

# 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

## 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,<sup>1-3</sup> 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”)<sup>4</sup>:
  - 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.

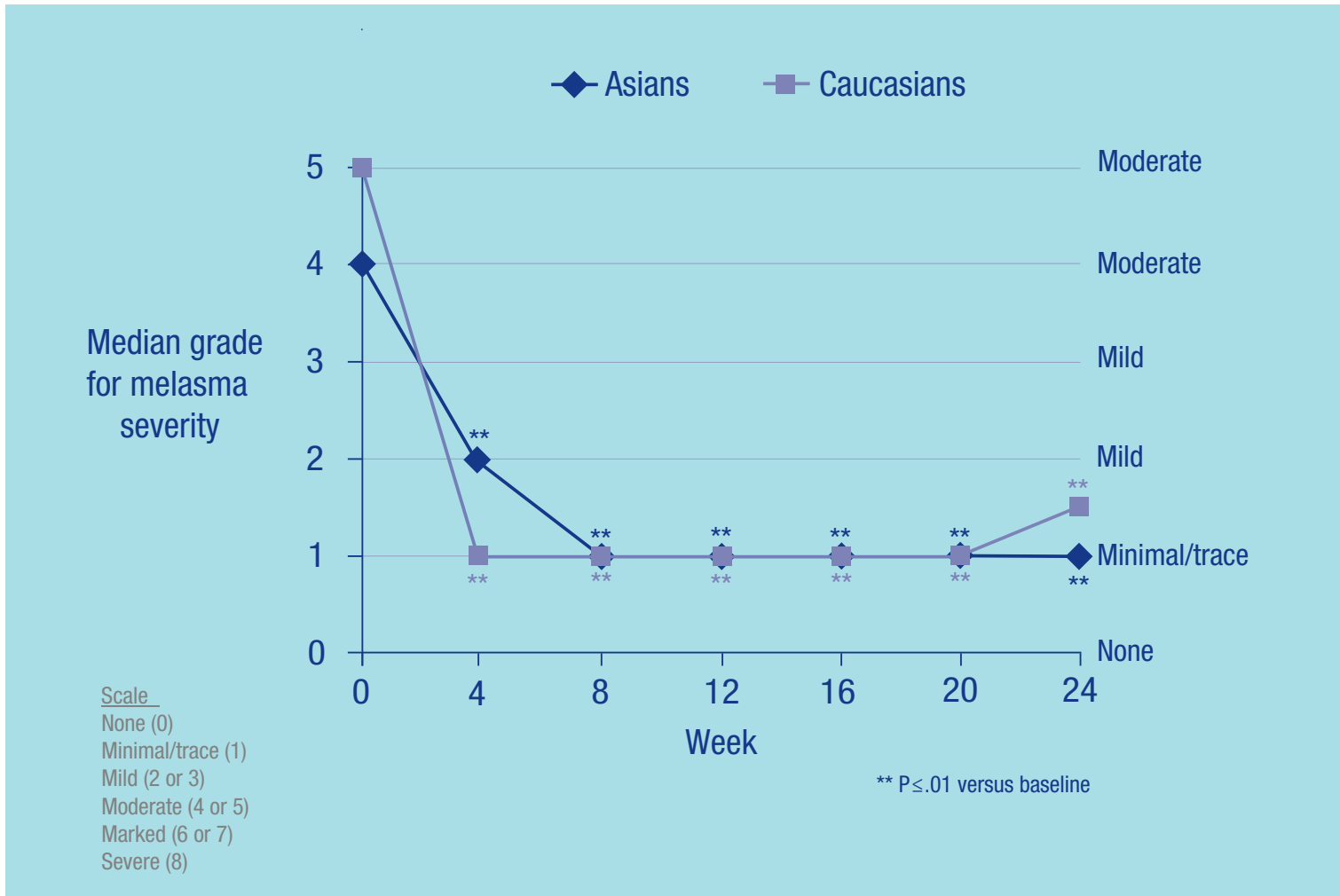


Figure 1. Overall melasma severity.

