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Sarecycline Improves Acne Severity, Symptoms, and Psychosocial Burden in Non-nodular Acne Vulgaris: PROSES Study

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ABSTRACT

Background: Patient-reported outcomes (PROs) are emerging as a fundamental component of disease impact assessment in acne vulgaris (AV), complementing clinician-reported outcomes. No data are available on PROs for patients with AV using sarecycline in real-world settings.
Methods: A single-arm, prospective cohort study that included patients ≥9 years old diagnosed with moderate or severe non-nodular AV was implemented as part of routine care in clinical practices (N=30). Patients received oral sarecycline (60 mg, 100 mg, or 150 mg) for 12 weeks, as part of usual care. The primary endpoint was Acne Symptom and Impact Scale (ASIS) responses from patients (≥12 years) and caregivers (for patients 9-11 years) at week 12 and change from baseline (CFB). Investigator's Global Assessment (IGA) of AV severity and adverse events (AEs) were also recorded.
Results: A total of 253 patients with AV completed the study (adults: 60.1%, females: 77.6%). ASIS mean scores significantly decreased (P <.0001) at week 12 for: signs (mean CFB ± standard deviation [SD]: –0.8 ± 0.7), impact (–1.0 ± 1.0), emotional impact (–1.2 ± 1.1), and social impact (0.6 ± 1.1). Significant reductions in AV severity (P <.0001) were reported by patients and caregivers. The IGA success rate was 58.9% and physician satisfaction with treatment outcomes was 88.1%. A total of 31 (10.3%) patients reported ≥1 AE during the study.
Conclusions: Patients with moderate-to-severe AV receiving acne management with an oral antibiotic for 12 weeks experienced a significant improvement in AV-related symptoms and psychosocial burden.

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INTRODUCTION

Acne vulgaris (AV) is a complex, inflammatory, cutaneous disorder of the pilosebaceous unit that affects 9.4% of the global population,[1,2] ranking it as the eighth most prevalent disease in the world.[3] AV can persist into adulthood with 85% of impacted individuals being adolescents and young adults,[4] and it has a higher prevalence among adult women than their male counterparts.[5] More than 5.1 million Americans sought medical treatment for AV in 2013 with direct costs estimated to exceed 3 billion dollars.[6] The condition is chronic, has a high potential for relapse and long-term sequelae, and its physical appearance contributes to the emotional and psychosocial burden of disease, impaired quality of life (QoL), low self-image,[7] poor self-esteem, and increased social and emotional anxiety.[8,9] Psychosocial impact on patients with AV is reported to be greater than that attributed to other dermatologic conditions (psoriasis and eczema)[10] and equivalent to that for other debilitating conditions such as asthma, epilepsy, diabetes, or arthritis.[11,12]

Antibiotics have been a standard of care in treating AV for >5 decades.[13,14] Oral antibiotics are recommended by the American Academy of Dermatology for the treatment of moderate and severe AV, and oral tetracyclines are used frequently for this condition. However, prolonged and repetitive use of broad-spectrum antibiotics, such as doxycycline and minocycline, have been associated with the development of antimicrobial resistance.[15-19]

Sarecycline is the first narrow-spectrum tetracycline-derived antibiotic approved by the US Food and Drug Administration (US FDA) for the treatment of inflammatory lesions of non-nodular moderate-to-severe AV, and it has a low potential to induce bacterial resistance.[20-23] Two identically designed, pivotal, double-blind, randomized, placebo-controlled clinical trials demonstrated sarecycline to be efficacious and well-tolerated with a favorable safety profile.[20] These studies assessed patient-reported outcomes (PROs) with the Skindex-16, and demon-

strated a positive impact of sarecycline. However, there have been no studies evaluating the effectiveness of sarecycline or any other oral antibiotics in AV through PROs in a real-world setting. PROs may be ideal for capturing the experience of patients with AV that is not adequately reflected by traditional clinical outcomes. Assessment of PROs is recommended in studies of patients with AV to complement standard outcomes reported and for use in routine clinical practice.[24,25] Clinical trials in AV have employed a wide range of PROs, hampering the interpretation of research findings and comparisons across studies.[26-28] PRO assessments in routine practice could complement clinical assessment and provide patients' perspectives on treatment, including with oral antibiotics, as well as the impact of therapy on their physical, emotional, and psychosocial well-being. This prospective study evaluated PROs using a validated tool – the Acne Symptom and Impact Scale (ASIS) – and assessed the clinical effectiveness and safety of sarecycline in community practice settings across the US.

