Lytic Tx Superior to 10% Benzoyl Peroxide for Acne Treatment

Clinical Assessment Results (Presented at 2006 AAD Annual Meeting Poster Exhibit No. P142)

ABSTRACT

A double-blind, split-face prospective, controlled clinical study used Epionce® Lytic Tx compared to nonprescription 10% benzoyl peroxide lotion in the treatment of mild to moderate acne vulgaris. According to the independent study, Lytic Tx was superior to benzoyl peroxide in reducing inflammatory papules at both 6 days and 12 weeks.

INTRODUCTION

Acne vulgaris afflicts 12% of women and 4% of men 25-44 years old, even though sebum production is significantly reduced after age 22.[1] Treatment for such adults consist of using acne products approved as safe and effective by the Federal Drug Administration (FDA) in teenagers. Unfortunately, the most common topical acne therapies, including benzoyl peroxide, retinoids, salicylates, sulfur/resorcinol, alpha hydroxy acids, azelaic acid and antibiotics have a relatively poor tolerance in adults due primarily to gels and solution formulations as dictated by the physiochemical characteristics of these active compounds.[2]

Lytic Tx was designed with a non-irritating and more emollient formulation, which has keratolytic functionality and prevents the release and activation of proinflammatory factors in the skin. This product consists of a naturally derived modified salicylate in a blend of novel botanical extracts with delivery systems to maximize efficacy while minimizing the risk of adverse reactions. This report details a double-blind, prospective, controlled split-face clinical trial documenting the efficacy of Lytic Tx for acne therapy and compares the results with an approved drug product.

PATIENTS

Eleven female panelists 24-42 years old of Caucasian, Hispanic and Asian origin with mild to moderate acne vulgaris signed the informed consent. People with abnormal menses, hirsutism, androgenic alopecia, rosacea and dermatitis were excluded from participation. The panelists used Lytic Tx twice daily for 12 weeks.

METHOD

At visit 1 (screening baseline), prospective subjects were examined for the presence of at least three inflammatory acne lesions (papules or pustules) of approximately equal size on each of the right and left sides of the face. Each of the target lesions were clinically graded by erythema and size with the following grading scales:

Erythema and Elevation
0=None 1 =Mild 2=Moderate 3=Severe

Lesional Size
0 = Any diameter that is macular (no elevation)
1 = 1-2 millimeters (mm) diameter with slight elevation

Elevation
2 = 2-4 mm diameter with moderate elevation
3 = Greater that 4 mm with prominent elevation

The total number of papules, pustules, and macules on the forehead, cheek and chin were counted. Subjects were randomly distributed units of Lytic Tx and 10% benzoyl peroxide lotion. Subjects were instructed to apply the appropriate test material to the entire assigned side of the face once each morning and once each evening. Subjects returned to the clinic for Visit 2 (Day 2), Visit 3 (Day 4), Visit 4 (Day 6), Visit 5 (Week 6) and Visit 6 (Week 12). At each of these visits, digital photographs were taken of the right and left sides of the face and clinical grading of target lesion parameters (erythema, elevation, size), irritation and acne lesion counts were performed as described for baseline. Subjects also completed a self-assessment questionnaire at each visit.

Mean values for clinical grading parameter and acne lesion counts were statistically compared to mean baseline values using a paired t-test at the p=0.05 significance level as indicated below:

- Target lesion parameter (erythema, elevation, size) at Days 2, 4 and 6.
- Objective and subjective irritation parameters at Days 2, 4 and 6; week 6 and week 12.
- Acne lesion counts at week 6 and week 12.

RESULTS

Physician Assessment

Lytic Tx (LL) decreased forehead papules by 53.3% (p=0.09); a trend toward statistical significance vs. baseline while benzoyl peroxide lotion (BP) increased forehead papules by 10.4%; a trend of statistical significant superiority for LL vs. BP (p=0.06).

