Efficacy and Tolerability of tazarotene foam 0.1% [Fabior®] Across Age, Gender, and Race
An Integrated Review of Two Phase III Trials

Rhonda Schreiber BSCN, MSSL; Kaytiana Crane, BS; Juhin Patel, PharmD

INTRODUCTION

Acne vulgaris is a complex disease with a diverse clinical presentation that affects males and females of all ages and ethnic backgrounds. Topical retinoids are considered to be part of the first line treatment protocol for both inflammatory and non-inflammatory acne. There are various formulations of tazarotene on the market, however tazarotene foam 0.1% [Fabior®] is an easy to apply, quickly absorbed, and elegant formulation that has been proven to have good tolerability and efficacy across a broad population of patients suffering from moderate to severe acne vulgaris. There has been very little comparative data published regarding efficacy and tolerability in sub-groups. The data presented here shows the utility of tazarotene foam 0.1% in clinical studies across age, gender, and race presenting with acne vulgaris.

OBJECTIVES

- Evaluate the efficacy and tolerability of tazarotene foam 0.1% [Fabior®] across age, gender, and race
- Present the favorable qualities of a foam formulation of tazarotene

METHODS

Study Designs

- Two multicenter, randomized, double-blind, vehicle controlled, parallel-group Phase III studies with 1485 patients who were randomized in a 1:1 ratio into two treatment groups tazarotene foam 0.1% (744) and vehicle foam (741)
- Study products were applied to the affected areas (face, trunk, or both) once daily for 12 weeks and no other medications were allowed
- Efficacy, safety and tolerability assessments were performed at baseline and weeks 2, 4, 8, and 12
- Efficacy was evaluated based on decrease in mean lesion counts and ISGA score from baseline to week 12 as assessed by investigators and tolerability was evaluated based on dryness, peeling, and erythema
- An ANCOVA model was used in an intent to treat (ITT) analysis to determine absolute change in total, inflammatory, and non-inflammatory lesion counts from baseline to week 12

Primary Endpoints

- The absolute change in lesion counts (total, inflammatory, and non-inflammatory) from baseline to week 12
- The proportion of participants who had a minimum 2-grade improvement in IGA score from baseline to week 12
- The proportion of participants who had an IGA score of 0 (clear) or 1 (almost clear) at week 12

REFERENCES & DISCLOSURES

Feldman, S. R., Werner, C. P., & Alio Saenz, A. B. (2013). The Efficacy and Tolerability of Tazarotene Foam, 0.1%, in the Treatment of Acne Vulgaris in 2 Multicenter, Randomized, Vehicle-Controlled, Double-Blind Studies. Journal of Drugs in Dermatology, 438-446.
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Zaenglein, A. L., Pathy, A. L., Schlosser, B. J., & et al. (2016). Guidelines for the Care and Management of Acne Vulgaris. Journal of the American Academy of Dermatology, 1-29.

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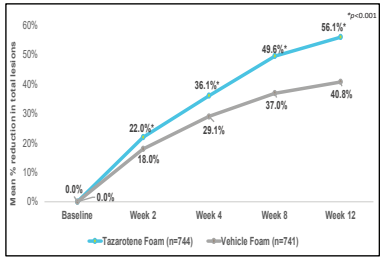
RESULTS

(Integrated ITT analysis set of the two studies)

There were no meaningful between-group differences in demographics or disease characteristics, with the exception of a statistically significant different proportion of non-white subjects in the tazarotene group (24% vs 21%, p-0.014).

Patient Demographics	n (%)
Males	729 (49)
Females	756 (51)
Age 12 - 17	860 (58)
Age 18 - 25	428 (29)
Age 26 - 35	143 (10)
Age 36 - 45	54 (4)
Hispanic or Latino	260 (18)
Not Hispanic or Latino	1225 (82)
Caucasian	1150 (77)
African American	219 (15)
Asian	63 (4)
Other	53 (4)
Baseline ISGA 3	1192 (80)
Baseline ISGA 4	293 (20)