METHODS

Study Design and Participants

This single-arm, prospective, observational cohort study evaluated the use of sarecycline in patients with moderate-to-severe non-nodular AV (N=300) in the US. Data were collected from 30 community dermatology practices between March 2021 and May 2022. The study was approved by the Advarra Institutional Review Board (SSU00149823 and SSU00150552). Study patients were followed for up to 12 weeks with evaluations at weeks 4, 8, and 12.

Patients ≥9 years old with a confirmed diagnosis of facial non-nodular moderate-to-severe AV (Investigator Global Assessment [IGA] score of 3 or 4) were included and received oral sarecycline (60 mg, 100 mg, or 150 mg). Appropriate sarecycline dosages were determined by the clinicians based on clinical judgment per US FDA prescribing guidelines.[21] Patients ≥18 years old provided informed written consent and those <18 years of age were consented to participate by their adult primary caregivers.

Patients were excluded if they had any facial conditions that interfered with AV clinical evaluations; had a history of allergy to tetracycline-class antibiotics or pseudomembranous or antibiotic-associated colitis; known resistance to other tetracyclines; were on concurrent treatment with penicillin or oral retinoids; were pregnant, lactating, or planning a pregnancy during the study period; or had inaccessible medical records.

FIGURE 1. ASIS questionnaire.

Please read and answer each of the following questions about **acne signs and symptoms**. Before answering each question, **look in the mirror and think about the acne on your face**. Select one answer for each question that best describes your experience with acne **right now**. There are no right or wrong answers.

1. How oily is your face right now?
   Not at all ☐ | A little ☐ | Somewhat ☐ | Quite a bit ☐ | Very ☐
2. How many pimples do you have on your face right now?
   None ☐ | A few ☐ | Some ☐ | Quite a bit ☐ | A lot ☐
3. How many acne scars (holes or indents) do you have on your face right now?
   None ☐ | A few ☐ | Some ☐ | Quite a bit ☐ | A lot ☐
4. How many scabs from acne do you have on your face right now?
   None ☐ | A few ☐ | Some ☐ | Quite a bit ☐ | A lot ☐
5. How many dark marks from acne do you have on your face right now?
   None ☐ | A few ☐ | Some ☐ | Quite a bit ☐ | A lot ☐
6. How many blackheads do you have on your face right now?
   None ☐ | A few ☐ | Some ☐ | Quite a bit ☐ | A lot ☐
7. How many whiteheads do you have on your face right now?
   None ☐ | A few ☐ | Some ☐ | Quite a bit ☐ | A lot ☐
8. How much redness do you have on your face right now?
   None ☐ | A few ☐ | Some ☐ | Quite a bit ☐ | A lot ☐

Please read and answer each of the following questions about how **acne impact your quality of life**. Before answering each question, look in the mirror and think about the acne on your face. Select one answer for each question that best describes your experience with acne in the past 7 days. There are no right or wrong answers.

