Efficacy and Tolerability of a Comprehensive Brightening Serum Plus a Dual Antioxidant System in Ethnically Diverse Subjects with Moderate to Severe Facial Hyperpigmentation

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OBJECTIVE

To evaluate the safety and efficacy of a cosmetic topical brightener (LYT2) in combination with a dual serum antioxidant system (LVS) in subjects of diverse ethnicity presenting with moderate to severe facial hyperpigmentation

CONCLUSIONS

The LYT2 + LVS regimen was well tolerated, and produced significant improvements in hyperpigmentation, skin-tone evenness, and radiance

The regimen produced high patient-perceived efficacy and overall satisfaction

LYT2 + LVS may be a novel, non-prescription regimen for ethnically diverse patients seeking to improve hyperpigmentation and overall skin quality

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INTRODUCTION

Background

- Facial hyperpigmentation is a common cosmetic complaint
  - While hyperpigmentation affects all races, it is of particular concern to Asian individuals
  - These disorders are highly prevalent among East Indians
- Treatment options are rarely formally evaluated in Asian populations, let alone Indian
  - The gold-standard, front line topical therapies such as those containing hydroquinone (HQ) cannot be used long-term because of adverse effects
  - Alternative cosmetic topical therapies are in demand, but current options lack efficacy
- Skin brightening agents combined with comprehensive antioxidant defense may complement each other to reduce the appearance of hyperpigmentation and improve skin quality
  - A comprehensive cosmetic topical brightener (LYT2) was previously shown to be similarly effective to 4% HQ at reducing hyperpigmentation in ethnically diverse patients[1,2]
  - A dual serum product providing broad antioxidant protection and skin repair support (LVS) was shown to protect from environmental damage and improve overall skin appearance in both Indians and Chinese[3,4]
  - A combination regimen using these agents has not been formally evaluated in diverse populations

METHODS

Study Design

- Open-label, single center study
- Individuals must have had investigator-assessed moderate to severe overall facial hyperpigmentation (score of 4-9 on the modified Griffiths' scale).
- Key exclusion criteria
  - a pre-existing dermatologic condition that could interfere with study assessments
  - known allergies or sensitivities to the ingredients in the study products
  - women who were pregnant or nursing

Treatment Regimen

- LVS Day and Night serum (Lumivive System, SkinMedica, Allergan Aesthetics, an AbbVie Company) – used each once daily
- LYT2 (Lytera 2.0, SkinMedica) - used twice daily
- Facial Cleanser (SkinMedica) – used twice daily
- Broad-spectrum SPF 35 sunscreen (SkinMedica) – used once daily, reapplied as needed
- Ultra Sheer Moisturizer (SkinMedica) - used twice daily

Study Assesments

- Study visits occurred at baseline, week 2, week 4, week 8 and week 12
- Standardized Digital Photography(Canfield VISIA-CR), and investigator assessments for the following parameters were conducted at all visits:
  - Overall Hyperpigmentation, Skin Tone Evenness, Radiance
  - 0-9 scale (0=none, 1-3=mild, 4-6=moderate, 7-9=severe)
- Subject self-assessment questionnaires were completed at all follow-up visits
- Tolerability of treatment was assessed via capture of adverse events at each follow-up visit

RESULTS

- Eighteen females, aged 34-54, enrolled in the study (Table 1)
  - All patients previously relapsed from or failed therapy with HQ (4 or 6%), or triple combination cream
- Of the 18 patients enrolled, 15 completed the study
  - One drop-out was due to non-compliance, and 2 patients withdrew consent
- Immediate significant improvements were observed for all investigator-assessed parameters (Figures 1&2)
  - Continous improvement was seen through the study
- By week 12, ≥80% of subjects rated "agreed" or "strongly agreed" to all attributes of perceived efficacy (Figure 3)
- All patients noted at least slight improvements in skin condition by week 4 (Figure 4)
- At week 12, 86% of subjects reported "good" or "excellent" overall satisfaction with the treatment (Figure 5)
- One adverse event was reported
  - Patient developed a red rash on the face and experienced itchy eyes that resolved once the regimen was discontinued, and the patient withdrew from the study

