POSTER 123

COMPARISON OF A NOVEL SOLUBILIZED BENZOYL PEROXIDE GEL WITH BENZOYL PEROXIDE/CLINDAMYCIN: A MULTICENTER, INVESTIGATOR-BLIND, RANDOMIZED STUDY

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INTRODUCTION

Benzoyl peroxide (BPO) is poorly soluble and some commercially successful formulations have vehicles that inhibit the ability of BPO to penetrate into the hair follicles. Using a patented technology, a novel formulation of solubilized BPO has now been developed that helps maximize the bioavailability of BPO and enhances its follicular penetration. The solubilized 5% BPO gel is available as part of a 3-step acne system that also incorporates the use of a proprietary toner and cleanser, both of which contain 2% salicylic acid.[1]

We report here a comparison of solubilized 5% BPO gel monotherapy (i.e. without the other components of the 3-step acne system) with a leading prescription 5% BPO/clindamycin combination product* in the treatment of moderate facial acne vulgaris.

METHODS

Study design

- Multicenter, investigator-blind, randomized, split-face study

Key inclusion criteria

- Moderate facial acne vulgaris (25-100 non-inflammatory lesions, 25-100 inflammatory lesions, up to 2 nodulocystic lesions)
- 11-45 years of age
- Willing to refrain from excessive exposure to the sun and the use of tanning booths
- Willing to refrain from facial use of non-study acne medications, moisturizers, sunscreens, fragrances, aftershaves, and make-up (however, oil-free non-comedogenic make-up, mascara, eyeshadow, and lipstick were allowed)

Key exclusion criteria

- Allergy to benzoyl peroxide, clindamycin, lincomycin, salicylic acid, sunscreens or other ingredients in the study products
- Facial cosmetic procedure in the preceding 6 months
- Papulopustular rosacea and other skin diseases on the face (other than acne) that could interfere with study evaluations
- Facial sunburn at the baseline visit
- Males with a beard or sideburn that could interfere with study evaluations
- Uncontrolled systemic disease or infection with human immunodeficiency virus
- History of regional enteritis, ulcerative colitis, or antibiotic-associated colitis
- Concurrent facial use of other medicated products
- Participation in an investigational study in preceding 30 days

*Gel product packaged in a pump.

Washout periods

- 1 week for medicated facial cleansers
- 2 weeks for topical alpha-hydroxy acids, anti-acne medications, topical retinoids, topical and systemic antibiotics, topical and systemic steroids
- 3 months for estrogens/birth control pills (unless use has been stable for at least 3 months)
- 6 months for systemic retinoids

Treatment regimen

- Patients were randomly assigned to apply one of the following to one side of their face and the other to the contralateral side of their face, twice daily for 4 weeks:
  - Solubilized 5% BPO gel
  - 5% BPO/1% clindamycin combination product.
- Before applying either product, patients were required to wash their face using a gentle cleanser (provided).
- Patients were instructed to avoid applying the test products around the lips and eyes and were allowed to use a non-comedogenic moisturizer with SPF 15 sunscreen as necessary during the study.

Outcome measures

- Non-inflammatory lesion count (open comedones plus closed comedones)
- Inflammatory lesion count (papules plus pustules plus nodules)
- Patient satisfaction that the study products leave the skin feeling refreshed and that the products feel like they are working (rated as excellent, good, fair, or poor)
- Stinging/burning, erythema, dryness, and itching (rated as none, mild, moderate, or severe)

Statistical analyses

- Between-group differences in lesion count and mean scores for stinging/burning, erythema, dryness, and itching were compared using a paired t-test or Wilcoxon signed rank test.
- A P value of ≤.05 was considered statistically significant.

RESULTS

Patients

- A total of 23 patients have completed the study to date.
- They had a mean age of 21 years and 52% were male.
- They were predominantly:
  - Caucasian (78% Caucasian, 13% Black, 4% Asian, 4% other)
  - Fitzpatrick skin type III (16% II, 47% III, 21% IV, 11% V, 5% VI).

Efficacy

- The solubilized BPO gel resulted in a significantly greater reduction in lesion count than BPO/clindamycin (P≤.05) for:
  - Non-inflammatory lesions at week 1 (Figure 1)
  - Inflammatory lesions at week 4 (Figure 2).
- At week 4, the non-inflammatory lesion count (Figure 1) was reduced by a mean of:
  - 42% with solubilized BPO gel
  - 28% with BPO/clindamycin.
- At week 4, the inflammatory lesion count (Figure 2) was reduced by a mean of:
  - 70% with solubilized BPO gel (P≤.05 versus BPO/clindamycin)
  - 61% with BPO/clindamycin.

