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Effects of Tazarotene 0.045% Lotion on Quality of Life in Patients With Moderate-to-Severe Acne

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ABSTRACT

Background: In two phase 3 trials (NCT03168334, NCT03168321), participants with moderate-to-severe acne had significant symptom improvements after 12 weeks of treatment with tazarotene 0.045% lotion. Given the negative psychosocial effects of acne on patients, data from these studies were analyzed to evaluate quality of life in various subgroups.

Methods: Mean changes from baseline to week 12 in Acne-Specific Quality of Life (Acne-QoL) domain and item scores were analyzed in the pooled intent-to-treat (ITT) population and in participants who were categorized as follows: Evaluator's Global Severity Score (EGSS) score=3 ("moderate") or score=4 ("severe") at baseline; Acne-QoL total score ≥60 (better quality of life) or <60 (worse quality of life), based on the median score at baseline. Exploratory analyses based on sex and race were also performed.

Results: In the pooled ITT population (N=1614), Acne-QoL improvements were greater with tazarotene 0.045% lotion versus vehicle lotion, with significant differences in the acne symptoms domain, 3 acne symptom items, 2 self-perception items, 1 role-emotional item, and 1 role-social item (all $P<0.05$). Acne-QoL improvements with tazarotene 0.045% lotion were comparable between the EGSS subgroups. However, participants who self-reported worse quality of life at baseline (Acne-QoL total score <60) had notably greater improvements than those with better quality of life. Female and Black participants had greater Acne-QoL improvements than male and White participants.

Conclusions: Participants treated with tazarotene 0.045% lotion had significant quality-of-life improvements. Clinician-rated symptom severity appeared to have a smaller effect on Acne-QoL outcomes than participants' own assessments of quality of life.

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INTRODUCTION

Topical retinoids are a mainstay for the treatment of *acne vulgaris* (acne), a prevalent skin condition that affects an estimated 40–50 million people in the United States.[1,2] However, tolerability issues associated with retinoids (eg, skin irritation or dryness) can make it difficult for patients to adhere to treatment.

Tazarotene 0.045% lotion, which is approved for the topical treatment of acne in patients 9 years and older,[3] was developed using a new polymeric emulsion technology that encapsulates tazarotene and hydrating/moisturizing ingredients within an oil-in-water emulsion, separated by a three-dimensional mesh matrix.[4] This easily spreadable and easy-to-use formulation allows for uniform and optimal delivery of tazarotene on the skin at lower concentrations relative to conventional formulations, as demonstrated in a phase 2 trial in which tazarotene 0.045% lotion showed comparable efficacy to tazarotene 0.1% cream but with fewer adverse events.[5]

In two phase 3 trials that included patients with moderate-

to-severe acne, once-daily treatment with tazarotene 0.045% lotion significantly reduced inflammatory and noninflammatory lesions relative to vehicle lotion.[6] Both studies included the 19-item Acne-Specific Quality of Life questionnaire (Acne-QoL),[7] which showed improvements in patient-reported quality of life with tazarotene 0.045% lotion after 12 weeks of treatment. Given the psychosocial impact of acne on quality of life,[8,9] post hoc analyses of the phase 3 data were conducted to evaluate which aspects of the Acne-QoL were of greatest concern to study participants and the effects of tazarotene 0.045% on those domains.

METHODS

Study Design

Detailed methods for the two phase 3 studies (NCT03168334 and NCT03168321) have been reported.[6] In brief, both were multicenter, double-blind, randomized, vehicle-controlled, parallel group phase 3 studies. Key eligibility criteria included: male or female, age 9 years or older; moderate or severe acne (Evaluator's Global Severity Score [EGSS] of 3 or 4); 20–50 facial inflammatory lesions (papules, pustules, and nodules); 25–100 noninflammatory lesions (open and closed comedones); and ≤2 facial nodules. Eligible patients were randomized 1:1 to receive tazarotene 0.045% lotion or vehicle, applied once-daily to the face for 12 weeks. CeraVe® hydrating cleanser and moisturizing lotion (L'Oreal, NY) were provided as an option for optimal cleansing and moisturization of the skin. The study protocol was approved by institutional review boards or ethics committees at all investigational sites. Studies were carried out in accordance with principles of Good Clinical Practice (GCP) and the Declaration of Helsinki. All patients or their legal guardians provided written informed consent.

