Patient Concerns and Treatment Satisfaction in Patients Treated With Azelaic Acid Foam for Rosacea

Williamson T[1]; Cameron J[1]; McLeod K[2]; Turner B[2]; Quillen A[2]; LaRose A[1]
Bayer HealthCare Pharmaceuticals Inc., Whippany, NJ, USA; [2]Xcenda, Palm Harbor, FL, USA

SYNOPSIS

- Rosacea is a common, chronic, inflammatory skin disorder affecting the convexities of the central face and can be categorized into 4 main subtypes: erythematotelangiectatic, papulopustular, phymatous, and ocular.[1,2]
- Regardless of subtype, non-pharmacologic or behavioral interventions are useful for the management of skin flares; however, for patients with mild to moderate cases, especially of papulopustular rosacea, topical therapies are usually used as first-line therapy.[1,3]
- The use of topical medications, including metronidazole and azelaic acid gel, has shown efficacy in clinical trials vs placebo in reducing inflammatory lesion counts in patients with papulopustular rosacea; however, these treatments were associated with higher incidences of post-application skin discomfort, as patients reported burning, itching, and stinging sensations.[1,2,4-6]
- Formulations like azelaic acid foam have the potential to offer improvements over the side effect profiles of these treatment options.

OBJECTIVE

- This study aimed to survey patients with rosacea about their concerns, treatment satisfaction, and quality of life (QoL) associated with their azelaic acid foam treatment.

METHODS

STUDY DESIGN

- The study utilized a non-interventional, prospective, observational design and enrolled participants via email in collaboration with a patient support program, the Rosacea Concierge Program.
- A cross-sectional design was used to assess key patient concerns, treatment satisfaction, and QoL related to azelaic acid foam for rosacea.

SAMPLE SELECTION

- 2,150 patients from the United States (US) who were enrolled in the Rosacea Concierge Program were invited to participate in the study.
- All inclusion and exclusion criteria were patient reported.
- Inclusion criteria:
  - At least 18 years of age
  - Diagnosis of rosacea by a medical professional
  - Currently using azelaic acid foam as topical monotherapy for rosacea
  - Willing and able to provide voluntary, informed consent to participate in the study
- Exclusion criteria:
  - Use of any other topical treatment for rosacea at the time of enrollment

STUDY ENDPOINTS

- Eligible, consenting patients completed a 1-time survey assessing demographics, clinical characteristics (ie, rosacea-relevant comorbidities and complications), treatment history, and adverse events.
- **Table 1** includes a brief overview of the 3 questionnaires included in the survey.

Table 1. Questionnaires Included in the Patient Survey

Questionnaire	Details
Rosacea Treatment Preference Questionnaire	• 9-question survey composed of both aided and unaided questions. • Assesses patient self-reported rosacea subtype and severity and evaluates drug characteristics that contribute to patient satisfaction/dissatisfaction and treatment decisions with rosacea topical treatments. • Respondents list up to 5 concerns as well as up to 5 side effects with their current topical rosacea treatment experienced in the past 4 weeks and rate the importance of each reported concern or side effect. • Respondents rank a list of pre-identified issues with topical rosacea treatment (eg, efficacy, cost, texture, dryness, etc) on a scale of importance from 0 to 10 (with 0 = not at all important; 10 = extremely important) in terms of how important the issue is when they consider using a new topical rosacea treatment.
SATMED-Q	• 17-question, validated, multidimensional, generic questionnaire designed for use in patients with any chronic disease treated with medicines measuring treatment satisfaction. • Composed of 6 domains: – Undesirable side effects (3 questions) – Efficacy (3 questions) – Convenience and ease of use (3 questions) – Impact of medicine (3 questions) – Medical follow-up/review (2 questions) – Overall opinion (3 questions)
DLQI	• 10-question, widely used dermatology-related QoL tool. • Questions are general and cover symptoms and feelings, daily activities, leisure, work and school, personal relationships, and treatment experience over the previous week.

Key: DLQI – Dermatology Life Quality Index; QoL – quality of life; SATMED-Q – Satisfaction with Medicines Questionnaire.