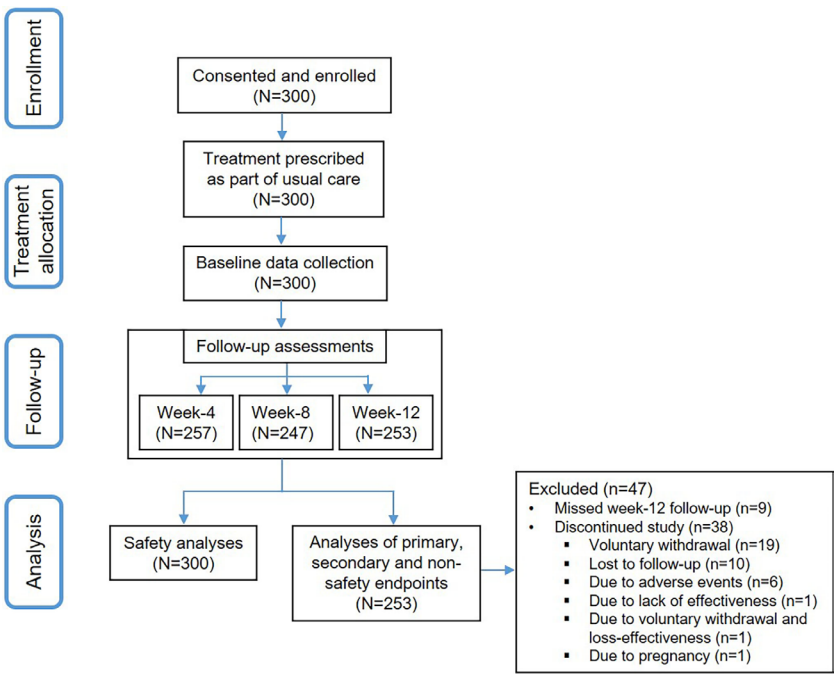
10. Over the past 7 days, rate how your face looked because of your acne.
    Excellent ☐ | Very good ☐ | Good ☐ | Fair ☐ | Bad ☐
11. Over the past 7 days, how often did you feel sad because of the acne on your face?
    Never ☐ | Rarely ☐ | Some of the time ☐ | Most of the time ☐ | All of the time ☐
12. Over the past 7 days, how often did you feel embarrassed because of the acne on your face?
    Never ☐ | Rarely ☐ | Some of the time ☐ | Most of the time ☐ | All of the time ☐
13. Over the past 7 days, how often did you feel self-conscious because of the acne on your face?
    Never ☐ | Rarely ☐ | Some of the time ☐ | Most of the time ☐ | All of the time ☐
14. Over the past 7 days, how often did you feel annoyed because of the acne on your face?
    Never ☐ | Rarely ☐ | Some of the time ☐ | Most of the time ☐ | All of the time ☐
15. Over the past 7 days, how often did you feel not confident because of the acne on your face?
    Never ☐ | Rarely ☐ | Some of the time ☐ | Most of the time ☐ | All of the time ☐
16. Over the past 7 days, how often did you choose not to be around other people because of the acne on your face?
    Never ☐ | Rarely ☐ | Some of the time ☐ | Most of the time ☐ | All of the time ☐
17. Over the past 7 days, how often did someone make bad comments about the acne on your face?
    Never ☐ | Rarely ☐ | Some of the time ☐ | Most of the time ☐ | All of the time ☐

TABLE 1.

Demographic Characteristics of Adult Patients and Caregivers (Safety Population)			
Demographic Data	**Adult Patient, ≥18 years old (N=184)**	**Pediatric Patient, <18 years old (N=116)**	**Caregiver (N=116)**
Age, years			
Mean (SD)	26.5 (7.6)	14.8 (1.7)	45.9 (7.7)
Median (min, max)	24.0 (18.0, 50.0)	15.0 (10.0, 17.0)	48.0 (18.0, 65.0)
Sex			
Male	42 (22.8)	57 (49.2)	22 (19.0)
Female	142 (77.2)	59 (50.9)	94 (81.0)
Race			
White/Caucasian	113 (61.4)	92 (79.3)	87 (75.0)
Black or African American	25 (13.6)	8 (6.9)	8 (6.9)
American Indian or Alaskan	1 (0.5)	2 (1.7)	1 (0.9)
Asian	13 (7.1)	6 (5.2)	3 (2.6)
Native Hawaiian or other Pacific Islander	1 (0.5)	2 (1.7)	3 (2.6)
Other	33 (17.9)	13 (11.2)	14 (12.1)
Prefer not to answer	5 (2.7)	4 (3.5)	4 (3.5)
Ethnicity: Hispanic, Latino, or of Spanish Ancestry			
Yes	65 (35.3)	36 (31.0)	36 (31.0)
No	119 (64.7)	80 (68.9)	80 (68.9)