Quality of Life Assessment

Quality of life was assessed using the Acne-QoL, which includes 19 items in 4 different domains: self-perception (items 1, 2, 3, 6, and 10); role-emotional (items 4, 5, 7, 8, and 9), role-social (items 11, 12, 13, and 14), acne symptoms (items 15, 16, 17, 18, and 19). For each item, participants were asked to rate the degree to which acne has affected them with a score of 0 ("extremely") to 6 ("not at all"). Higher scores indicated better quality of life, and a positive score change indicated improvement.

Post Hoc Analyses

All analyses were based on the pooled intent-to-treat (ITT) population, defined as randomized participants who were provided with study drug. Mean changes from baseline to week 12 in Acne-QoL domain and item scores were analyzed in the pooled ITT population using an analysis of covariance (ANCOVA) with treatment group as a factor and baseline score as a covariate; $P<0.05$ indicated statistical significance between tazarotene 0.045% lotion and vehicle lotion. The ANCOVA model was also used to investigate Acne-QoL outcomes in participants categorized by EGSS score at baseline (score of 3 [moderate acne symptoms] or 4 [severe acne symptoms]) and by median Acne-QoL total score at baseline in the pooled ITT population (score ≥60 [better quality of life] or <60 [worse quality of life]).

Because differences in sex and race had been observed between the EGSS subgroups and between the Acne-QoL subgroups, exploratory analyses were conducted in demographic subgroups. Mean changes from baseline to week 12 in Acne-QoL domain scores were analyzed descriptively in tazarotene-treated participants categorized by sex (male or female) and by race (Black or White).

RESULTS

Participants

In the pooled ITT population (N=1614), mean Acne-QoL domain scores at baseline were similar between participants who received tazarotene 0.045% and those who received vehicle lotion (Table 1). Relative to the subgroup with moderate acne symptoms at baseline (EGSS score=3; n=1467), the subgroup with severe acne symptoms (EGSS score=4; n=147) had fewer female participants (52.4% vs 67.3%) and Black participants (8.2% vs 17.0%). This trend was reversed in Acne-QoL subgroups. Relative to the subgroup with better patient-reported quality of life at baseline (total score ≥60; n=819), the subgroup with worse quality of life (total score <60; n=791) had more female participants (80.5% vs 52.0%) and Black participants (19.1% vs 13.4%). Mean age was comparable between EGSS subgroups (20.5 vs 19.8 years [score=3 vs score=4]) and between Acne-QoL subgroups (22.5 vs 18.6 years [score <60 vs score ≥60]).

Quality of Life Improvements

In the pooled ITT population, mean improvements from baseline to week 12 in Acne-QoL scores (domains and items) were generally greater in participants treated with tazarotene 0.045% lotion than in those who received vehicle lotion (Figure 1). Significant differences between tazarotene 0.045% lotion and vehicle lotion ($P<0.05$) were found as follows: the acne symptoms domain; 3 items within the acne symptom domain (bumps on face, bumps full of pus, concerned with scarring); 2 items within the self-perception domain (feel embarrassed, dissatisfied with appearance); 1 item within the role-emotional domain (feel upset), and 1 item within the role-social domain (interacting with opposite sex or same sex if applicable).

