QUALITY OF LIFE IS SIGNIFICANTLY IMPROVED USING A BENZOYL PEROXIDE 5%/CLINDAMYCIN 1% COMBINATION GEL VERSUS ADAPALENE 0.1% IN THE TREATMENT OF MILD TO MODERATE ACNE

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INTRODUCTION

Results of a previous single-blind, multi-center study demonstrated that in 130 subjects with mild to moderate acne, a fixed-dose combination benzoyl peroxide 5%/clindamycin 1% gel (BPO/C) produced an earlier onset of action, was more effective against inflammatory and total lesions and was better tolerated than adapalene 0.1% (AP) gel.[1]

This comparative study was undertaken to further compare the profiles of these two products, specifically quality of life. The effects on quality of life were assessed using the Skindex-29 questionnaire, which evaluates a subject's quality of life in 3 domains: emotional, functional, and symptomatic.[2] The instrument has shown good psychometric qualities (eg, internal consistency, reproducibility, construction and content validity, feasibility, and sensitivity to change).[3]

METHODS

Study Design
• 12-week, multi-center, randomized, investigator-blind, comparative, parallel group

Key Inclusion Criteria
• Male and females, 12 to 39 years of age
• Subjects with mild to moderate facial acne consisting of at least 15 inflammatory and/or non-inflammatory, but no more than 3 nodular cystic lesions and an acne grade between 2.0 and 7.0

Treatments
• Subjects were randomized in a 1:1 ratio to receive either BPO/C or AP for 12 weeks.
• Treatments were applied to facial acne once daily in the evening.

Assessments
• Efficacy, tolerance, and safety were assessed at Baseline and at Weeks 1, 2, 4, 8 and 12.

Primary
• Global Skindex-29 quality of life score after 2 weeks of treatment

Key Secondary
• Global Skindex-29 quality of life scores scores at weeks 1 and 12
• Inflammatory, non-inflammatory, and total lesion counts.
• Tolerability (peeling, erythema, and dryness assessed by investigator; pruritus and burning assessed by subject)
• Overall tolerability score (Poor, Fair, Good, Excellent)
• Adverse events (AEs) were monitored during the study and during a 14-day minimum follow-up period

RESULTS

• In total, 168 subjects were enrolled. The demographics and baseline characteristics were similar between the groups.
• The primary efficacy endpoint was assessed in 167 of the 168 subjects.
• 114 subjects completed the study. The proportion of subjects that discontinued was similar between groups; the most common reasons for discontinuation were lost to follow-up, subject considered their disease cured, and non-compliance. Thirteen of the 15 subjects that discontinued because they considered their disease cured were within the BPO/C treatment group.

PRIMARY ENDPOINT

Quality of Life

• After 2 weeks of treatment, subjects in the BPO/C group achieved a small, but significantly better improvement in global quality of life compared with those in the AP group. Improvement from baseline (as demonstrated by a reduction in the mean global score) was -4.9 and -1.2 for the BPO/C and AP group, respectively. The difference between the 2 treatment groups was -4.04 (P <0.001), in favor of BPO/C (Figure 1).

• Similarly, subjects using BPO/C achieved significant improvements in global quality of life scores at Week 1 and 12 compared with those using AP (P <0.001) (Figure 1).

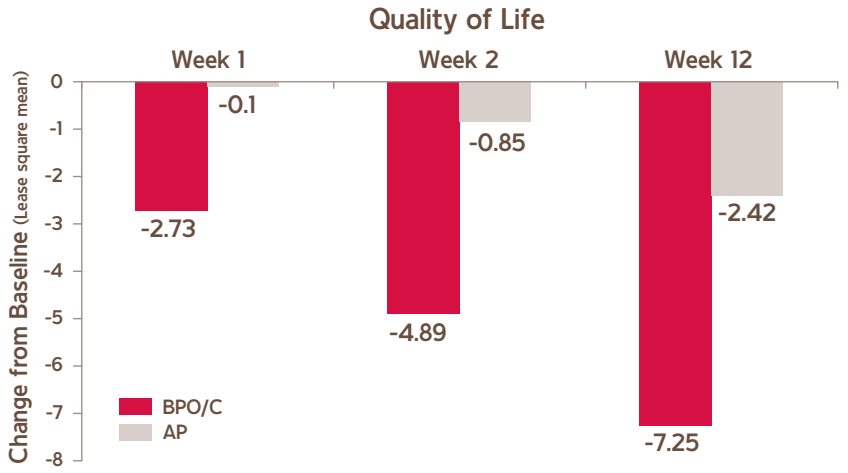

Figure 1 Change from Baseline in Global Score of the Quality of Life Skindex-29 at Week 1, 2 and 12 (Intention-to-Treat Analysis Set). Lower values represent better quality of life.

SECONDARY ENDPOINTS

Lesion Counts
• BPO/C demonstrated a rapid improvement in number of acne lesions, with a significantly greater percent reduction in both total lesions and non-inflammatory lesions at every time point (P <0.05) (Figure 2).
• A significant difference in favor of BPO/C (P ≤0.01) in the percent change from baseline in non-inflammatory lesion count was observed at weeks 8 and 12.

Tolerability
• BPO/C was significantly better tolerated than AP from week 2 onwards with respect to all investigator-rated (erythema, dryness, peeling) and week 1 onwards patient-rated (burning, itching) outcomes (P ≤.03) (Figure 3).
• The proportion of subjects with an overall tolerance score of excellent was higher in the BPO/C group (34 [43%] subjects) than in the AP group (17 [20%] subjects). Conversely, tolerance was rated as fair or poor in 4 (5%) and 19 (23%) subjects in the BPO/C and AP groups, respectively. Overall tolerance was significantly different between the 2 treatment groups at week 12/early termination in favor of BPO/C (P <0.0001).

Safety
• The majority of AEs were reported by those in the AP treatment group (41 of 60 total). The most common AEs involved mild application site events (35 total, 8 in the BPO/C group, 27 in the AP gel group). No serious AEs were reported during the study.

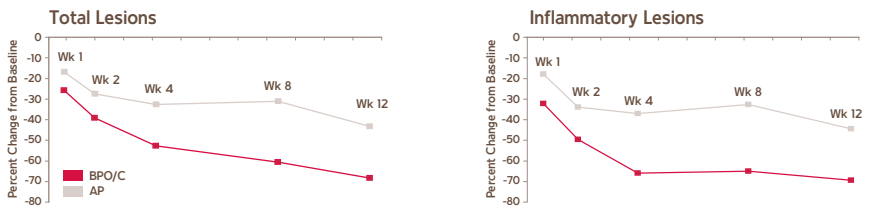

Figure 2 Percent change in total lesion count (a) and inflammatory lesion count (b) over time in subjects using either BPO/C or AP once daily for 12 weeks.

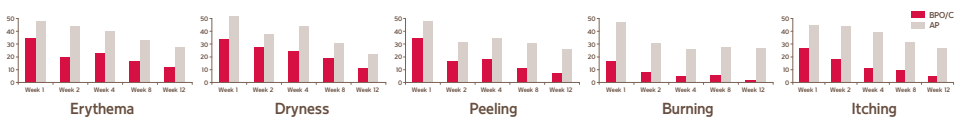

Figure 3 Percentage of subjects experiencing tolerability events during the study as rated by Investigators and Subjects.

CONCLUSIONS

A significantly better quality of life was achieved with BPO/C compared with AP. These quality of life improvements are likely the result of the superior efficacy and tolerability profile observed with BPO/C.

References:
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