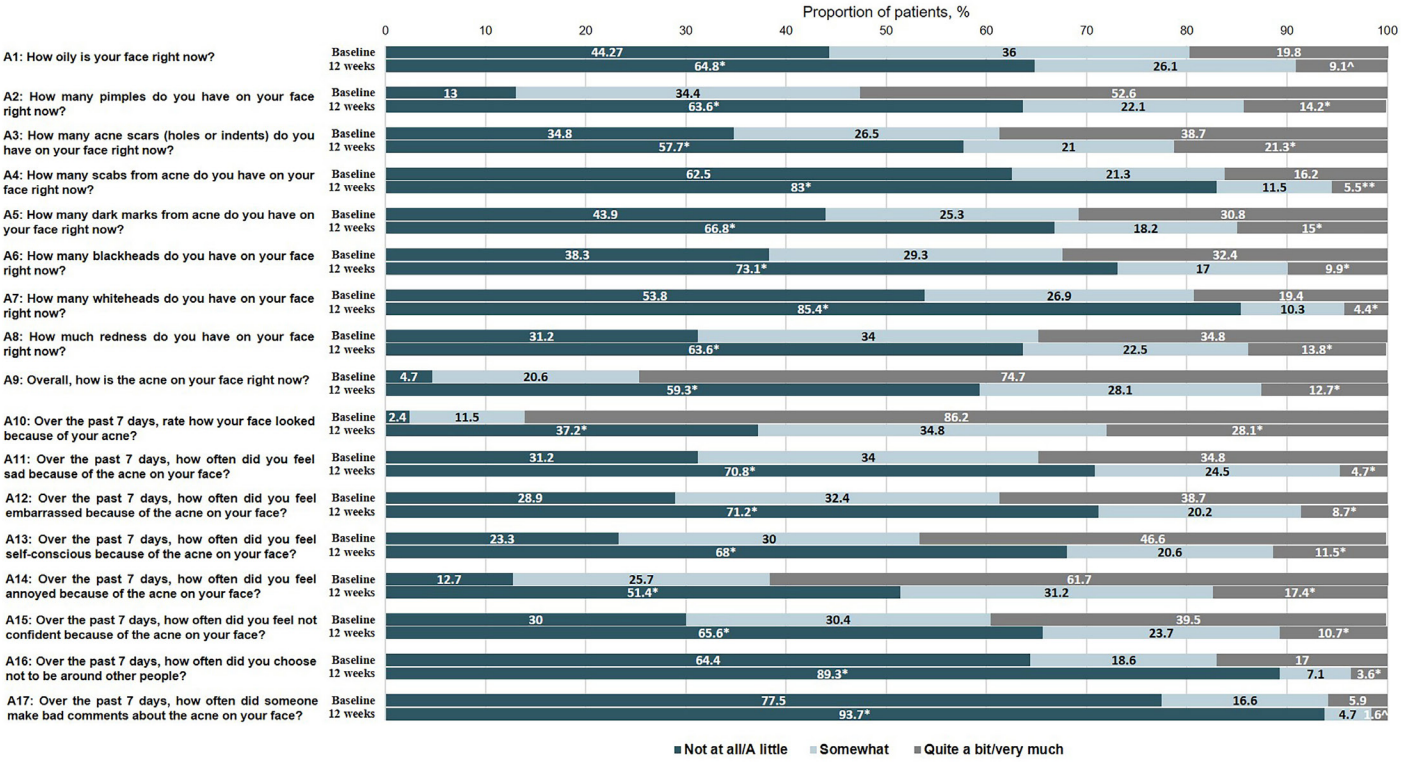
max, maximum; min, minimum; N, population size; n, sample size; SD, standard deviation

FIGURE 2. CONSORT flow diagram of study.



N, population size; n, sample size

FIGURE 3. ASIS Individual Item responses (analytic population).



N=253 for all items. In comparison to baseline: $^{*}P<.0001$; $^{**}P=.0001$; $^{\wedge}P=.0006$; $^{\wedge\wedge}P=.01$

Assessments

The primary endpoint was ASIS questionnaire responses at week 12 and change from baseline (CFB) from patients ≥12 years old and with the assistance of caregivers for patients aged 9-11 years. ASIS is a validated 17-item questionnaire that contains a signs domain (items A1-A9) and an impact domain (emotional impact [items A10-A15] and social impact [items A16-A17]) (Figure 1).[29,30] All items in the questionnaire are scored on a 5-point adjectival response scale (score 0-4). Higher scores indicate severe symptoms or a negative impact of AV on appearance, emotions, or social activities, and a score of 0 indicates lack of negative impact from AV or positive impact on psychosocial well-being and QoL. Data were scored according to developer guidelines, reporting domain (signs and impact), and subdomain (emotional impact and social impact) scores.[29,30] The secondary endpoint was the IGA of AV severity at week 12. This measure uses a 5-point adjectival response scale (score 0 [clear] – 4 [severe]) and IGA success was defined as a 2-point decrease in IGA score and a score of 0 (clear) or 1 (almost clear) at week 12. Additional outcomes included clinician satisfaction with AV treatment for individual patients as well as safety.