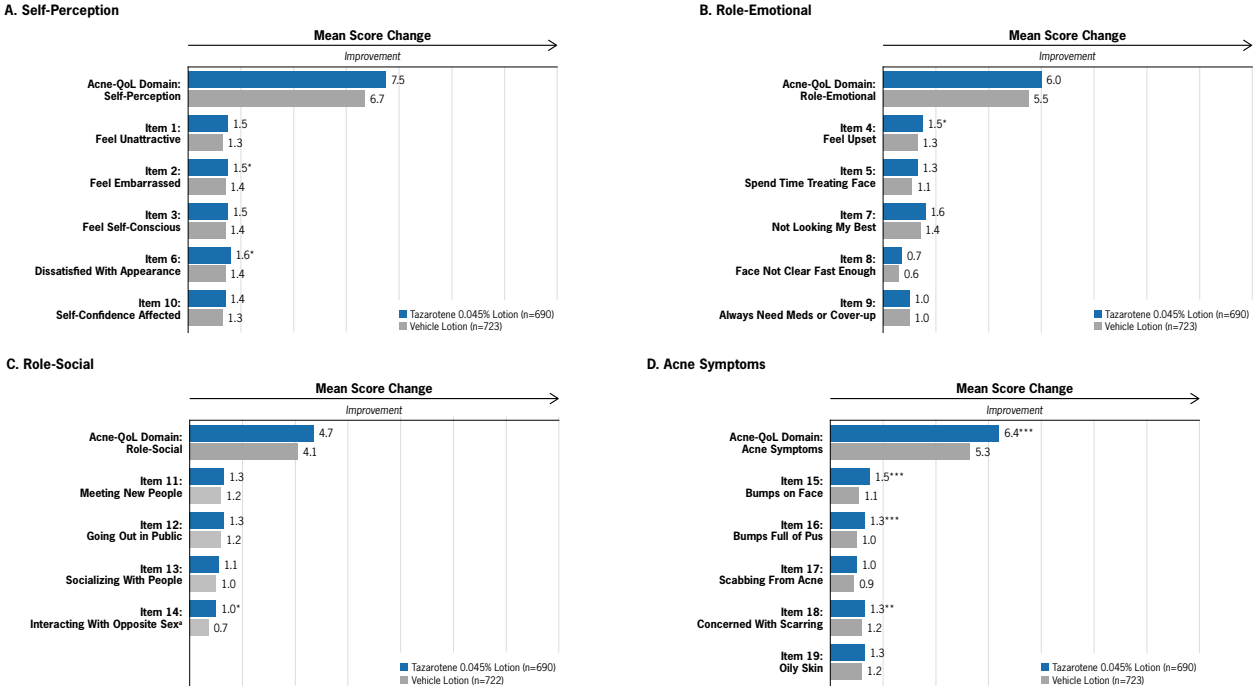
In the EGSS subgroups, the magnitude of Acne-QoL improvements with tazarotene 0.045% lotion was generally comparable between participants with moderate symptoms at baseline (score=3) and those with severe symptoms (score=4; Figure 2). In the EGSS score=3 subgroup, statistical significance for tazarotene 0.045% lotion was found in the acne symptoms domain and in 3 acne symptoms items (bumps on face, bumps full of pus, concerned with scarring; $P<0.05$ versus vehicle lotion;

TABLE 1.

Baseline Acne-QoL Scores and Severity Subgroups (ITT population, pooled)		
	Tazarotene 0.045% Lotion	Vehicle Lotion
Acne-QoL domains, ITT, mean score (SD)[a]	n=796	n=814[b]
Self-perception	19.9 (8.9)	20.2 (8.7)
Role-emotional	20.6 (8.3)	20.5 (8.3)
Role-social	19.2 (7.3)	19.3 (7.1)
Acne symptoms	19.3 (5.7)	19.4 (5.7)
EGSS subgroups, n (%)	n=799	n=815
Score=3 (moderate acne symptoms)	726 (90.9)	741 (90.9)
Female	490 (67.5)	497 (67.1)
Black	117 (16.1)	133 (17.9)
Score=4 (severe acne symptoms)	73 (9.1)	74 (9.1)
Female	41 (56.2)	36 (48.6)
Black	8 (11.0)	4 (5.4)
Acne-QoL subgroups, n (%)[c]	n=796	n=814
Total score ≥60 (better quality of life)	389 (48.9)	430 (52.9)
Female	198 (50.9)	228 (53.0)
Black	46 (11.8)	64 (14.9)
EGSS score=4	29 (7.5)	31 (7.2)
Total score <60 (worse quality of life)	407 (51.1)	384 (47.2)
Female	333 (81.8)	304 (79.2)
Black	78 (19.2)	73 (19.0)
EGSS score=4	44 (10.8)	43 (11.2)

[a]Score range is 0–30 for self-perception, role-emotional, and acne symptoms; range is 0–24 for role-social.
[b]n=813 for role-social.
[c]Based on the median Acne-QoL score in the pooled ITT population. Total score range is 0–114.
Acne-QoL, Acne-Specific Quality of Life questionnaire; EGSS, Evaluator's Global Severity Score; ITT, intent to treat; SD, standard deviation.

FIGURE 1. Mean changes from baseline in Acne-QoL scores (ITT population, pooled).