6 Days

- Lesional erythema, size and elevation were reduced by LL by 41.1-47.8%, statistically significant over baseline (p=0.002), while BP reduced these parameters by 20.0-27.2%.
- LL is statistically significantly superior to BP at all above lesional parameters with p=0.0001-0.004.
- LL decreased erythema by 11.7%, which is statistically significant (p=0.05) vs. both baseline and BP.
- BP increased scaling by 18.3%, which is statistically significantly worse vs. LL as well as baseline.
- LL decreased itching by 6.7% while BP increased itching by 13.3%; for a trend toward statistical significant difference (p<0.09).

12 Weeks

- LL decreased cheek papules by 51.2% (p=0.002) vs. baseline while BP decreased cheek papules by 39.7% (p=0.03) vs. baseline. There was no statistical difference between the two treatments.
- Adverse reactions were comparable except erythema, with LL producing a trend of less erythema toward statistical significance (p<0.09).

Continued

Patient Assessment

6 Days

- 80% of BP patients agreed or strongly agreed their face is less oily while 60% of LL patients agreed face is less oily.
- 50% of BP patients complained that face was drier/scalier while 30% of LL patients complained of this.
- BP was preferred by 60%
- None of these differences reached statistical significance.

12 Weeks

- LL was preferred by 72.7% (p=0.05).
- Texture improved by LL 63.6% vs. BP 36.4% with a trend toward statistical significance (p=0.10).
- Both groups agree or strongly agree pimples were improved by 72.7% and overall appearance is improved in 63.6%, both statistically significant over baseline (p=0.02).
- No LL patient face was drier/scalier, while 45.5% using benzoyl peroxide complained of face being drier and scalier (p=0.05).

DISCUSSION

Acne vulgaris afflicts 85% of young people ages 12-24.[3] Androgen stimulation of sebum secretion and infundibular hyperkeratinization inducing the microcomedone are the initiating steps of overt acne vulgaris. Propionibacterium acnes contribute to the production of inflammatory lesions.[2] Treatment requires multiple mechanisms of action, therefore the most individual therapeutic compounds include those with multiple functions. Antibiotics with sebosuppressive and anti-inflammatory effects are used as first line oral therapy.

Benzoyl peroxide is primarily a potent bacteriostatic agent with no reported resistance.[2] It is now the acne therapy used by the most consumers since it is available both by prescription and over-the-counter. Topical acne therapies are formulated for the teenage market since most patients are teens. This results in a higher incidence of adverse reactions in adults due to reduced sebum production.

Retinoids, alpha hydroxy acids and benzoyl peroxide increase photosensitivity, thus sunscreen use is recommended concurrently. Thus, safe, effective multifunctional and sufficiently emollient therapeutic products to treat acne without associated photosensitivity, such as Lytic Tx, are needed in the marketplace.

In this clinical study, Lytic Tx (LL) was superior to 10% benzoyl peroxide lotion (BP) in reducing forehead inflammatory papules with a 53.3% reduction after 12 weeks of twice-daily use, resulting in a trend toward statistical significance of $p<0.06$. LL also reduced the cheek inflammatory papules by 51.2%, which was statistically significant versus baseline ($p<0.002$), as was the resolution in forehead inflammatory papules. Adverse reactions by physician assessment revealed a trend toward statistical significance ($p<0.09$) of LL superiority in producing less erythema than BP.

At only six days, lesional erythema, size, and elevation were reduced by 41.1-47.8% by LL while BP reduced these parameters 20.2-27.2%, depending on facial site. The LL was statistically significantly superior to BP at all three facial sites (p=0.0001-0.004).

At completion of the 12-week study, LL was statistically significantly preferred by 72.7% of patients ($p<0.05$). Regarding adverse reactions, LL induced a significant decrease (p=0.05) in scaling and dryness as no LL patients suffered these changes while 45.5% of BP patients experienced scaling and dryness.

In conclusion, this study documents the safety and efficacy of the cosmeceutical product, Epionce Lytic Tx, as a valuable addition to the therapeutic armamentarium for adults suffering from acne vulgaris.

REFERENCES

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