Data Analysis

All patients who received ≥1 dose of sarecycline during the study comprised the *safety population* and were included in the safety data analyses. All patients in the safety population who had ≥1 question answered pertaining to the study's primary endpoint at week 12 comprised the *analytic population*, which was included in analyses of all non-safety endpoints.

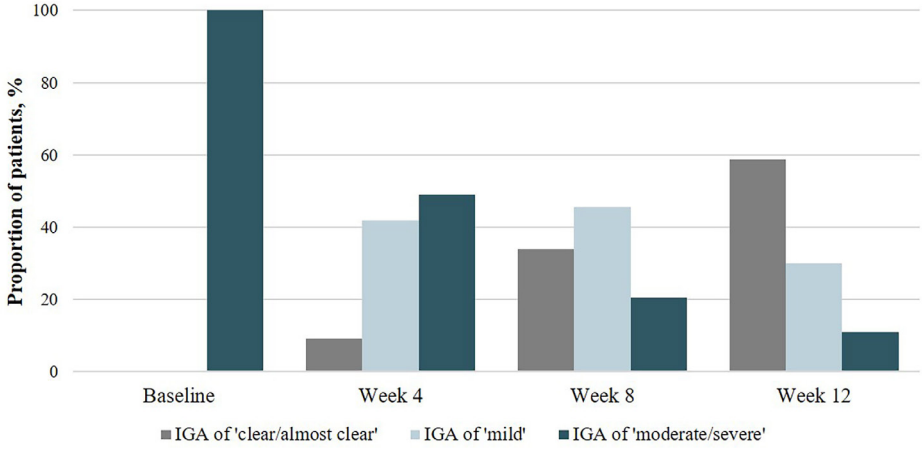
Continuous variables are presented as mean, median, standard deviation (SD), and number of patients. Categorical variables are presented as counts and percentages. Discrete variables were analyzed using Chi-square tests. Statistical differences in continuous measures were assessed using paired-sample t-tests. Missing values for IGA at weeks 4 and 8 were imputed using the last observation carried forward (LOCF). All statistical analyses were conducted using SAS statistical software, and $P \leq .05$ was considered significant.

RESULTS

Patient and Caregiver Characteristics

The disposition of patients is summarized in Figure 2. A diverse population of 300 patients (N=253 in the analytic population at week 12) with AV were recruited, comprising 61.3% adults (N=184; mean age ± SD: 26.5 ± 7.6 years; 77.2% female) and 38.7% pediatric patients (N=116; 14.8 ± 1.7 years; 50.9% female). The majority of adult (61.4%) and pediatric (79.3%) patients were White/Caucasian (Table 1). The demographics of the analytic population were comparable to the safety population with 86.6% having moderate and 13.4% having severe facial AV. Many patients reported previous use of medications for AV, including topical retinoids (47.8%), benzoyl peroxide (39.5%), topical antibiotics (36.4%), and tetracycline or macrolide oral antibiotics (24.5%). Sarecycline monotherapy was used by 49.8% of patients. The most frequently used concomitant medications were topical retinoids (24.5%), topical antibiotics (13.4%), and adapalene/benzoyl peroxide combination (11.1%).

FIGURE 4. IGA for facial AV severity during the 12-week study (analytic population).



*Change from baseline statistically significant at $P < .0001$

Healthcare Professional Use and Attitudes Regarding Oral Antibiotics

Treaters included 29 board-certified dermatologists and one nurse practitioner from private community dermatology practices; 60% of the clinicians reported frequently prescribing broad-spectrum antibiotics; 66.7% were moderately/extremely concerned about antibiotic resistance; and 63.3% were moderately/extremely concerned about disruption of the microbiome associated with long-term antibiotic use. Most clinicians (90%) recognized the importance of antibiotic stewardship.