*$P<0.05$; **$P<0.01$; ***$P<0.001$ for tazarotene 0.045% lotion versus vehicle lotion
[a]Or same sex if applicable.
Acne-QoL, Acne-Specific Quality of Life questionnaire; ITT, intent to treat.

TABLE 2.

Effects of Tazarotene 0.045% Lotion on Acne-QoL Domain Scores in Demographic Subgroups (ITT population, pooled)

	At Baseline		At Week 12			
Acne-QoL Domain Subgroup	n	Mean Score (SD)	n	Mean Score (SD)	n	Mean Change (SD)
Self-perception						
Male	265	24.9 (8.2)	243	29.4 (5.9)	241	4.3 (6.7)
Female	531	17.4 (8.2)	449	26.9 (7.1)	449	9.2 (8.2)
White	589	20.4 (8.9)	511	28.0 (6.7)	509	7.2 (7.7)
Black	124	17.5 (8.8)	102	27.8 (7.3)	102	10.3 (9.7)
Role-emotional						
Male	265	25.2 (7.6)	243	28.2 (6.1)	241	2.9 (7.1)
Female	531	18.3 (7.6)	449	26.0 (7.6)	449	7.6 (8.5)
White	589	21.0 (8.3)	511	27.1 (6.9)	509	5.9 (7.9)
Black	124	18.2 (7.9)	102	26.8 (7.6)	102	8.5 (10.0)
Role-social						
Male	265	22.0 (6.7)	243	25.1 (4.6)	241	3.0 (5.7)
Female	531	17.8 (7.2)	449	23.7 (5.8)	449	5.6 (6.9)
White	589	19.7 (7.1)	511	24.5 (5.2)	509	4.4 (6.2)
Black	124	16.8 (7.5)	102	23.8 (5.9)	102	7.2 (8.0)
Acne symptoms						
Male	265	21.4 (5.5)	243	26.6 (4.7)	241	5.0 (5.8)
Female	531	18.3 (5.5)	449	25.7 (5.5)	449	7.1 (6.4)
White	589	19.7 (5.5)	511	26.2 (5.1)	509	6.2 (5.9)
Black	124	18.0 (6.4)	102	26.6 (5.3)	102	8.4 (7.8)

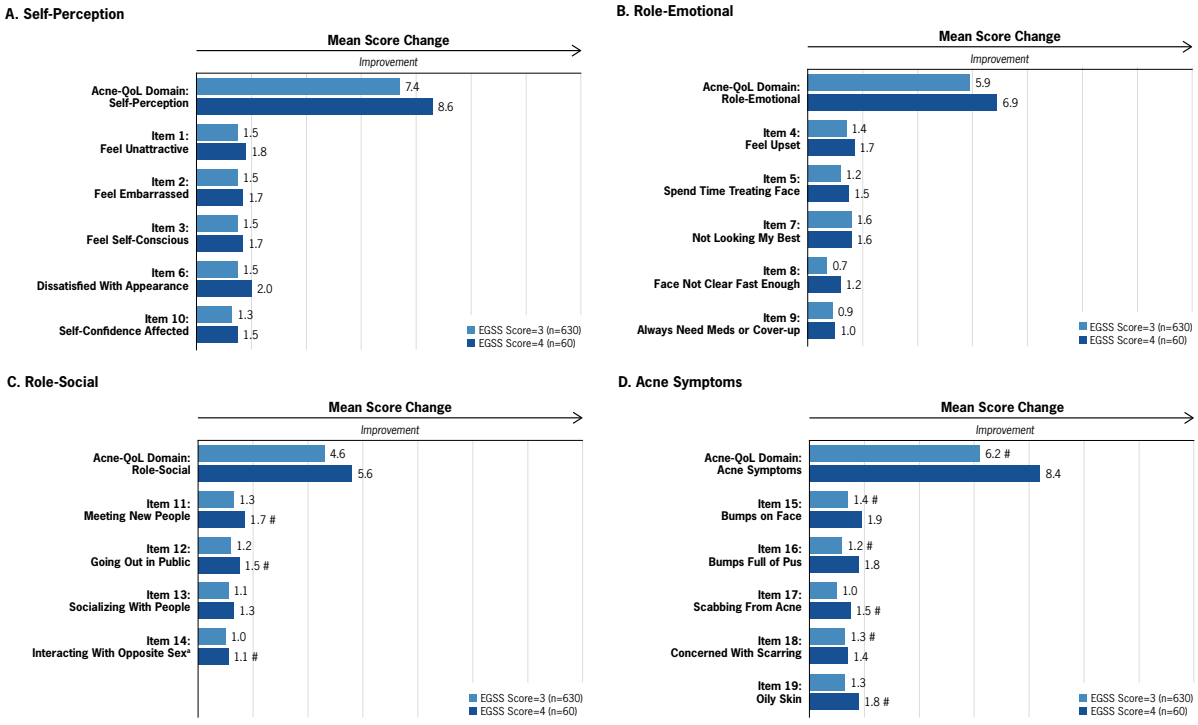
Acne-QoL, Acne-Specific Quality of Life questionnaire; ITT, intent to treat; SD, standard deviation.