STATISTICAL ANALYSIS

- All study analyses conducted were exploratory and descriptive in nature.
- The primary analysis population set included all patients who met the eligibility criteria and completed the survey.
  - Baseline characteristics were calculated as mean values for continuous variables and percentages for categorical variables.
  - Proportions of patients listing each concern or side effect related to azelaic acid foam in the Rosacea Treatment Preference Questionnaire were assessed.
  - All the importance or tolerability scores that patients assigned to each concern or side effect, the satisfaction score from the Satisfaction with Medicines Questionnaire (SATMED-Q), and the QoL score from the Dermatology Life Quality Index (DLQI) were computed and summarized using means standard deviations and medians as appropriate.
- As an exploratory analysis to assess the association between concerns and side effects vs overall treatment satisfaction and overall QoL, regression analyses were conducted.

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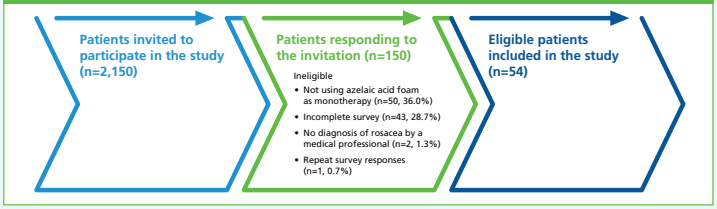
RESULTS

PATIENT ATTRITION

- Study recruitment and patient attrition are summarized in **Figure 1**.
- 2,150 program-identified patients were invited to participate, 150 patients responded, and 54 met all eligibility criteria and were included in the study.

Figure 1. Study Recruitment and Patient Attrition



DEMOGRAPHICS

- A total of 54 patients were included in the study. Patient population characteristics and rosacea medical history are described in **Table 2**.
- Participants were primarily female (90.7%), ranging in age from 26 to 63 years.
- The majority of participants (77.8%) reported no rosacea-relevant medical conditions.

Table 2. Baseline Characteristics and Rosacea-relevant Medical Conditions

		Total, N=54	
Gender, n (%)	Female	49	90.7
	Male	5	9.3
Age (years)	Mean (standard deviation)	48.1	(9.4)
	Min	26.0	-
	Median	48.5	-
	Max	63.0	-
Health insurance coverage type, n (%)	Preferred provider organization	41	75.9
	Health maintenance organization	8	14.8
	Worker's compensation/motor vehicle/third-party liability	0	0.0
	Medicaid	2	3.7
	Medicare/Medicare supplemental	0	0.0
	Indemnity	0	0.0
	Other	5	9.3
Rosacea-relevant medical conditions, n (%)	None	42	77.8
	Depression	5	9.3
	Migraine	5	9.3
	Conjunctivitis	4	7.4
	Blepharitis	1	1.9
	Corneal neovascularization/keratitis	0	0

- The most common subtypes reported by study participants were erythematotelangiectatic and papulopustular (74.1% each), with 59.3% of participants reporting "mild" rosacea symptoms (16.7% "absent"; 24.1% "moderate") in the 4 weeks before enrollment.
- Only 13.0% of patients reported no previous rosacea treatment.
- The most commonly reported topical agent for prior rosacea treatment was metronidazole gel (7.4%).

PATIENT CONCERNS

- The majority of patients reported no concerns (74.1%) with their treatment (**Figure 2**). The biggest concern reported was cost (11.1% of patients), with a mean importance score (IS) on a 10-point scale of 9.3 (**Figure 3**).

Figure 2. Patient Concerns With Rosacea Treatment

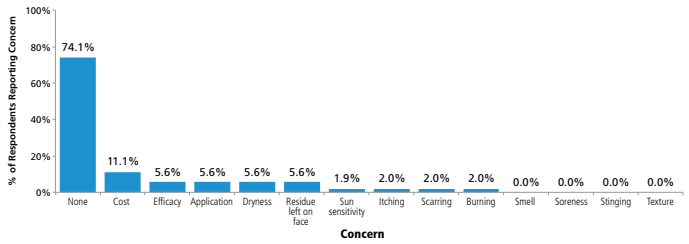
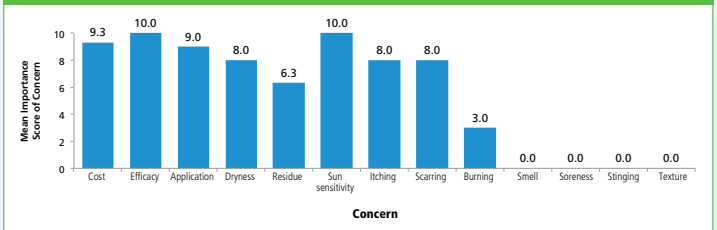


