INVESTIGATOR GLOBAL ASSESSMENT (IGA) OF ACNE VULGARIS AND IGA SUCCESS AMONG PATIENTS WITH MODERATE TO SEVERE NON-NODULAR ACNE VULGARIS (AV) ADMINISTERED SARECYCLINE IN COMMUNITY PRACTICES ACROSS THE U.S IN PROSES STUDY: ANALYSIS BY CONCOMITANT MEDICATION USE

Hilary Baldwin,[1] James Del Rosso,[2] Leon Kircik,[3] Linda Stein Gold,[4] Adelaide Hebert,[5] Evan A Rieder,[6] Andrew F. Alexis,[7] Julie C. Harper,[8] Richard G. Fried,[9] Siva Narayanan,[10] Volker Koscielny,[11] Ismail Kasujee,[11] Emmy Graber[12]

[1]Acne Treatment and Research Center, Brooklyn, NY; [2]JDR Dermatology Research/Thomas Dermatology, Las Vegas, NV; [3]Icahn School of Medicine, Mount Sinai, New York, NY; [4]Henry Ford Health System, Bloomfield, MI; [5]UTHealth McGovern Medical School, Houston, TX; [6]New York University Grossman School of Medicine, New York, NY; [7]Weill Cornell Medical College, New York, NY; [8]The Dermatology and Skin Care Center of Birmingham, Birmingham, AL; [9]Yardley Dermatology Associates, Yardley, PA; [10]Avant Health LLC, Bethesda, MD; [11]Almirall SA, Barcelona, Spain; [12]The Dermatology Institute of Boston and Northeastern University, Boston, MA.

SYNOPSIS

Introduction: Objective of the analysis was to evaluate facial IGA and the associated IGA success, stratified by the use of concomitant acne medications, among AV patients administered sarecycline in community practices across the U.S. **Methods:** A single-arm, prospective cohort study (PROSES) was conducted with moderate-to-severe non-nodular AV patients >9 years who were prescribed sarecycline in real-world community practices in the US. Facial IGA of AV status was collected on a five-point adjectival response scale (0(clear)-4(severe)). IGA success at week-12 was defined as >2-grade improvement and score 0-clear or 1-almost clear at week-12. Proportion of patients achieving IGA success was analyzed, stratified by the use of any concomitant AV medication during the study (Yes vs. No (monotherapy)). **Results:** A total of 253 AV patients completed the study. Half of the patients (49.80%) were on sarecycline monotherapy (i.e., did not use any concomitant treatments for AV). For the overall study cohort, IGA success at week-12 was 58.89%. At week-12, IGA success was 59.84% among patients using concomitant AV medications, and 57.94% among patients using no concomitant AV medications (i.e., on sarecycline monotherapy). **Conclusion:** Within the study cohort administered sarecycline, a narrow-spectrum, tetracycline-derived antibiotic, for 12 weeks, majority of patients achieved IGA success at week-12, and the outcomes were similar among patients on sarecycline monotherapy and those on concomitant AV medications.

OBJECTIVE

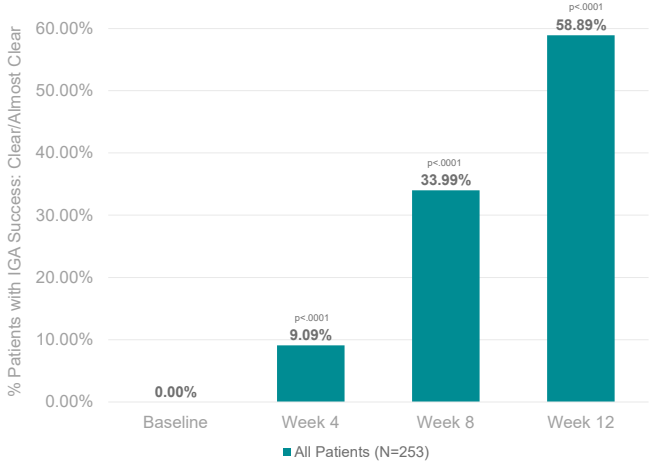
- The objective of this analysis was to evaluate facial IGA and the associated IGA success, stratified by the use of concomitant acne medications, among AV patients administered sarecycline in community practices across the U.S.