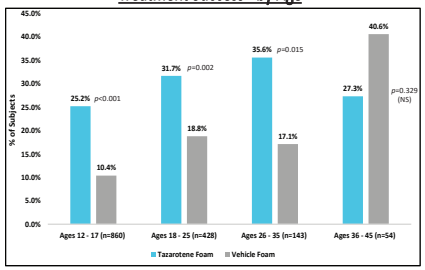
Mean % Reduction in Total Lesions vs. Baseline Over Time



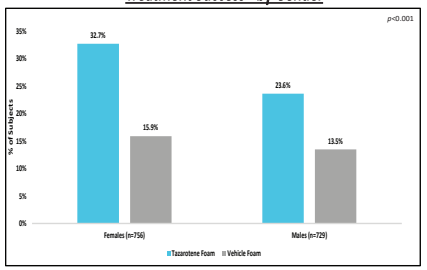
- Mean reduction in non-inflammatory lesions was statistically significant at every visit (Weeks 2, 4, 8, and 12).
- Mean reduction in inflammatory lesions was statistically significant at Weeks 8 and 12

Efficacy with tazarotene foam 0.1% [Fabior®] was statistically significant and similar across age, gender, and race groups studied versus vehicle foam with the exception of the group aged 36 - 45. The foam vehicle received favorable quality ratings in questionnaires completed by patients.

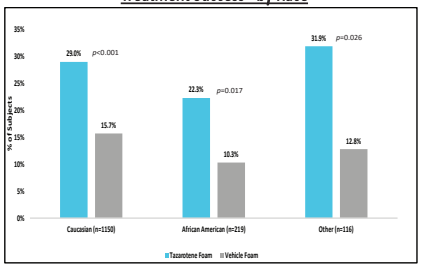
Treatment Success* by Age



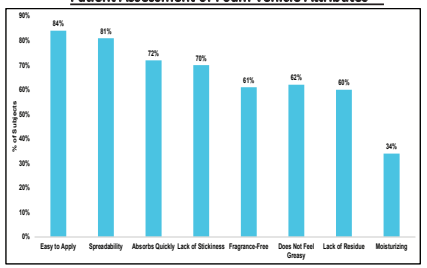
Treatment Success* by Gender



Treatment Success* by Race



Patient Assessment of Foam Vehicle Attributes**



*Treatment success was defined as a minimum 2-grade improvement in IGA score and a score of 0 or 1 at study end (week 12)
**Top 2 Box Score (Categories: Excellent and Good)

While subjects in the tazarotene foam 0.1% [Fabior®] group experienced more adverse reactions initially vs the vehicle group, these peaked at week 2 and gradually reduced with continued use. Tolerability in the tazarotene group was similar across age, gender, and race groups studied.

	Tazarotene Foam (n=744)	Vehicle Foam (n=741)
Patients with any ARs	**22%**	**3%**
Application site irritation	14%	1%
Application site dryness	7%	1%
Application site erythema	6%	<1%
Application site exfoliation	6%	<1%
Application site pain	1%	0
Application site photosensitivity (including sunburn)	1%	<1%
Application site pruritis	1%	<1%
Application site dermatitis	1%	<1%

Adverse reactions in ≥1% of patients	Tazarotene Foam (n=744)
Males (n=729)	22%
Females (n=756)	22%
Age 12 - 17 (n=860)	22%
Age 18 - 25 (n=428)	19%
Age 26 - 35 (n=143)	29%
Age 36 - 45 (n=54)	27%
Caucasian (n=1150)	21%
African American (n=219)	24%
Other (n=116)	23%

Less than 3% of patients discontinued use of tazarotene foam due to local skin reactions

CONCLUSIONS

While the overall efficacy of tazarotene foam 0.1% [Fabior®] has been well established, there has been little emphasis on the breakdown across age, gender, and race. The data presented here has been extracted from the tazarotene foam 0.1% [Fabior®] pivotal trials and shows clear efficacy in all groups barring the age group 36-45, which may have been affected by the small population size and/or disease characteristics in this demographic. The patient assessments, although blinded as to active or vehicle, showed that the proprietary foam technology used is positively rated in attributes that may affect patient adherence. The adverse reaction data reinforces that tazarotene foam 0.1% [Fabior®] is similarly well tolerated across age, gender, and race. The data presented in this poster confirms that tazarotene foam 0.1% [Fabior®] has a strong efficacy and tolerability profile across a broad demographic population.