PROs and Clinician-Reported Outcomes

Significant improvements in AV-related signs domain scores (mean CFB ± SD: –0.8 ± 0.7; $P < .0001$), impact domain scores (–1.0 ± 1.0; $P < .0001$), emotional impact subdomain scores (–1.2 ± 1.1; $P < .0001$), and social impact subdomain scores (–0.6 ± 1.1; $P < .0001$) measured by ASIS were observed by week 12. For individual ASIS items, most patients reported significant decreases from baseline to week 12 in AV-related signs (items 1-8; $P \leq .0006$) including oily face, pimples, scars, scabs, dark marks, blackheads, whiteheads, and redness. In addition, 59.3% of patients responded clear/almost clear to the question "How is your acne on your face right now?" at week 12 ($P < .0001$); and 37.2% responded excellent/very good to the question "Rate how your face looks because of acne" ($P < .0001$). Most patients reported a significant decrease in AV-related emotional impact at week 12 (ASIS items 11-15; $P < .0001$). This included feeling sad, embarrassed, self-conscious, annoyed, and being less confident. Most also reported a significant decrease in AV-related social impact at week 12, with fewer patients choosing not to be around other people ($P < .0001$), and fewer patients receiving criticism about acne ($P = .0101$; Figure 3).

Clinicians reported a significant increase in the proportion of patients with IGA of 0 or 1 (IGA success) from baseline (0%) to week 12 (58.9%; $P < .0001$; Figure 4). The proportion of patients with IGA of 3 or 4 significantly declined from 100% at baseline to 11.1% at week 12 ($P < .0001$). Clinicians were *very satisfied* or *satisfied* with treatment outcomes at week 12 for 88.1% of patients.

Safety

The safety population included 184 adults (61.3%) and 116 pediatric patients (38.7%). The mean treatment duration among all patients was 53.2 days with an overall compliance rate of 89.7%. Thirty-eight (12.7%) patients discontinued before week 12 with the most frequent cause being patient voluntary withdrawal or loss to follow-up (n=30; 10.0%; Figure 1). Thirty-one (10.3%) patients reported ≥1 adverse events (AEs) during the study. The majority were mild AEs (n=27; 9.0%). One patient (0.3%) had a serious AE of intracranial hypertension that resolved upon drug withdrawal. Two patients (0.7%) and 4 patients (1.3%) discontinued/withdrew from the study due to AEs not related to oral antibiotic use and related AEs, respectively (Table 2). Among non-related AEs, the most frequently noted groups were skin and subcutaneous tissue disorders (2.0%), nervous system disorders (1.7%), and infections (1.3%). The most frequently reported related AEs were gastrointestinal (2.3%) and nervous system disorders (1.7%). No individual non-related or related-AEs were reported for ≥2% of patients.

DISCUSSION

AV has a peak prevalence at puberty, impairs multiple aspects of QoL including self-perception, socialization, emotional health, and is often associated with anxiety, depression, and even suicidal intentions.[2] More than 40% of patients with AV are anxious regarding their skin condition[31] and nearly 70% suffer from depression, more often in females than in males.[32] A recent meta-analysis indicated a positive correlation between AV and suicidal ideation[33] with 9-12% of suicidal patients indicating acne as the primary cause.[31,34,35] Younger patients are more prone to such tendencies than older individuals.[34] Better understanding of the psychosocial ramifications of AV and how they might influence treatment selection and outcomes has the potential to improve outcomes and decrease patient burden. Patient-centered research is recognized as valuable in skin conditions as they substantially impact patients' health-related QoL.[36] PROs are useful for evaluating new or existing medications,[37] and the validated ASIS questionnaire is considered a high-quality tool for real-world assessment of patient-reported QoL and AV impact of acne.

TABLE 2.

AEs (Safety Population)			
	N (%)		
	Non-related AE	Related AE	Any AE[a]
Patients with ≥1 AE	18 (6.0)	14 (4.7)	31 (10.3)
Intensity of AE (patients with ≥1 AE)[b,c]			
Mild	16 (5.3)	11 (3.7)	27 (9.0)
Moderate	3 (1.0)	3 (1.0)	6 (2.0)
Severe	0 (0.0)	1 (0.3)	1 (0.3)
Action taken with sarecycline (patients with ≥1 AE)			
Drug withdrawal/Study discontinuation	2 (0.7)	4 (1.3)	6 (2.0)
Other actions: dose not changed	16 (5.3)	10 (3.3)	25 (8.3)
Patients with ≥1 serious AE	0 (0.0)	1 (0.3)[d]	1 (0.3)[d]
Patients with ≥1 serious AE resulting in death	0 (0.0)	0 (0.0)	0 (0.0)