Figure 3. Rosacea Treatment Concerns' Mean Importance Scores



- A majority (77.8%) of patients reported no side effects (**Figure 4**). Dryness was the most commonly reported side effect (13.0%; IS: 5.3). Other side effects reported included stinging (7.4%, IS: 2.5), itching (5.6%; IS: 4.7), redness (5.6%; IS: 8.3), and burning (3.7%; IS: 7.0) (**Figure 5**).

Figure 4. Side Effects With Rosacea Treatment

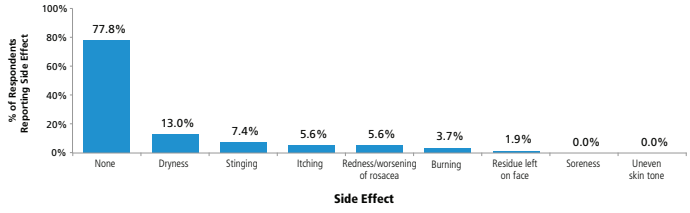
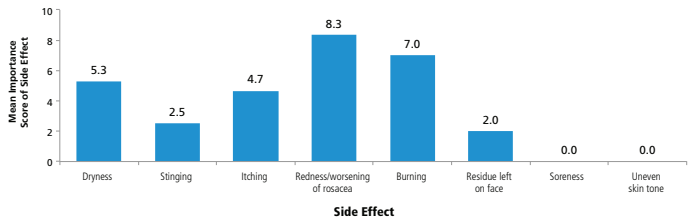


Figure 5. Mean Importance Scores of Rosacea Treatment Side Effects



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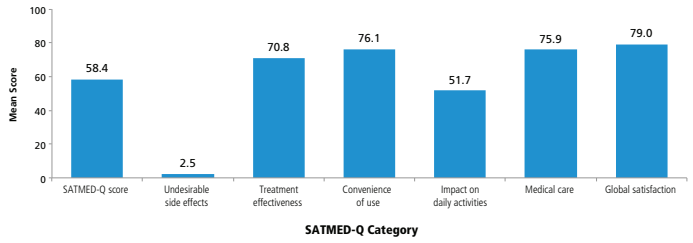
TREATMENT SATISFACTION AND QOL

- The global satisfaction (SATMED-Q) mean score was 79.0 and treatment effectiveness mean score was 70.8 (**Figure 6**). Standardized scores for the SATMED-Q ranged from 0 to 100, with an overall score of 59.3 indicating feeling neutral and each additional 13.4-point increase indicating a clinically meaningful movement toward satisfaction.
- The impact of rosacea on QoL was "minimal" (mean DLQI score: 2.35). DLQI scores ranged from 0 to 30 (with 0–1 indicating rosacea has no effect on QoL and 21–30 indicating rosacea has an extremely large effect on QoL).

Figure 6. Mean SATMED-Q Scores



Key: SATMED-Q – Satisfaction with Medicines Questionnaire.

EXPLORATORY ANALYSIS

- In regression models used for the exploratory analysis, increasing dryness importance scores were significantly associated with worsening treatment satisfaction and QoL in SATMED-Q and DLQI.

LIMITATIONS

- Due to the limited respondent pool, further research is needed to confirm these results.
  - The International Society of Pharmacoeconomics and Outcomes Research (ISPOR) recommends that a minimum sample size of 200 patients is needed to obtain meaningful survey results in research on patient-reported outcomes. A total of 2,150 patients were invited to participate in this study, and 150 responded; however, only 54 met eligibility criteria and were enrolled in the study.

CONCLUSION

- Azelaic acid foam was well tolerated and efficacious, with less than 26% of participants reporting any concerns or side effects and 6% reporting a concern with treatment efficacy.
- Azelaic acid foam users reported favorable results in the domains of burning, itching, and stinging.
- Due to the limited respondent pool, further research is needed to confirm these results.

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