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

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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.1,3,4,6
- 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.

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.

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.
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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 patients (77.8%) reported no rosacea-relevant medical conditions.

Table 2. Baseline Characteristics and Rosacea-relevant Medical Conditions

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

• 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

• 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

• The most commonly reported topical agent for prior rosacea treatment was metronidazole gel (7.4%).

LIMITATIONS
• Due to the limited respondent pool, further research is needed to confirm these results.

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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

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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