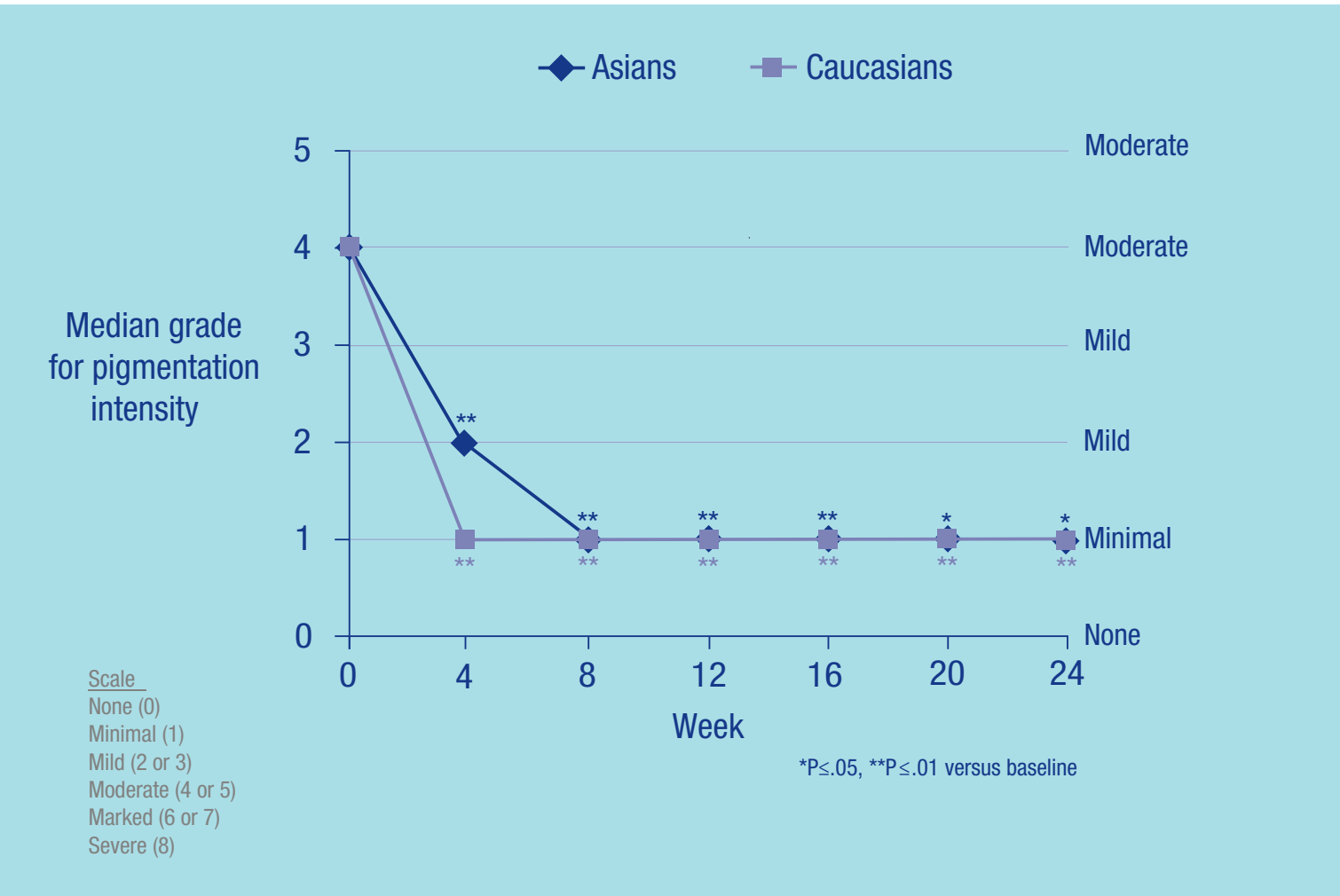


Figure 2. Intensity of pigmentation in target lesion.



