Randomized Comparison of Tazarotene 0.1% Cream and Adapalene 0.3% Gel in Patients With at Least Moderate Facial Acne Vulgaris and Postinflammatory Hyperpigmentation (PIH)

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INTRODUCTION

- Use of topical acne treatment is to reduce the severity and postinflammatory pigmentation associated with acne. Therapy can prevent and/or improve the healing of acne lesions.
- Topical retinoids are frequently used for the treatment of acne because they effectively reduce the number of comedones and inflammatory acne. They are the preferred treatment for PIH that can occur with acne.1
- Adverse reactions can include the greatest risk to those young nucleated skin, such as keloid and PIH.
- The purpose of the clinical trial was to evaluate the efficacy and safety of tazarotene 0.1% cream compared to adapalene 0.3% gel in the treatment of moderate to severe facial acne vulgaris. We report here the results of an important secondary endpoint, which compared the severity and distribution of PIH in patients with detectable PIH at baseline.

STUDY DESIGN AND METHODS

- This was a double-blind, randomized, vehicle-controlled study.
- Patients were randomly assigned to receive tazarotene 0.1% gel or adapalene 0.3% gel. Patients were instructed to wash their face with a mild cleanser before applying the treatment to the face.
- The mean age was approximately 20 years, and the mean duration of acne was 10 years.
- The most common adverse events were burning and dryness.
- There was no statistically significant between-group difference in pruritus or dryness at any time during the study.
- The mean baseline PIH index (product of PIH severity and distribution) was slightly lower in the tazarotene group than in the adapalene group. The mean percentage reduction from baseline in the PIH index was 47.2% in patients treated with tazarotene 0.1% cream but was near zero in patients treated with adapalene 0.3% gel.
- The mean percentage reduction from baseline in PIH index was statistically significant in favor of tazarotene 0.1% cream treatment compared to adapalene 0.3% gel treatment (P = .011, 12 patients in the tazarotene group and 16 patients in the adapalene group). The mean percentage reduction from baseline in the PIH index was 47.2% in patients treated with tazarotene 0.1% cream but was near zero in patients treated with adapalene 0.3% gel. The mean percentage reduction from baseline in PIH index was statistically significant in favor of tazarotene 0.1% cream treatment compared to adapalene 0.3% gel treatment (P = .011, 12 patients in the tazarotene group and 16 patients in the adapalene group).

RESULTS

- There were no significant differences in PIH index between the two treatment groups at baseline.
- The mean percentage reduction from baseline in the PIH index was 47.2% in patients treated with tazarotene 0.1% cream but was near zero in patients treated with adapalene 0.3% gel.
- The mean percentage reduction from baseline in the PIH index was statistically significant in favor of tazarotene 0.1% cream treatment compared to adapalene 0.3% gel treatment (P = .011, 12 patients in the tazarotene group and 16 patients in the adapalene group).

CONCLUSIONS

- In this study, tazarotene 0.1% cream was significantly more effective than adapalene 0.3% gel in the treatment of PIH in patients with at least moderate acne.

REFERENCE


ACKNOWLEDGMENTS

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Mean Percentage Change From Baseline PIH Index

<table>
<thead>
<tr>
<th>Group</th>
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<th>Week 12 PIH Index</th>
<th>% Change From Baseline</th>
</tr>
</thead>
<tbody>
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<td>Tazarotene</td>
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<td>14.2</td>
<td>-53.3%</td>
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Safety

- Minor adverse events were reported in 8 of 28 patients (28.6%) treated with tazarotene 0.1% cream and in 10 of 28 patients (35.7%) treated with adapalene 0.3% gel.
- There were no serious adverse events reported in either group.
- No patient withdrew from the study due to an adverse event.

Necklace

- The mean percentage change from baseline in the PIH index was statistically significant in favor of tazarotene 0.1% cream treatment compared to adapalene 0.3% gel treatment (P = .011, 12 patients in the tazarotene group and 16 patients in the adapalene group).

DISCUSSION

- This study represents the first direct comparison between tazarotene 0.1% cream and adapalene 0.3% gel in acne vulgaris.
- The results of the present study are consistent with an earlier study that reported benefits of tazarotene 0.1% cream in PIH in darker-skinned patients.2
- The percentage reduction in the PIH index was significantly greater following treatment with tazarotene 0.1% cream compared with adapalene 0.3% gel (p = .011).
- The potential benefits of tazarotene in the treatment of PIH are well-documented. After 12 months of treatment with adapalene gel, the study did have some improvement in PIH in patients with severe PIH in a study but very little improvement in a study in patients with less than 50% PIH.
- Both tazarotene 0.1% cream and adapalene 0.3% gel were well-tolerated.