data not shown for vehicle). In the EGSS score=4 subgroup, the difference between tazarotene 0.045% lotion and vehicle lotion was not statistically significant for the acne symptoms domain; however, significance was found in 2 acne symptom items (scabbing from acne and oily skin; $P<0.05$). Statistical significance in the EGSS score=4 subgroup was also found in 3 role-social items (meeting new people, going out in public, and interacting with the opposite sex or same sex if applicable; $P<0.05$).

Mean Acne-QoL improvements from baseline to week 12 were markedly greater in participants who self-reported worse quality of life at baseline (total score <60) than in participants with better quality of life (total score ≥60; Figure 3). In the Acne-QoL score ≥60 subgroup, statistical significance for tazarotene 0.045% lotion was found in the acne symptoms domain and in 2 acne symptoms items (bumps on face, bumps full of pus; $P<0.05$ vs vehicle lotion; data not shown for vehicle). In the Acne-QoL score <60 subgroup, statistical significance was also found in the acne symptoms domain, along with 3 acne symptom items (bumps on face, bumps full of pus, concerned with scarring; $P<0.05$). This subgroup with worse quality of life at baseline also had significantly greater mean improvements with tazarotene 0.045% lotion versus vehicle lotion in 1 role-emotional item (not looking my best) and 2 role-social items (meeting new people and interacting with the opposite sex or same sex if applicable; $P<0.05$).

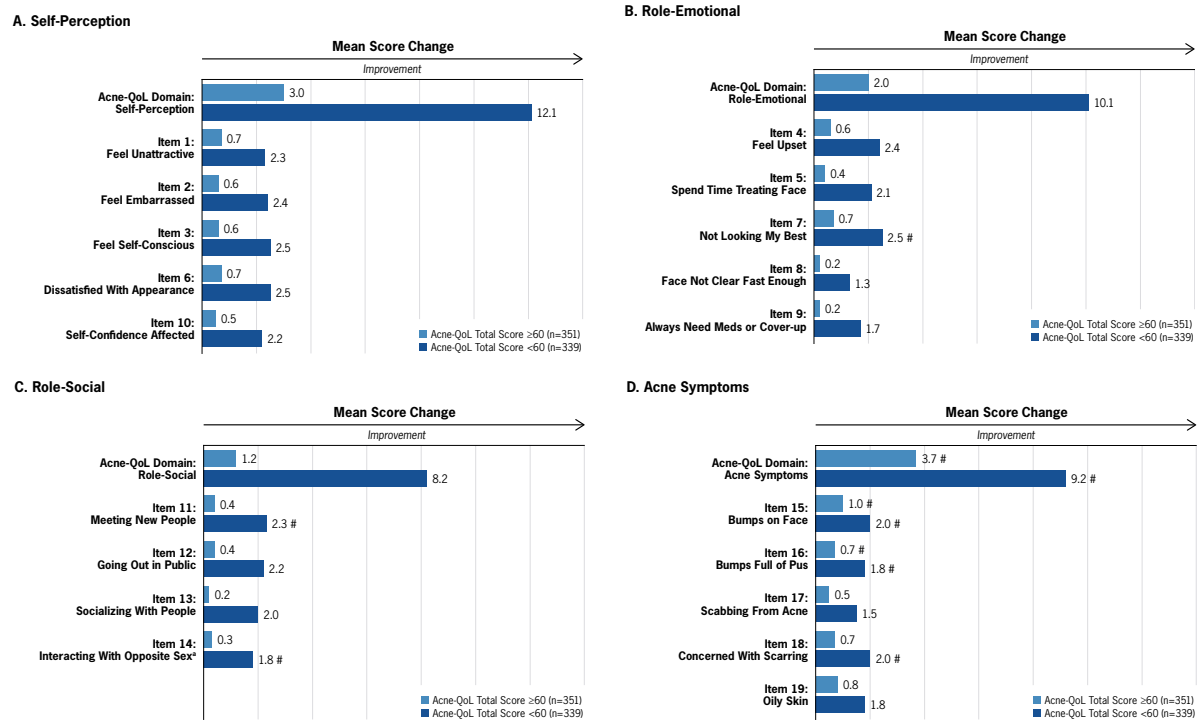
Exploratory analyses indicated that mean Acne-QoL domain scores at baseline were lower (worse) in female versus male participants, as well as in Black versus White participants (Table 2). However, mean improvements in female and Black participants were relatively greater than those in male and White participants, resulting in comparable Acne-QoL scores at week 12.