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)

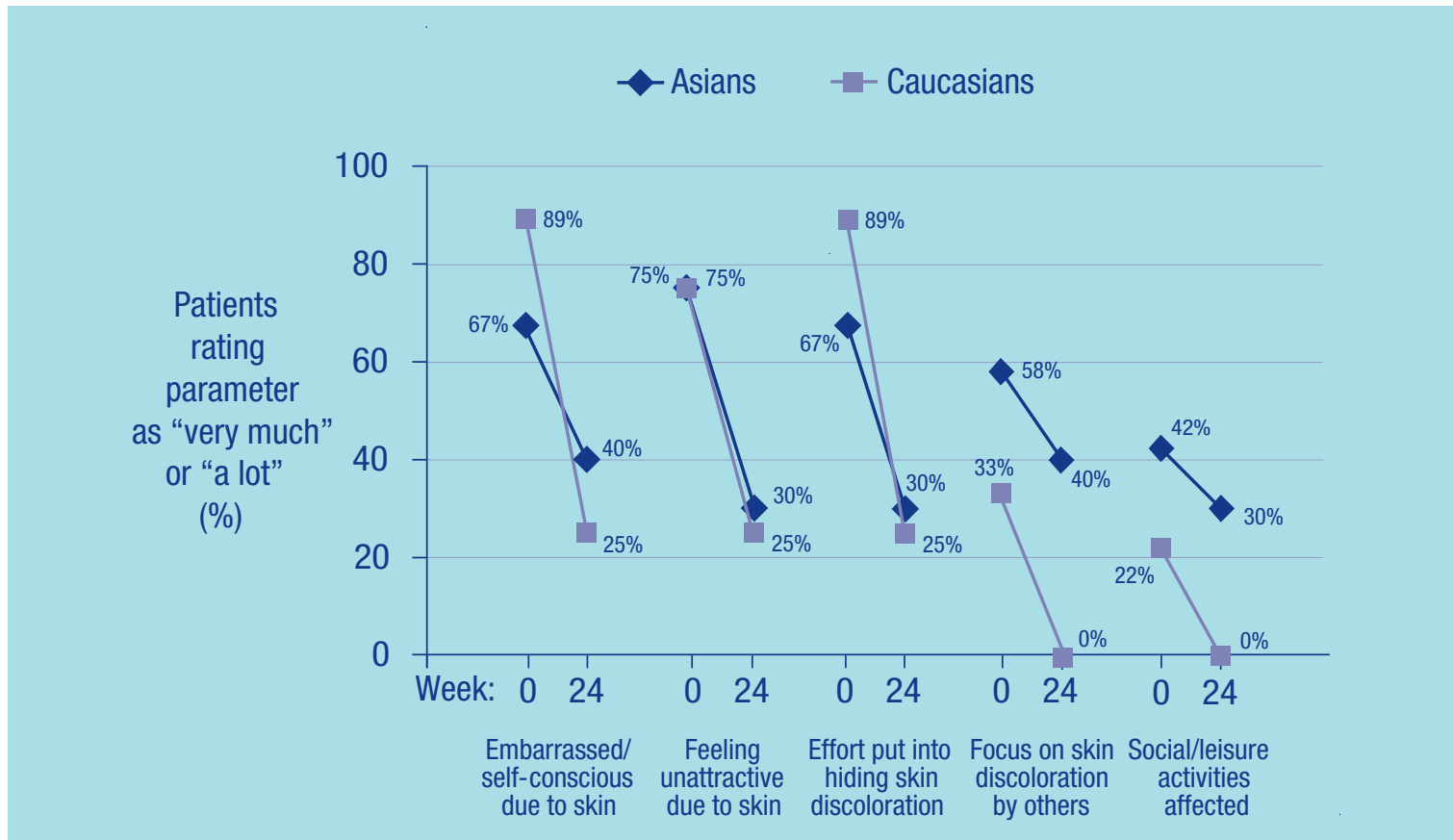


Figure 4. Improvements in quality of life indicators.

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- 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.

