”, or “much less effective”)
 - Satisfaction with the overall effectiveness of study treatment (rated as “very satisfied”, “satisfied”, “indifferent”, “dissatisfied”, or “very dissatisfied”).

RESULTS

Patients

- Among 21 patients (12 Asian, 9 Caucasian) enrolled:
 - 18 (86%) completed 24 weeks of treatment
 - 1 discontinued during initial 12-week study due to non-compliance (Asian)
 - 2 voluntarily withdrew during extension study (1 Asian, 1 Caucasian)
- Mean age of 48 years
- Fitzpatrick skin type III (38%) or IV (62%)
- Melasma was:
 - Combination epidermal and dermal (67%) or epidermal (33%)
 - Malar (67%), centrofacial (29%), or mandibular (5%)

Investigator evaluations of efficacy

- From week 4 onward, both Asians and Caucasians showed significant improvements in overall melasma severity and in target lesion intensity of pigmentation (Figures 1-3), with no significant between-group differences.

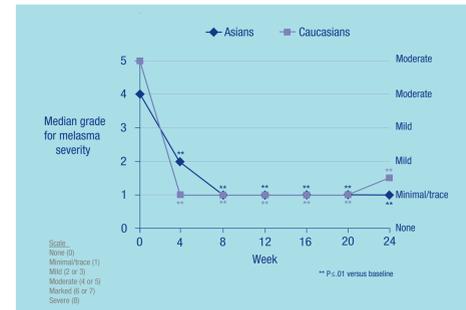


Figure 1. Overall melasma severity.

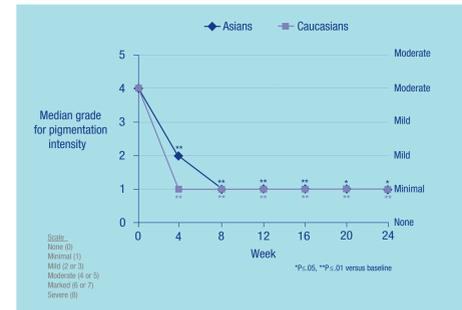


Figure 2. Intensity of pigmentation in target lesion.



Figure 3. Improvement in melasma in first few weeks of treatment.

Patient evaluations

- Both groups showed considerable improvements in quality of life indicators (Figure 4), with some indicators appearing to improve less and/or more slowly in Asians than in Caucasians.
- At week 24, similar proportions of patients considered that:
 - The study treatment was “easy” or “very easy” to apply (100% of Asians versus 88% of Caucasians)

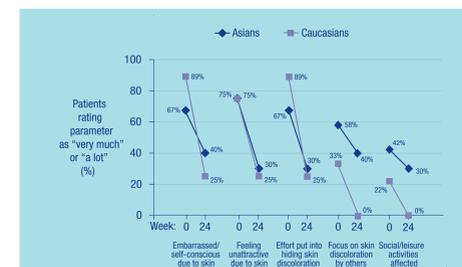


Figure 4. Improvements in quality of life indicators.

- Their skin was “smoother” or “much smoother” than before treatment began (90% of Asians versus 100% of Caucasians).
- At week 24, 100% of patients in both groups:
 - Had a “favorable” or “highly favorable” impression of treatment
 - Considered the study treatment was “more effective” or “much more effective” than other medications
 - Were “satisfied” or “very satisfied” with the overall effectiveness of treatment.

Tolerability

- Tolerability was similar in Asians and Caucasians:
 - No treatment-related adverse events in either group
 - No significant between-group differences in median scores for erythema, dryness, peeling, or burning/stinging except less erythema in Asians than Caucasians at week 4 ($P \leq .05$) (Figure 5).
- All patients except 1 Asian used the study moisturizer; all use was preventive rather than as a treatment for dryness.

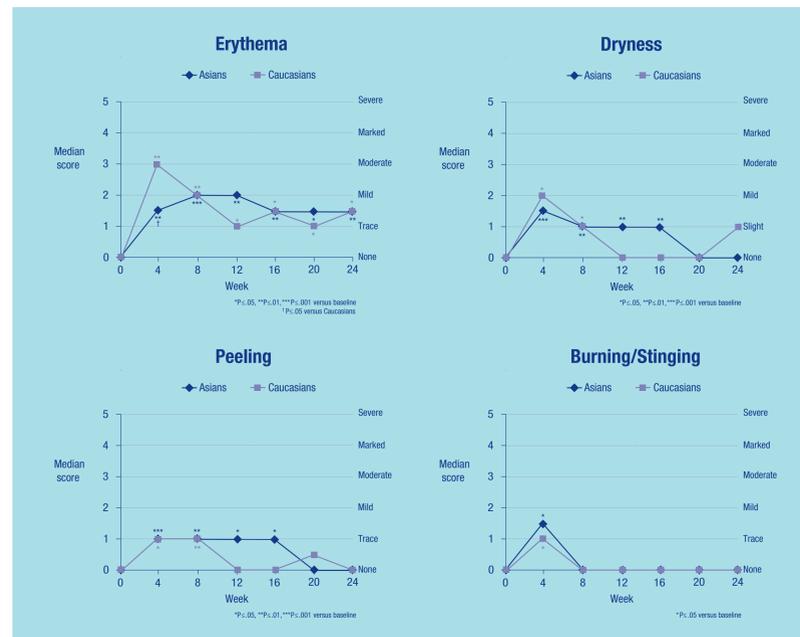


Figure 5. Tolerability comparisons between Asians and Caucasians.

CONCLUSION

The efficacy and tolerability of treatment were generally comparable in both groups. The only differences detected in Asians compared with Caucasians were a significantly lower median erythema score at week 4, and a possibly smaller and/or slower improvement in some indicators of quality of life. Using the 4% hydroquinone skin care system plus 0.1% tretinoin cream to treat melasma is as efficacious and well tolerated in Asians as it is in Caucasians.

REFERENCES

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DISCLOSURE

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