Table 1. Patient Demographic Enrolled at Baseline

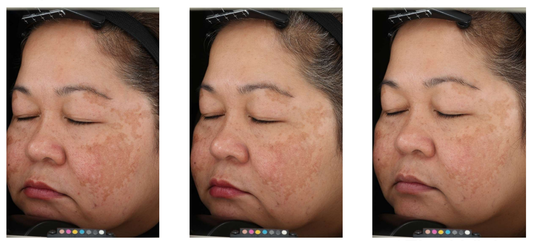
	# of subjects (N=18)
Age (years)	
Mean (SD)	45
Min, Max	33-57
Gender, n (%)	
Female	18 (100%)
Ethnicity, n (%)	
Caucasian	6 (33%)
Asian	9 (50%)
East Indian	*6 (33%)*
South Asian	*1 (6%)*
Not Specified	*2 (11%)*
Other	3 (17%)
Fitzpatrick Skin Type, n (%)	
II	7 (39%)
III	2 (11%)
IV	9 (50%)

Figure 1A&B. VISIA-CR Images (Standard Lighting 2) Showing Improvements from baseline in Overall Hyperpigmentation, Skin-Tone Evenness, and Radiance at Week 4 and at Final Evaluation

(A) 46 year-old, East Indian Female, Fitzpatrick type IV

Baseline Week 4 *Final Visit

(B) 51 year-old, Asian Female, Fitzpatrick type IV



Baseline Week 4 *Final Visit

***The final visit was conducted off-schedule at week 19 (A) or week 14 (B) instead of week 12 due to restrictions from Covid-19**

Figure 2. Improvements in Overall Hyperpigmentation, Skin Tone Evenness, and Radiance as Assessed by Investigator

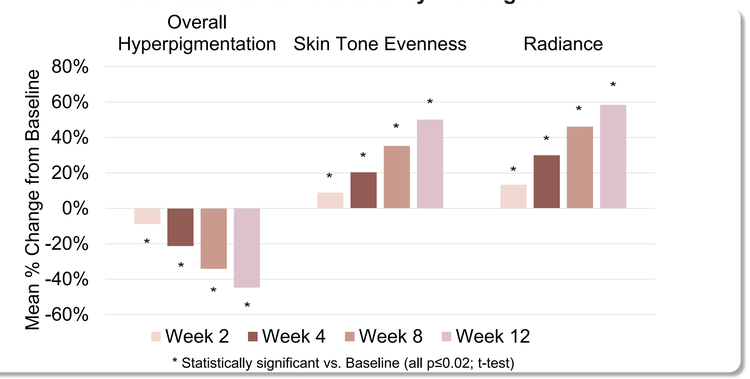


Figure 3. Subject Questionaire Results for Self-Assessed Efficacy at Week 12

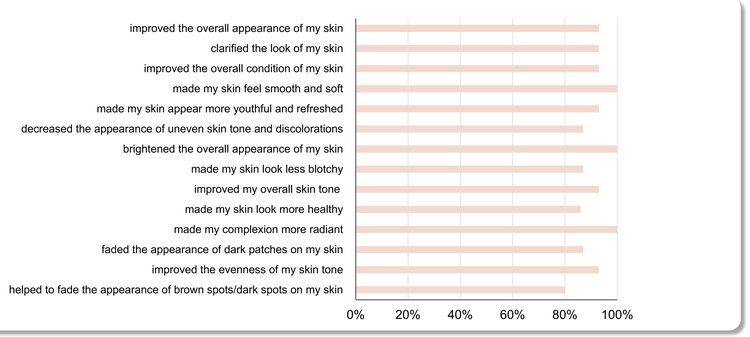


Figure 4. Subject Graded Overall Improvements

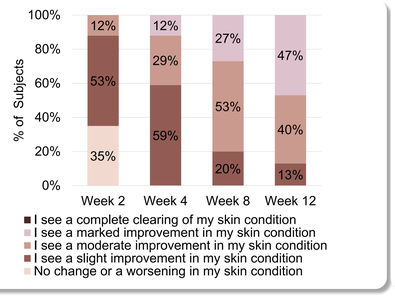


Figure 5. Subject Overall Satisfaction