AE, adverse event, N, sample size
[a]Includes non-related and related AEs
[b]Among non-related AEs: 1 patient had 2 AEs each that were of different intensities (1 AE was mild and 1 AE was moderate); 1 patient had 2 mild AEs; 1 patient had 3 mild AEs
[c]Among related AEs: 1 patient had 2 mild AEs, 1 patient had 2 moderate AEs, and 1 patient had 2 AEs that were of different intensities (1 AE was moderate and 1 AE was severe)
[d]Idiopathic intracranial hypertension was noted at week 8, which resolved upon drug withdrawal

The findings of this study confirmed the substantial disease burden and psychological distress of AV and indicated a significant effect of sarecycline in relieving them. Twelve weeks of sarecycline treatment not only improved patients' acne signs but also significantly reduced psychological comorbidities by increasing patient confidence, self-acceptance, and self-appreciation. Patients' self-assessments revealed improved appearance and clear/almost clear skin, implying treatment satisfaction. Clinicians reported a significant decrease in AV severity as measured by IGA success at week 12 and were satisfied with the treatment outcomes for the majority of patients.

Study results also showed that a treatment regimen including sarecycline in real-world clinical practice resulted in a two-fold higher IGA success rate than those reported in Phase III clinical trials.[26] There also was close agreement between the clinician-reported IGA success (58.9%) and patients' global assessment of AV severity as clear/almost clear (59.3%). The safety profile for sarecycline reported here was consistent with previous studies,[20] and no AE was reported in ≥2% of patients. The high compliance rate further supports the efficacy and tolerability of sarecycline.

To our knowledge, this is the first real-world study that evaluated an oral antibiotic in pediatric and adult patients with moderate-to-severe non-nodular AV in routine clinical practice using a PRO along with conventional efficacy and safety assessments. Study results also showed that administering a validated PRO instrument, the ASIS questionnaire, accurately assessed the severity of AV signs and impacts in both pediatric and adult patients. All of these assessments support the use of sarecycline in this broad patient population. Additional multi-center real-world studies that incorporate PROs in routine clinical practice may further enhance understanding of how other acne treatments influence patients' psychological well-being.

Study Limitations

Sarecycline was administered as a part of real-world clinical practice and investigators could add other AV medications, as per usual care. This could have influenced all study outcomes. In addition, results were potentially subject to recall bias, reporting bias, selection bias, and other biases commonly seen in real-world and open-label studies. Approaches such as standardized study inclusion/exclusion criteria, consecutive sampling, and geographically diverse dermatology clinics, having varied experience with oral antibiotics were employed to minimize these biases. An LOCF imputation method was employed for missing data at weeks 4 and 8, but there were no missing data for the analysis population at week 12.

CONCLUSIONS

AV patient management involving sarecycline was effective and well-tolerated, with low rates of AEs in patients with moderate-to-severe AV over a 12-week study period. In addition, treatment with this oral antibiotic demonstrated significant improvements in emotional and psychosocial impacts of AV at week 12 compared to baseline, as measured using the validated ASIS questionnaire. Patient self-reported ASIS responses correlated with physician assessments and the tool proved useful in demonstrating both disease burden and treatment effectiveness. Most of the patients experienced IGA success and clinicians expressed treatment satisfaction with the outcomes for the majority of their patients. PROSES study results reinforce that oral antibiotics, such as sarecycline, are an effective and safe treatment option for AV patients.

DISCLOSURES

Dr Graber reported receiving royalties from Wolters Kluwer Health and served as a consultant/advisor, research investigator and/or speaker for Almirall SA, Cutera, Digital Diagnostics, Hovione, Keratin Biosciences,

