

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.: PROSES STUDY ANALYSIS BY GENDER AND AGE

Emmy Graber,¹ Hilary Baldwin,² Julie C. Harper,³ Linda Stein Gold,⁴ Andrew F. Alexis,⁵ Richard G. Fried,⁶ Evan A Rieder,⁷ James Del Rosso,⁸ Leon Kirciq,⁹ Siva Narayanan,¹⁰ Volker Koscielny,¹¹ Ismail Kasujee,¹¹ Adelaide Hebert¹²

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

SYNOPSIS

Introduction: The objective of this analysis was to evaluate facial IGA and the associated IGA success, stratified by age and gender, 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 gender and age (9-17yrs, >=18yrs).

Results: A total of 253 AV patients completed the study (female: 66.40%; 9-17yrs: 39.92%; >=18yrs: 60.08%; Facial IGA success at week-12 was 56.47% for male and 60.12% for female; 57.43% for patients 9-17yrs old and 59.87% for patients >=18yrs old.

Conclusion: Within the study cohort of adolescent and adult patients with moderate to severe AV at baseline administered sarecycline, a narrow-spectrum, tetracycline-derived antibiotic for 12 weeks, across the gender and age groups, majority of patients achieved IGA success at week-12.

OBJECTIVE

- The objective of this analysis was to evaluate facial IGA and the associated IGA success, stratified by age and gender, 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.
- Facial IGA of AV status was collected on a five-point adjectival response scale (0 (clear), 1 (almost-clear), 2 (mild), 3 (moderate), 4 (severe)) at baseline and weeks 4, 8 & 12.
- 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 gender and age (9-17yrs, ≥18yrs).

RESULTS

Figure 1: Clinician Acne Evaluation of Patient Facial IGA Success: Stratified by Gender

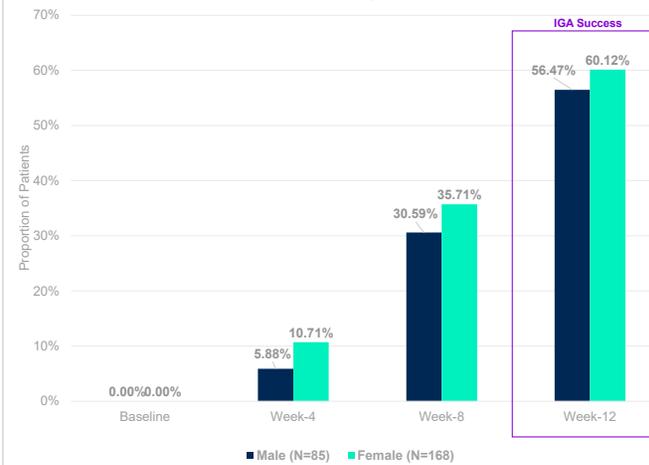
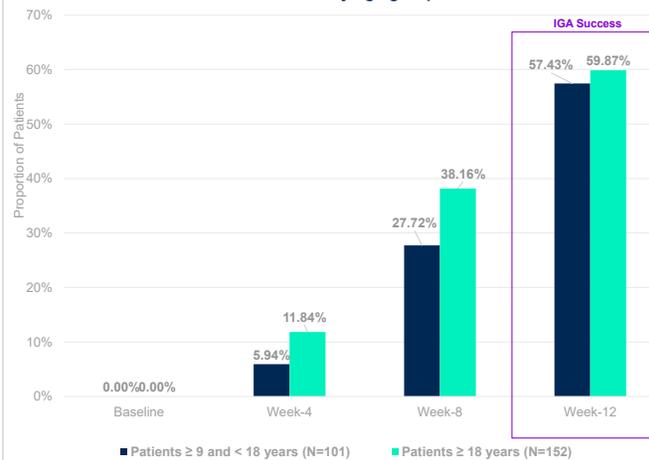


Figure 2: Clinician Acne Evaluation of Patient Facial IGA Success: Stratified by age group



- A total of 253 AV patients completed the study at week-12 with 58.90% of patients achieving IGA success by week-12.
- The proportion of patients with an IGA of clear/almost clear increased from 0% at baseline to 58.90% at Week-12 (p<0.0001). Proportion of patients with IGA success stratified by gender and age group as shown in Figures 1 & 2 respectively.
- There was no statistically significant difference in IGA success between genders and between age groups.

RESULTS

Table 1: Site Characteristics

Domain	N=30
Current workplace, %	
Private, office-based practice	100.00
Hospital-based practice	0.00
Total number of board-certified dermatologists in the practice, %	3.10
At present, how many patients with acne vulgaris do you personally manage in a given month? Mean	86.90
How long have you been practicing dermatology, post-residency?	19.30
How often do you prescribe broad-spectrum antibiotics (such as doxycycline and minocycline)? %	
Never	0.00
Rarely	3.33
Some of the time	36.67
Most of the time	33.33
All of the time	26.67

Table 2: 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
Ethnicity, % (Hispanic, Latino or of Spanish Origin)	Native Hawaiian/Pacific Islander	0.40
	Yes	33.99
Baseline IGA, %	No	66.01
	Moderate	86.56
	Severe	13.44

CONCLUSIONS

- Within the study cohort of adolescent and adult patients with moderate to severe AV at baseline administered sarecycline, a narrow-spectrum, tetracycline-derived antibiotic for 12 weeks, across the gender and age groups, majority of patients achieved IGA success at week-12.