FIGURE 2. Mean changes from baseline in Acne-QoL scores with tazarotene 0.045% in EGSS subgroups (ITT population, pooled).



[#]*P*<0.05 for tazarotene 0.045% lotion versus vehicle lotion (data not shown for vehicle)
[a]Or same sex if applicable.
Acne-QoL, Acne-Specific Quality of Life questionnaire; EGSS, Evaluator's Global Severity Score; ITT, intent to treat.

FIGURE 3. Mean changes from baseline in Acne-QoL scores with tazarotene 0.045% lotion in Acne-QoL subgroups (ITT population, pooled).



[#]*P*<0.05 for tazarotene 0.045% lotion versus vehicle lotion (data not shown for vehicle).
[a]Or same sex if applicable.
Acne-QoL, Acne-Specific Quality of Life questionnaire; ITT, intent to treat.

DISCUSSION

Pooled data from two phase 3 studies indicate that participants with moderate-to-severe acne experienced improved quality-of-life with tazarotene 0.045% lotion, applied once daily for 12 weeks. In the pooled population, significant differences between tazarotene 0.045% lotion and vehicle lotion were found in the acne symptoms domain of the Acne-QoL, along with 3 items from that domain (bumps on face, bumps full of pus, and concerned with scarring). These results were consistent with the previously reported clinician-rated symptom assessments in the pooled population, which showed significantly greater reductions from baseline to week 12 with tazarotene 0.045% in inflammatory lesions (-57.9% vs -47.8% [tazarotene 0.045% vs vehicle]; $P<0.001$) and noninflammatory lesions (-56.0% vs -42.0%; $P<0.001$).[10]

To understand the potential effects of symptom severity on quality of life, Acne-QoL outcomes were analyzed in participants who had an EGSS score=3 ("moderate") or score=4 ("severe") at baseline. In participants treated with tazarotene 0.045% lotion, the magnitude of Acne-QoL score improvements was comparable between EGSS subgroups. However, statistical comparisons between tazarotene 0.045% lotion and vehicle lotion within each subgroup revealed some potential differences. The EGSS score=4 subgroup had significantly greater improvements with tazarotene 0.045% lotion ($P<0.05$ versus vehicle lotion) in 3 role-social items (meeting new people, going out in public, and interacting with the opposite sex or same sex if applicable), none of which were statistically significant in the EGSS score=3 subgroup. Mean improvements for the acne symptoms domain was significantly greater for tazarotene 0.045% lotion in the EGSS score=3 subgroup ($P<0.05$ vs vehicle lotion) but not the EGSS score=4 subgroup. Moreover, acne symptoms items that were significant the EGSS score=3 subgroup (bumps on face, bumps full of pus, concerned with scarring) were different from those that were significant in the EGSS score=4 subgroup (scabbing from acne, oily skin). Together, these results suggest that patients with either moderate or severe acne symptoms will likely experience improved quality of life with tazarotene 0.045% lotion. However, patients with more severe symptoms may have greater concerns about social situations and may differ as to which acne symptoms have negative effects on quality of life than those with moderate symptoms.