La Roche Posay, Lipidor AB, L'Oreal, Ortho Dermatologics, Sebacia, SolGel, Verrica, and WebMD. Dr Harper reported receiving honoraria for serving as a consultant, speaker, and/or investigator for Almirall, Cassiopeia, Cutera, EPI, Galderma, Journey, L'oreal, Ortho, Sol Gel, Sun, and Vyne and received honoraria for holding stocks in Cutera. Dr Alexis reported receiving grants and/or royalties from Abbvie, Almirall SA, Amgen, Arcutis, Bristol-Myers-Squibb, Cara, Castle, Dermavant, Galderma, Leo, Novartis, Springer, Wiley-Blackwell, Wolters Kluwer Health, Valeant (Bausch Health), and Vyne; and served as a consultant/advisor and/or speaker for Abbvie, Allergan, Almirall SA, Amgen, Arcutis, Bausch health, Beiersdorf, BMS, Cara, Castle, Cutera, Dermavant, Eli Lilly, EPI, Galderma, Incyte, Janssen, Leo, L'Oreal, Ortho, Pfizer, Sanofi-Genzyme, Sanofi-Regeneron, Swiss American, Regeneron, UCB, VisualDx, and Vyne. Dr Stein Gold served as an investigator, advisor and/or speaker for Almirall SA, Galderma, Ortho Derm, and Sun. Dr Kircik served as an investigator, speaker, advisory board member, and/or consultant for Abbott Laboratories, Aclaris, Inc, Allergan, Inc, Almirall, Anacor Pharmaceuticals, Inc, Assos Pharma, Astellas Pharma US, Inc, Asubio Pharma Co, Ltd, Berlex Laboratories (Bayer Healthcare Pharmaceuticals), Biogen-Idec, Inc, Biolife, Biopelle, Boehringer Ingelheim, Breckinridge Pharma, Celgene Corporation, Centocor, Inc, Colbar, CollaGenex, Combinatrix, Connetics Corporation, Coria, Dermik Laboratories, Dermira, Inc, Dow Pharmaceutical Sciences, Inc, Dusa Pharmaceuticals, Inc, Eli Lilly & Co, Embil Pharmaceutical Co, Ltd, EOS, Ferndale Laboratories, Inc, Galderma Laboratories, LP, Genentech, Inc, GlaxoSmithKline, PLC, Health Point Ltd, Idera, Inc, Innocutis Medical, LLC, Innovail, Intendis, Inc, Johnson & Johnson, Laboratory Skin Care, Inc, Leo Pharmaceuticals, Inc, L'Oreal SA, 3M, Maruho Co, Ltd, Medical International Technologies, Medicis Pharmaceutical Corp, Merck & Co, Inc, Merz, Nano Bio Corporation, Novartis Pharmaceutical Corporation, Noven Pharmaceuticals, Inc, Nucryst Pharmaceuticals Corporation, Obagi Medical Products, Inc, Onset, Ortho Dermatologics, Ortho Neutrogena, PediaPharma, Inc, Promius Pharma, LLC, PharmaDerm, Pfizer, Inc, PuraCap, QLT, Inc, Quatrix, Quinnova, Serono (Merck-Serono International SA), SkinMedica, Inc, Stiefel Laboratories, Inc, Sun Pharmaceutical Industries, Ltd, Taro, TolerRx, Inc, Triax, UCB, Inc, Valeant Pharmaceuticals North America LLC, Warner-Chilcott, XenoPort, Inc, and ZAGE. Dr Del Rosso served as a research investigator, consultant/advisor, and/or speaker for AbbVie, Aclaris, Almirall, Amgen (Celgene), AnaptysBio, Arcutis, Athenex, Bausch (Ortho Dermatologics), Biofrontera, BioPharmX, Biorasi, Blue Creek, Botanix, Brickell, Bristol Myers Squibb, Cara Therapeutics, Cassiopea, Dermata, Dermavant, Encore, EPI Health, Ferndale, Galderma, Genentech, Incyte, Jem Health, LEO Pharma, La Roche-Posay, Lilly (Dermira), MC2, NOVAN, Pfizer, Ralexar, Regeneron, Sanofi-Genzyme, Sente, Solgel, Sonoma (Intraderm), Sun Pharma, UCB, Verrica, and VYNE (Foamix/Menlo). Dr Hebert reported receiving grants and/or honoraria from Almirall SA, Amryt, Arcutis, Dermavant, GSK, Incyte, Leo, Lilly, Novan, Pfizer, and Sun Pharma; and served as a member of Data and Safety Monitoring Board for GSK, Ortho Dermatologics, and Regeneron-Sanofi. Dr Fried served as a research investigator and/or scientific advisor for AbbVie, BI, BMS, Dermavant, Dermira, EPI, Incyte, Janssen, LEO, Lilly, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sanofi Sun, and UCB. Dr Siva Narayanan reported receiving consulting honoraria or research funding from Almirall, Biogen, Johnson and Johnson, Sarepta Therapeutics, SeaGen, and Takeda. Dr Koscielny and Dr Kasujee are employees of Almirall, SA. Dr Hilary E. Baldwin has served as an advisor, speaker, consultant and/or investigator for: Almirall, Arcutis, Bausch, Cutera, EPI, Galderma, Journey, La Roche-Posay, L'Oreal, Novan, Sol-Gel, and SUN.

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