

Acne-Related Quality of Life: Efficacy of a Novel Tretinoin 0.05% Lotion in Male and Female Patients with Moderate-to-Severe Disease

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SYNOPSIS

- Quality of life (QoL) in patients with acne has been shown to correlate more strongly with patient-reported severity than physician-reported severity, suggesting that patient perception may be important to consider during acne treatment¹
- Compared with other dermatologic conditions, acne is associated with greater negative psychosocial impacts, particularly with feelings of despair and distress²
- Acne-related QoL has been shown to be worse in women, possibly because of differences in perceptions regarding self-appearance and cosmetic concerns²
- The first lotion formulation of tretinoin, developed by utilizing novel polymeric emulsion technology,³ has been evaluated in two phase 3 studies that included male and female patients with moderate-to-severe acne (NCT02932306, NCT02965456)⁴

OBJECTIVE

- To determine potential improvements in QoL with tretinoin 0.05% lotion and assess potential gender differences in these outcomes in a post hoc analysis of the pooled data from these two phase 3 studies

METHODS

- Data were pooled from two multicenter, randomized, double-blind, vehicle-controlled studies in which participants were randomized (1:1) to receive tretinoin 0.05% lotion or vehicle, once-daily for 12 weeks
 - During these studies, CeraVe[®] hydrating cleanser and CeraVe[®] moisturizing lotion (L'Oreal, NY) were provided as needed for optimal moisturization/cleaning of the skin
- QoL was assessed using the validated Acne-QoL questionnaire in 4 different domains (self-perception, role-emotional, role-social, acne symptoms)
- In addition, participants completed a Patient Satisfaction Survey (PSS) at baseline and Week 12 to assess satisfaction with previous acne therapy using a 10-point scale, where 10=most satisfied

RESULTS

- The pooled population included 1640 participants (tretinoin, n=819; vehicle, n=821), 909 (55.4%) of whom were female; participants' ages ranged from 9 to 58 years
- Mean PSS scores at baseline were 4.7 and 4.6 for tretinoin 0.05% lotion and vehicle, respectively, indicating similar satisfaction with prior acne treatment
 - At Week 12, satisfaction was significantly greater with tretinoin 0.05% lotion vs vehicle (7.2 vs 6.6, $P<0.001$)
- Acne-QoL scores at baseline indicated impairment in all domains (Figure 1), with lower (worse) mean scores in female participants as follows: self-perception (2.6 vs 3.5 for males); role-emotional (2.6 vs 3.4); role-social (3.5 vs 4.1); acne symptoms (2.7 vs 3.2; Figure 2)
 - Mean scores for all domains increased (improved) significantly by Week 12 ($P<0.001$) in the overall population
 - While domain scores in the male participants remained significantly greater compared to those in female participants, changes from baseline in the female participants were much greater (Figures 2 and 3)
 - At Week 12, mean scores for self-perception, role-emotional, role-social and acne symptoms were 4.3 (65% improvement), 4.2 (62%), 4.8 (37%), and 4.1 (52%) in females, compared to 4.8 (37%), 4.6 (35%), 5.2 (27%), and 4.4 (38%) in males (Figure 3)

FIGURE 1: Average Acne-QoL Domain Scores at Baseline for all Participants in the Tretinoin 0.05% Lotion or Vehicle Treatment Groups (ITT Population; Pooled Data)

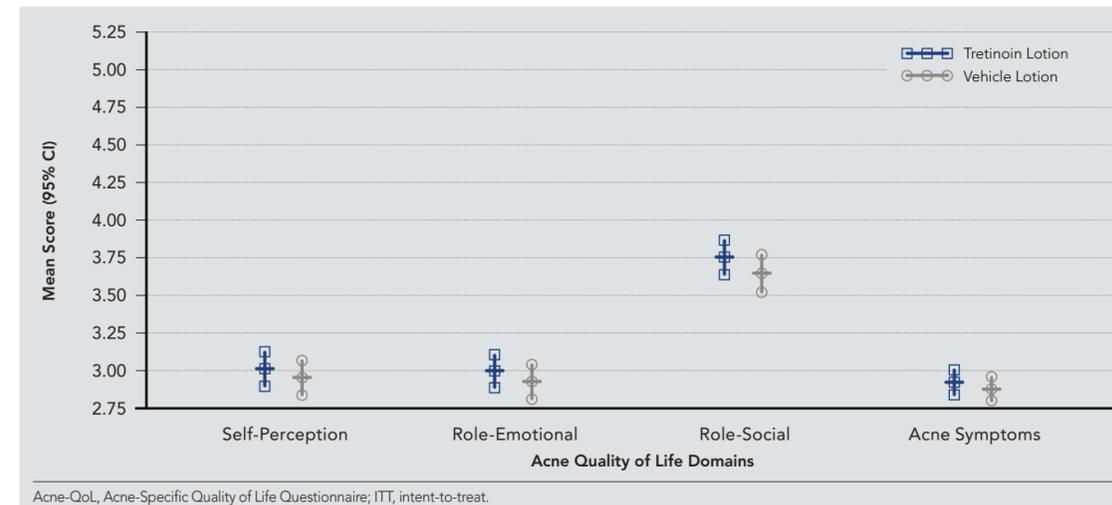


FIGURE 2: Average Acne-QoL Domain Scores at Baseline for Males and Females in the Tretinoin 0.05% Lotion Group (ITT Population; Pooled Data)



CONCLUSION

- Tretinoin 0.05% lotion was significantly more effective than its vehicle in achieving improvements in QoL, especially in female participants
- Improvements seen in each QoL domain were mirrored by a significant improvement in participant satisfaction

REFERENCES

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AUTHOR DISCLOSURES

Dr. Sharleen St. Surin-Lord is a paid Speaker for Galderma and Pfizer, and a paid consultant for Bausch Health.
 Dr. William Philip Werschler has served as an investigator for Ortho Dermatologics.
 Dr. Eric Guenin is an employee of Ortho Dermatologics.

FIGURE 3: Average Acne-QoL Domain Scores at Week 12 for Males and Females in the Tretinoin 0.05% Lotion Group (ITT Population; Pooled Data)