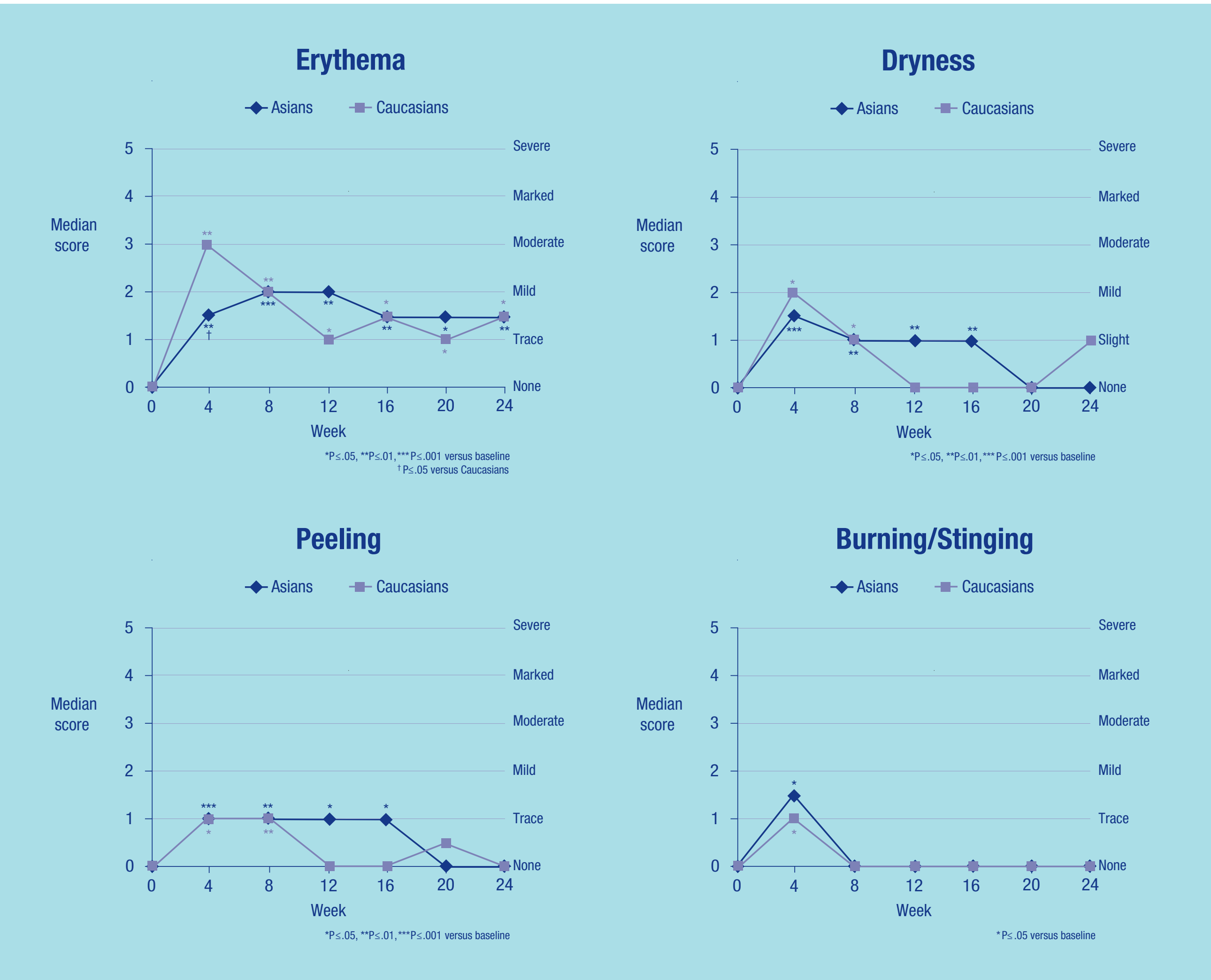


Figure 5. Tolerability comparisons between Asians and Caucasians.

## 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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4. Balkrishnan R, Kelly AP, McMichael A, Torok H. Improved quality of life with effective treatment of facial melasma: the pigment trial. *J Drugs Dermatol* 2004;3:377-81.

## DISCLOSURE

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