

CHANGES IN ACNE SIGNS AND IMPACT OF ACNE ON EMOTIONS AND SOCIAL FUNCTIONING, AMONG PEDIATRIC PATIENTS WITH MODERATE TO SEVERE NON-NODULAR ACNE VULGARIS ADMINISTERED SARECYCLINE IN REAL-WORLD COMMUNITY PRACTICES ACROSS THE U.S. (PROSES STUDY)

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BACKGROUND

- Acne Vulgaris, hereinafter referred to as acne, affects up to 50 million Americans and is the most common skin condition in the United States (US).¹
- Acne has been shown to negatively affect QoL; resulting in low self-esteem and increased social and emotional anxiety.^{2,3}
- Patients with acne report more effects of their skin condition on their functioning, emotions, and symptoms than do patients with isolated benign skin lesions or those in the normative sample.⁴
- Acne has been associated with considerable psychosocial impact, causing significant negative effects on self-image, leading to feelings of isolation and loneliness, and a significantly lower self-attitude, uselessness feeling, sense of pride and self-worth, and body satisfaction.⁵
- Sarecycline is a newer oral tetracycline class of narrow spectrum antibiotic, a first line therapy treatment for moderate to severe acne patients. Sarecycline is a viable option for Acne patients to reduce disease burden, due to its safety profile and efficacy demonstrated in two identical Phase-III randomized, controlled trials.⁶
- Assessing PROs among pediatric patients in real-world setting is important to inform HCPs and patients to aid optimal disease management.

OBJECTIVE

- Evaluate changes in acne signs and impact of acne on emotions and social functioning, among pediatric patients with moderate to severe non-nodular Acne Vulgaris (AV) in community practices across the U.S.

METHODS

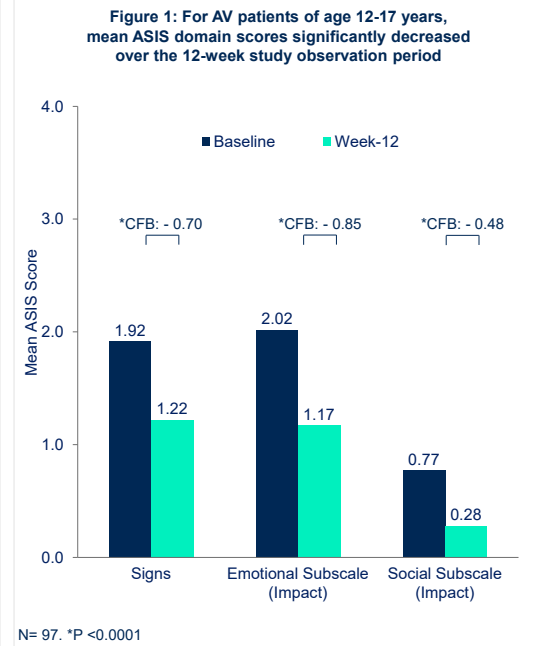
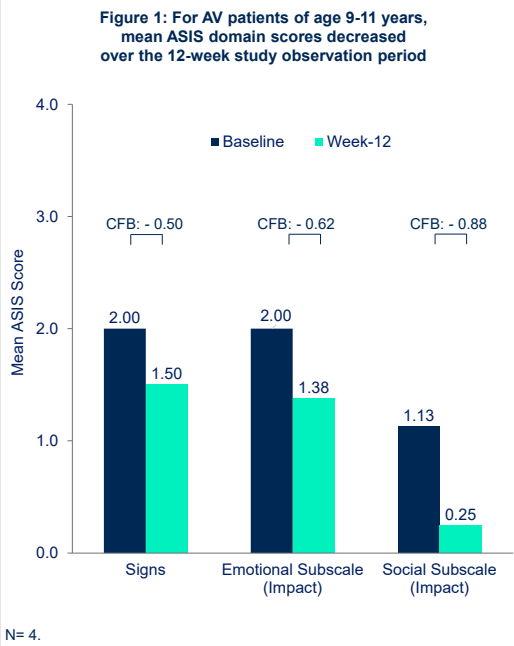
- Single-arm, prospective cohort study (PROSES) was conducted with moderate to severe non-nodular acne patients ≥9 years who were prescribed sarecycline in real-world community practices in the US.
- A total of 300 subjects were enrolled from 30 community practices across the U.S.
 - Primary outcome measures included validated Acne Symptom and Impact Scale (ASIS) questionnaire responses (from subjects ≥12 years) and caregivers (for subjects 9-11 years) at week-12 and corresponding change from baseline (CFB).
 - ASIS is a 17-item validated instrument that asks patients about the signs and impact of acne on emotional and social wellbeing and is a viable tool to assess disease burden and treatment outcomes.
 - ASIS contains Signs domain (items 1-9) and Impact domain (emotional (items 10-15) & social (items 16-17)); all items are scored on a five-point adjectival response scale (score 0-4); higher scores indicate severe symptoms or negative impact of Acne.
 - Change from baseline (CFB) in ASIS domain scores at Week-12 are analyzed, for the pediatric cohorts (9-11 & 12-17 yrs of age).

RESULTS

- 101 pediatric patients who completed the study at week-12 were included in the final analyses.

		N=101
Age, %	9-11 years	3.96
	12-17 years	96.04
Gender, Female %		50.86
Race, %	White	79.31
	Other	11.21
	Black / African American	6.90
	Asian	5.17
	Prefer not to answer	3.45
	Native Hawaiian / Pacific Islander	1.72
American Indian / Alaskan	1.72	
Hispanic, Latino, or of Spanish Origin, %		31.03

	N=30
Current workplace: Private, office-based practice, %	100
Total number of board-certified dermatologists in the clinic/practice, Mean	3.10
Number of patients with AV managed by the clinic in a given month, Mean	86.90
Number of years practicing dermatology, Mean	19.30



REFERENCES

- Bickers DR, Lim HW, Margolis D, et al. *J Am Acad Dermatol*. 2006; 55:490-500.
- Tiemstra RM. *Psychol Health Med*. 2013; 18(3):310-320.
- Revol O, Milliez N, Gerard D, Br J Dermatol. 2015; 172(Suppl 1):52-58.
- Lasek RJ, Chren MM. *Arch Dermatol*. 1998; 134: 454-8.
- Geiler U et al. *JEADV*. 2015; 29 (Suppl. 4):12-14.
- Moore A, Green LJ, Bruce S, et al. *J Drugs Dermatol*. 2018 Sep 1;17(9):987-996.

CONCLUSIONS

Moderate to severe AV burden/impact was observed in this prospective cohort of pediatric patients with AV in the U.S; this burden decreased following the administration of sarecycline, a narrow-spectrum, tetracycline-derived antibiotic, for 12 weeks.