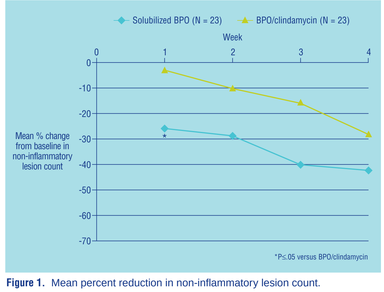

Figure 1. Mean percent reduction in non-inflammatory lesion count.

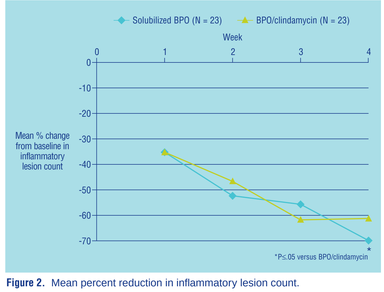

Figure 2. Mean percent reduction in inflammatory lesion count.

Patient satisfaction

- Patient satisfaction that the products leave the skin feeling refreshed and that the products feel like they are working was comparable in both groups (Figure 3).

Tolerability

- Mean levels of stinging/burning, erythema, dryness, and itching were less than mild in both groups at all timepoints (Figures 4-7).
- Although the mean levels of stinging/burning, erythema, and dryness were higher with the solubilized BPO gel than with BPO/clindamycin at weeks 1 and 2 (P≤.05), these differences were transient (resolving by week 3) and were likely not clinically significant as they did not reduce mean patient satisfaction scores. Furthermore, no patient discontinued prematurely.

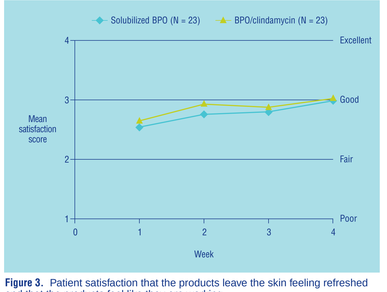

Figure 3. Patient satisfaction that the products leave the skin feeling refreshed and that the products feel like they are working.

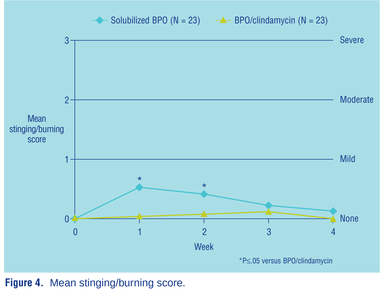

Figure 4. Mean stinging/burning score.

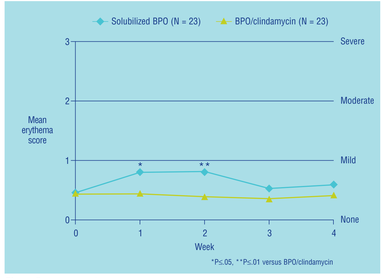

Figure 5. Mean erythema score.

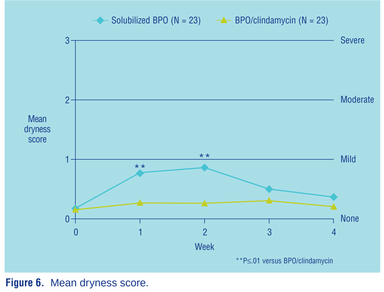

Figure 6. Mean dryness score.

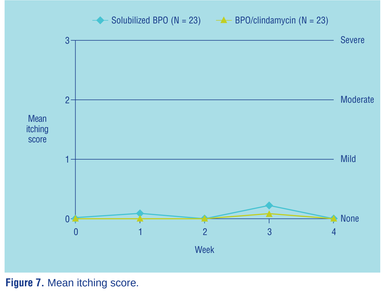

Figure 7. Mean itching score.

CONCLUSIONS

In this study, twice-daily monotherapy with the solubilized 5% BPO gel resulted in a significantly greater reduction in the number of non-inflammatory lesions (at week 1) and inflammatory lesions (at week 4)—as well as comparable patient satisfaction—when evaluated against twice-daily therapy with a BPO/clindamycin combination product.

The early reduction in lesion counts observed with the solubilized BPO gel in the absence of an antibiotic is of considerable clinical importance. It is likely that the solubilized BPO formulation facilitates the significant reduction in lesion count during the first week of therapy as a consequence of enhancing the follicular penetration of BPO. Further research will help confirm these findings and evaluate the benefits of longer-term treatment.

REFERENCES

1. CLENZIderm M.D.™ Introducing a breakthrough acne solution from Obagi. Available at: http://www.obagi.com/article/forpatients/obagiclenzidermmd/clenziderm.html. Accessed November 6, 2007.

DISCLOSURES

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