Comparison of a Novel Benzoyl Peroxide Formulation and a Combination Benzoyl Peroxide/Clindamycin Gel in the Treatment of Acne Vulgaris: A Randomized, Double-Blind Clinical Trial

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INTRODUCTION

- Propionibacterium acnes *(P.acnes)* is a gram positive anaerobic bacterium that colonizes the sebaceous follicles and is implicated in the pathogenesis of acne.
- Benzoyl peroxide *(BPO)* is a potent topical anti-*P.acnes* drug with demonstrated efficacy for the treatment of acne. Commercial formulations of 2.5% to 10% are available *(OTC or prescription)*.
- BPO effectively reduces both inflammatory and non-inflammatory lesion counts.
- BPO is often recommended for use concurrently with other topical agents for the treatment of acne, including antibiotics such as clindamycin. However, it is possible that BPO alone can reduce acne lesions counts to a comparable degree as combination products.

STUDY DESIGN AND METHODS

Objective

- To compare the efficacy and safety of a novel BPO 5% formulation and a commercially available BPO 5%/clindamycin 1% *(BenzaClin®)* formulation in patients with mild to moderate acne vulgaris based on:
  - Change in inflammatory and non-inflammatory lesion counts a 12 week period.
  - Physician's Global Assessment of Acne.

Design

- 12-week randomized, double-blind single-center trial.

Patient Eligibility

▼ Inclusion criteria

- Male/female 13-35 years of age.
- Mild to moderate facial acne *(10-30 inflammatory lesions, 10-100 non-inflammatory lesions, no nodules)*.

▼ Exclusion criteria

- Papulo-pustular rosacea or other skin diseases on the face.
- Known sensitivity to benzoyl peroxide, clindamycin or any other ingredients of the study medication.
- Use of the following medications within the described period:
  - Topical anti-acne medications or hydroxy acids – 2 weeks
  - Topical retinoids, topical and systemic antibiotics and topical and systemic steroids – 4 weeks
  - Investigational drugs – 4 weeks
  - Systemic retinoids – 1 year
- Concurrent use of other medicated products on face, unless approved by the study physician.
- Use of cosmetics on face during study.

Efficacy Variables

- Efficacy assessments were conducted at baseline and Weeks 2, 4, 6, 8, 10 and 12 *(final visit)*
- Primary efficacy assessments
  - Non-inflammatory lesion *(open and closed comedones)* count.
  - Inflammatory lesion *(papules, pustules and nodules)* count.
  - Physician Global Assessment of Acne. *(PGA; from 0 = normal, clear skin with no evidence of acne vulgaris, to 5 = highly inflammatory lesions predominate, with variable number of comedones, many papules/pustules, nodulo-cystic lesions)*

Safety Assessments

- Adverse events *(AEs)*
- Local irritation *(including erythema, dryness, stinging/burning and itching)*, assessed on a scale of 0 = none to 3 = severe.

Statistical Analyses

▼ Efficacy Variables

- Analyses were performed on the per protocol *(PP)* population, defined as all randomized subjects who completed all 12 weeks of treatment and did not miss two or more consecutive efficacy visits.

▼ Safety Variables

- Descriptive analyses were performed on the intent-to-treat *(ITT)* population, defined as all randomized subjects who received at least one dose of treatment.

RESULTS

▼ Demographics and baseline characteristics

Demographic	Novel BPO Formulation (n=19)	Branded BPO/Clindamycin Gel (n=19)
Age, Mean (years)	22.2	20.7
Gender, N [%]		
Male	5	5
Female	14	14
Fitzpatrick Skin Type, N [%]		
Types I, II, III	14	5
Types IV-V	5	14
Baseline Characteristic (ITT Population)		
Non-Inflammatory Lesions, Mean	31.3	34.0
Inflammatory Lesions, Mean	18.5	14.0
Physicians Global Assessment of Acne, Mean	3.2	2.9

- There were no apparent differences between treatment groups on any demographic variables, or between the ITT and PP populations on any baseline disease characteristics.

▼ Efficacy

- There was a comparable reduction in both non-inflammatory (Figure 1) and inflammatory (Figure 2) lesion counts in the two treatment groups.
- The reduction in both types of lesions counts was rapid and progressive in both treatment groups, generally reaching a plateau at Week 8.
- Physician's Global Assessment of Acne scores at Week 12 were similar in the novel BPO and branded BPO/clindamycin groups.

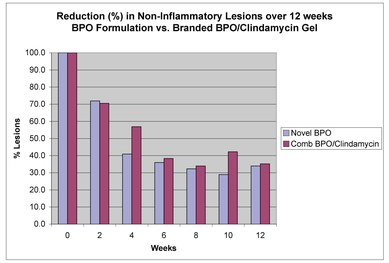

Fig. 1 Percent reduction in non-inflammatory lesions over time

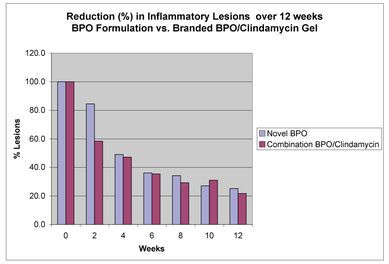

Fig. 2 Percent reduction in inflammatory lesions over time.

▼ Safety

- 18 of the 38 patients (10 in novel BPO group and 8 in BPO/clindamycin group) reported an AE. The most common AEs were upper respiratory infections and headaches.
- There were no observable differences between treatment groups in AEs.
- Physician-rated erythema and dryness, and subject-rated itch were mild and similar between groups.
- Subject assessment of stinging/burning was initially noticeable in the novel BPO group, although this occurred early in treatment and generally diminished over time.

CONCLUSIONS

- Mild to moderate facial acne vulgaris is improved by the use of a novel BPO formulation.
- Both non-inflammatory and inflammatory lesion counts decreased rapidly and continually over 8 weeks, and the reduction was sustained through 12 weeks after treatment with the novel BPO formulation. A similar pattern was observed with treatment with a branded BPO/clindamycin gel.
  - o Subjects tolerated both treatments equally well throughout the study.
- Physician's Global Assessment of Acne ratings also were similar in the two treatment groups.
- Further clinical evaluation of this novel therapeutic product is on-going.

REFERENCES

Golnick H. Global Alliance to Improve Outcomes in Acne. Management of acne: a report from the Global Alliance to Improve Outcomes in Acne. J Am Acad Dermatol. 2003;49:S1-S37.

DISCLOSURES

This study was funded by OMP, Inc.