

ACNE SYMPTOMS AND IMPACT OF ACNE ON SOCIAL FUNCTIONING, EMOTIONAL FUNCTIONING, AND ACTIVITIES OF DAILY LIVING (ADL) AMONG PATIENTS WITH MODERATE TO SEVERE NON-NODULAR ACNE VULGARIS (AV) IN COMMUNITY PRACTICES ACROSS THE U.S: AN ANALYSIS OF PROSES STUDY COHORT

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SYNOPSIS

Objective: Evaluate patient self-perceived AV symptoms and impact of AV on emotional/social functioning and ADL, among AV patients in community practices across the U.S. **Methods:** Single-arm, prospective cohort study (PROSES: NCT04820673) was conducted with moderate-to-severe non-nodular AV patients >9yrs who were prescribed sarecycline in real-world U.S community practices. Validated ASIS questionnaire (with Signs and Impact (emotional & social) domains) and an Expert Panel Questionnaire (EPQ; emotional functioning (items 1-4), social functioning (items 5-7), and ADL (items 8-11)) were completed by patients (>12yrs) and caregivers (for patients 9-11yrs) at baseline and week-12. All items were scored on five-point adjectival response scale (score: 0 (never/not at all) – 4 (all the time/very much/extremely)); a higher ASIS domain score indicate severe symptoms or negative impact of AV. ASIS domain scores and proportion of patients reporting score=2/3/4 (moderate to high burden/impact or parent understanding (EPQ10)) for EPQ items at baseline were analyzed. **Results:** A total of 253 AV patients completed the study (pediatric: 39.92%; female: 66.40%; moderate AV: 86.56%; severe AV: 13.44%). At baseline, patients reported moderate AV burden in most domains, as depicted by the following domain score: signs: 1.96, impact: 2.06, emotional impact subdomain: 2.43; social impact subdomain: 0.98. From EPQ items, proportion of patients reporting score=2/3/4 (moderate to severe burden) at baseline were: patients' mood/anger (EPQ1) – 56.13%; worries about AV worsening (EPQ2) – 79.45%; thinking about acne (EPQ3) – 84.19%; level of acne worries (EPQ4) – 72.73; patients' social media/selfie' activity (EPQ5) – 51.38%; impact on real-life plans (EPQ6) – 44.66%; efforts to hide AV (EPQ7) – 72.73%; picked-on/judged due to AV (EPQ8) – 26.88%; ability to reach future goals (EPQ9) – 27.27%; sleep impact (EPQ11) – 27.67%; parent understanding of AV concerns (for patients<18yrs; EPQ10) – 84.16%. **Conclusion:** Moderate to severe AV burden/impact was observed in this prospective cohort of AV patients in the U.S. Emotional impact and social impact of AV were especially more pronounced among the AV population.