METHODS

- A single-arm, prospective cohort study (PROSES) was conducted with moderate-to-severe non-nodular AV patients >9 years who were prescribed sarecycline in real-world community practices in the US.
- A total of 300 subjects were enrolled from 30 community practices across the U.S.
  - Patients and clinicians completed surveys and clinical assessments at baseline and weeks 4, 8 & 12. Concomitant medication use was collected at baseline and week-12.
  - Facial IGA of AV status was collected on a five-point adjectival response scale (0(clear)-4(severe)). IGA success at week-12 was defined as >2-grade improvement and score 0-clear or 1-almost clear at week-12.
  - Last observation carried forward (LOCF) imputation was considered for imputing missing data for the calculation of IGA and IGA success; however, there was no missing data at week-12, within the analytic population.
  - Proportion of patients achieving IGA success was analyzed, stratified by the use of any concomitant AV medication during the study (Yes vs. No (monotherapy)).

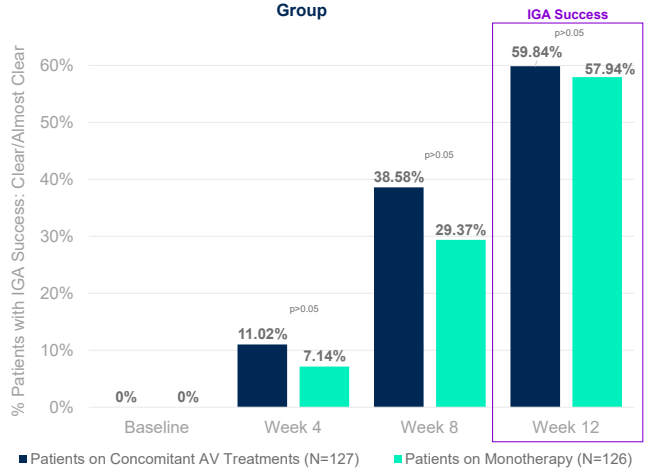
RESULTS

Figure 1: Proportion of Patients with a Facial IGA of "Clear/Almost Clear" Significantly Increased Over 12-Week Study Period.



P-values for 4,8,12 refers statistical significance of change from baseline.

Figure 2: Facial IGA Success Did Not Differ Significantly between The Concomitant AV Treatment Group and The Monotherapy Group



- A total of 253 AV patients completed the study, demographics shown in table 1.
- Key concomitant treatments for AV observed during the study included: topical retinoids, topical antibiotics, benzoyl peroxide, topical dapsone, and adapalene/benzoyl peroxide.
- For the overall study cohort, IGA success at week-12 was 58.89%.
- There was no statistically significant difference between the facial IGA of the group of patients on concomitant AV treatments and those patients only on sarecycline monotherapy (figure 2).

RESULTS

Table 1: Patient Demographics (N=253)

Demographic	Group	Proportion of Patients
Age Group, %	Pediatric (<18 yrs)	39.92
	Adult (≥18 yrs)	60.08
Age Group, Mean	Pediatric (<18 yrs)	26.63
	Adult (≥18 yrs)	14.81
Gender, %	Male	33.60
	Female	66.40
Race,%	White	66.80
	Other	15.81
	Black/African American	9.88
	Asian	5.93
	Prefer not to answer	3.16
	American Indian or Alaskan	0.79
	Native Hawaiian/Pacific Islander	0.40
Ethnicity,% (Hispanic, Latino or of Spanish Origin)	Yes	33.99
	No	66.01
Baseline IGA, %	Moderate	86.56
	Severe	13.44

Table 2: Concomitant Medication Use (N=253)

Medication Class	n (%)
Has not used any acne medication	126 (49.80)
Topical medication	
Topical retinoids	62 (24.51)
Salicylic acid	3 (1.19)
Benzoyl peroxide	15 (5.93)
Topical antibiotics	34 (13.44)
Topical Dapsone	13 (5.14)
Azelaic acid	7 (2.77)
Topical Clascoterone	2 (0.79)
Other*	43 (17.00)
Oral Medication^	12 (4.74)

*28 patients were on adapalene/benzoyl peroxide among others; ^11 were on spironolactone

CONCLUSIONS

- Within the study cohort administered sarecycline, a narrow-spectrum, tetracycline-derived antibiotic, for 12 weeks, majority of patients achieved IGA success at week-12, and the outcomes were similar among patients on sarecycline monotherapy and those on concomitant AV medications.

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