EFFECT OF COMBINATION THERAPY ON VISIBLE/NON-VISIBLE SYMPTOMS, AND DISEASE BURDEN ASSOCIATED WITH SEVERE ROSACEA: RESULTS FROM A POST-HOC ANALYSIS OF A RANDOMIZED CONTROLLED TRIAL

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SYNOPSIS

Rosacea affects over 14 million people in the US with symptoms in central areas of the face, causing flushing, stinging/burning, chronic erythema, and inflammatory lesions, with major negative impact on quality of life.1-3

The disease is chronic and inflammatory in nature and burden typically extends beyond visible symptoms with impact on emotional, social, and psychological aspects of life.4-6 In a global survey (N = 710) evaluating impact of symptoms associated with disease burden in rosacea, non-visible symptoms such as itching, burning/pain, and swelling were significantly associated with high disease burden.6

• Combination therapy with multiple mechanisms of action is often used to manage symptoms associated with rosacea. However, limited numbers of controlled studies have evaluated impact of combination therapy in rosacea on reducing the signs and symptoms associated with rosacea.7

METHODS

The study was a 12-week, multicenter, randomized, investigator-blinded, parallel group comparative study in 273 adults with severe rosacea, as previously described (ClinicalTrials.gov number: NCT03075891).4 Post-hoc analyses assessed the correlations between changes in visible symptoms, stinging/burning, flushing severity, and Dermatology Life Quality Index (DLQI) and impact on disease burden using the Spearman’s rank correlation coefficient, as previously reported.8

The relationship between the following parameters was assessed:

• Impact of changes in the visible and non-visible symptoms on Dermatology Life Quality Index (DLQI).
• Significant correlations between the reduction in stinging/burning and individual DLQI parameters were found for itchy, feelings embarrassed, relationship with partners, friends, family (0.222, P < 0.001), feeling underressed (0.243, P < 0.000), and social activities (0.237, P < 0.000) (Figures 1a–b).

RESULTS

• Impact of stinging/burning and ‘clear’ or ‘almost clear’ on DLQI:

- A significant correlation was seen between change in stinging/burning over 12 weeks and change in DLQI score over 12 weeks (0.222, P < 0.001). (Figure 1a–b).

- Significant correlations between the reduction in stinging/burning and individual DLQI parameters were found for itchy, feeling underressed (0.243, P < 0.000), problems with partners, friends (0.241, P < 0.000), feeling underressed (0.241, P < 0.000), and social activities (0.237, P < 0.000) (Figures 1a–b).

- Significant correlations between ‘clear’ or ‘almost clear’ and individual DLQI parameters were found for feeling embarrassed (0.222, P < 0.001), relationship with partners, friends (0.241, P < 0.000), and social activities (0.237, P < 0.000) (Figures 1a–b).

• Severity of flushing and impact on DLQI:

- There was a significant correlation between changes in flushing severity over 12 weeks and DLQI changes over 12 weeks (0.222, P < 0.001) (Figure 2).

- Impact of baseline lesion count, pretreatment and topical treatment, and disease duration on efficacy of combination therapy

- At week 12, there was a significant and strong correlation (0.727, P < 0.000) between lesions at baseline and absolute change in lesion counts for the combined treatment arms. (Figure 3a c).

- In the combination therapy arm, the highest significant percent reduction in lesion count was observed for previous oral and topical treatment (P ≤ 0.016). (Figure 4).

- Disease duration for ≥ 10 years was significantly correlated with highest percent change in lesion counts from baseline to week 12 in the combination therapy arm (P < 0.001). (Figure 5).

CONCLUSIONS

Combined IVM and DM benefit both visible (erythema, inflammatory lesions, stinging/burning, flushing) and non-visible symptoms (itching, burning/pain) of rosacea. Correlations between symptom reduction and DLQI suggest improvements in different aspects of quality of life. Results from this Phase 4 study and this post-hoc analysis emphasize the importance of targeting both the visible and non-visible signs and symptoms in patients with severe rosacea with combination therapy to create best outcomes.

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