OBJECTIVE

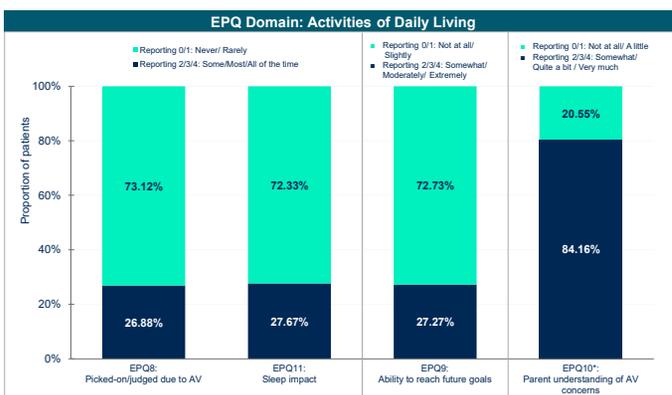
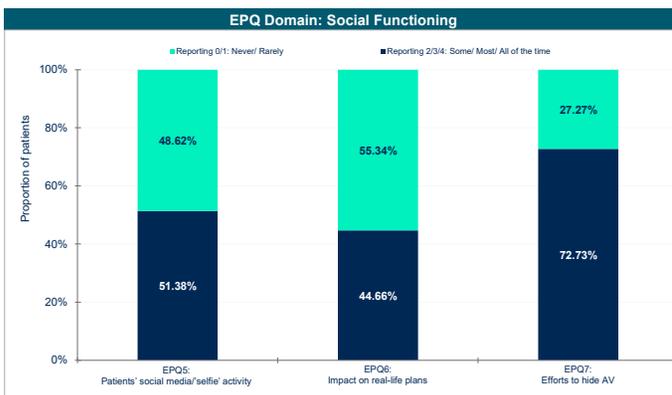
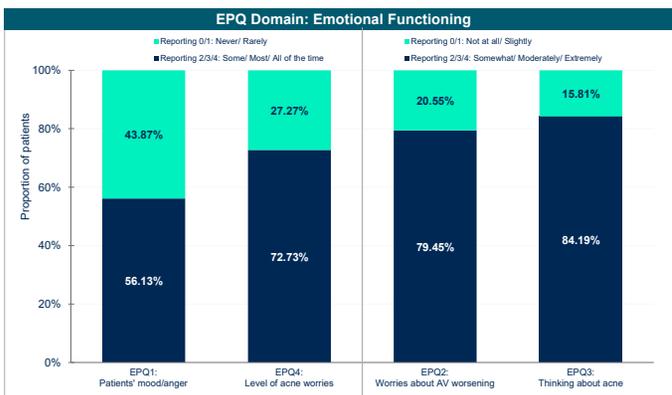
- Evaluate patient self-perceived AV symptoms and impact of AV on emotional/social functioning and ADL, among AV patients in community practices across the U.S.

METHODS

- Single-arm, prospective cohort study (PROSES: NCT04820673) was conducted with moderate-to-severe non-nodular AV patients ≥ 9yrs who were prescribed sarecycline in real-world U.S community practices.
- A total of 300 subjects were enrolled from 30 community practices across the U.S.
- Validated ASIS questionnaire (with Signs and Impact (emotional & social) domains) and an Expert Panel Questionnaire (EPQ; emotional functioning (items 1-4), social functioning (items 5-7), and ADL (items 8-11)) were completed by patients (>12yrs) and caregivers (for patients 9-11yrs) at baseline and week-12.
 - ASIS items are scored on a five-point adjectival response scale (score 0-4); higher scores indicate severe symptoms or negative impact of Acne.
 - EPQ items (1-9 & 11) were scored on five-point adjectival response scale (score: 0 (no burden/impact) – 4 (most burden/impact)); a higher EPQ score indicate severe symptoms or negative impact of AV.
 - EPQ item 10 was scored on five-point adjectival response scale (score: 0 (not at all) – 4 (very much), this question only asked to the pediatric/caregiver subgroup; higher score indicate better understanding.
- ASIS domain scores and proportion of patients reporting score=2/3/4 (moderate to high burden/impact) for individual EPQ items at baseline were evaluated, as observed.

RESULTS

Majority of patients reported moderate to severe AV burden in several areas associated with emotional and physical functioning, and ADL



Note: N=253
*Only asked for pediatric patient/caregiver subgroup (N=101).

Table 1: Baseline Patient Characteristics

		N=253
Age Group, %	Pediatric (<18 yrs)	39.92
	Adult (≥18 yrs)	60.08
Age Group, Mean	Pediatric (<18 yrs)	14.81
	Adult (≥18 yrs)	26.63
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

Table 2: Site Characteristics

		N=30
Current workplace, %	Private, office-based practice	100.00
	Hospital-based practice	0.00
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

Table 3: ASIS Domain Scores at Baseline Depicting Moderate to Severe AV Burden

ASIS Domain	Domain Scores at Baseline (N=253)
Signs	1.96
Impact	2.06
Emotional Impact	2.43
Social Impact	0.98

CONCLUSIONS

- Moderate to severe AV burden/impact was observed at study entry, in this prospective cohort of AV patients in the U.S. Emotional impact and social impact of AV were especially more pronounced among the AV population.