It was expected that segregating the pooled ITT population by the median Acne-QoL total score at baseline would show greater improvements in the subgroup with worse quality of life (total score <60). However, the magnitude of difference between these participants and those with better quality of life (total score ≥60) was somewhat surprising. No statistical testing was conducted between the Acne-QoL subgroups, but mean improvements in all 4 domains were markedly different between subgroups (score <60 vs ≥60): self-perception (12.1 vs 3.0); role-emotional (10.1 vs 2.0); role-social (8.2 vs 1.2); acne symptoms (9.2 vs 3.7; Figure 3). Some participants in the Acne-QoL score ≥60 subgroup might have experienced a ceiling effect (ie, domain score improved to the maximum possible score), but mean scores at week 12 in this subgroup were below the maximum possible score in all 4 domains (mean, maximum): self-perception (25.5, 30); role-emotional (24.3, 30); role-social (22.1, 24); acne symptoms (22.0, 30); data for mean scores at week 12 not shown in figures.

Both Acne-QoL subgroups had significantly greater improvements with tazarotene 0.045% lotion in the acne symptoms domain and in 2 acne symptoms items (bumps on face, bumps full of pus; $P<0.05$ vs vehicle lotion). However, the Acne-QoL score <60 subgroup had significant improvements with tazarotene 0.045% lotion in 4 additional items (not looking my best, meeting new people, interacting with the opposite sex, concerned with scarring) that were not significant in the Acne-QoL score ≥60 subgroup. In conjunction with the Acne-QoL domain results, these findings strongly suggest that in patients who report poor quality of life due to acne, evaluations should not be limited to clinical assessments of lesions and skin condition. For these patients, issues of social and emotional wellbeing may be equally important, and it is critical to understand whether improvements in the physical symptoms of acne are coinciding with quality-of-life improvements.

Other studies have shown the negative impact of acne on quality life in female and non-White patients.[11-13] Therefore, demographic factors may also need to be considered when assessing quality of life in patients with moderate-to-severe acne. At baseline in participants who were randomized to tazarotene 0.045%, the Acne-QoL subgroup with worse quality of life (score <60) had a higher percentage of participants who were female or Black versus those with better quality of life (score ≥60): female (81.8% vs 50.9%); Black (19.2% vs 11.8%). In addition, results from the exploratory analyses indicated greater improvements for females versus males in all 4 Acne-QoL domains, with the largest differences in self-perception (9.2 vs 4.3) and role-emotional (7.6 vs 2.9). Black participants also had greater mean improvements versus White participants in all 4 domains, particularly in the domains of self-perception (10.3 vs 7.2) and role-social (7.2 vs 4.4). Given the clinical improvements that have been demonstrated in both of these subgroups,[14,15] tazarotene 0.045% lotion may be an attractive treatment option for female and/or Black patients who express negative feelings about their appearance, self-confidence, or ability/willingness to socialize.

These post hoc analyses are limited by the study designs. Acne-QoL was not a primary endpoint in either study, with no Acne-QoL criteria required for eligibility. In addition, the studies were limited to patients with moderate-to-severe acne and therefore, the results of this post hoc analysis may not be gen-

eralizable to patients with mild acne. Moreover, since <10% of participants had an EGSS rating of "severe" at baseline, results from the EGSS score=4 subgroup should be interpreted with some caution.

CONCLUSION

Data pooled from two phase 3 studies indicate that patients with moderate-to-severe acne experienced quality-of-life improvements after 12 weeks of treatment with tazarotene 0.045% lotion. Acne-QoL outcomes appeared to be less affected by clinician-rated acne severity than by participants' own assessments of their quality of life, which tended to be worse in female and Black participants. However, the subgroup with worse quality of life at baseline also had the largest mean Acne-QoL improvements, highlighting the importance of asking patients how acne affects their everyday lives.

DISCLOSURES

Leon Kircik, Edward Lain, and Michael Gold have all acted as investigator, advisor, speaker, and consultant for Ortho Dermatologics. Bruce Katz has nothing to disclose. Hilary Baldwin has served as an advisor, investigator, and on speakers' bureaus for Almiral, Cassiopea, Foamix, Galderma, Ortho Dermatologics, Sol Gel, and Sun Pharmaceuticals. Eric Guenin is an employee of Ortho Dermatologics and may hold stock and/or stock options in its parent company. Anya Loncaric and Radhakrishnan Pillai are employees of Bausch Health US, LLC and may hold stock and/or stock options in its parent company.

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