

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

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SYNOPSIS

Objective: Evaluate patient self-perceived AV symptoms and impact of AV on emotional/social functioning and ADL, among pediatric patients with AV in community practices across the U.S. **Methods:** Single-arm, prospective cohort study (PROSES) was conducted with moderate-to-severe non-nodular AV patients ≥ 9 yrs 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 (≥ 12 yrs) and caregivers (for patients 9-11 yrs) at baseline and week-12. All items were scored on five-point adjectival response scale (score: 0 (no burden/impact) – 4 (most burden/impact)); 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) for EPQ items at baseline for pediatric age strata (Grp1: age 9-11 yrs, Grp2: age 12-17 yrs) was analyzed. **Results:** A total of 101 pediatric patients with AV were included in the analysis. At baseline, patients reported moderate AV burden in most domains, as depicted by signs domain scores of Grp1: 2.00, Grp2: 1.92; emotional impact subdomain scores of Grp1: 2.00, Grp2: 2.02; social impact subdomain scores of Grp1: 1.13, Grp2: 0.77. From EPQ items, proportion of patients reporting score=2/3/4 (moderate to severe burden) within age strata at baseline were: patients' mood/anger (EPQ1)- Grp1: 25.00%, Grp2: 41.24%; worries about AV worsening (EPQ2)- Grp1: 50.00%, Grp2: 74.23%; thinking about acne (EPQ3)- Grp1: 50.00%, Grp2: 75.26%; level of acne worries (EPQ4)- Grp1: 50.00%, Grp2: 64.95%; patients' social media/'selfie' activity (EPQ5)- Grp1: 50.00%, Grp2: 37.11%; impact on real-life plans (EPQ6)- Grp1: 25.00%, Grp2: 27.84%; efforts to hide AV (EPQ7)- Grp1: 75.00%, Grp2: 63.92%; picked-on/judged due to AV (EPQ8)- Grp1: 25.00%, Grp2: 26.80%; ability to reach future goals (EPQ9)- Grp1: 25.00%, Grp2: 16.49%; parent understanding of AV concerns (EPQ10)- Grp1: 75.00%, Grp2: 82.47%; sleep impact (EPQ11)- Grp1: 50.00%, Grp2: 20.62%. **Conclusion:** Moderate to severe AV burden and psychosocial impact was observed in this prospective cohort of pediatric patients with AV in the U.S. Emotional impact and social impact of AV were more pronounced across the pediatric age groups.

OBJECTIVE

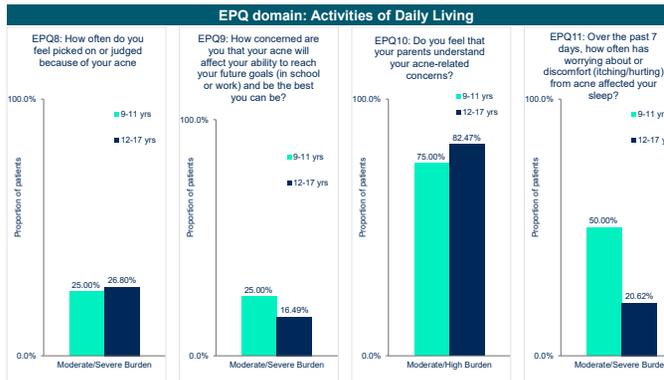
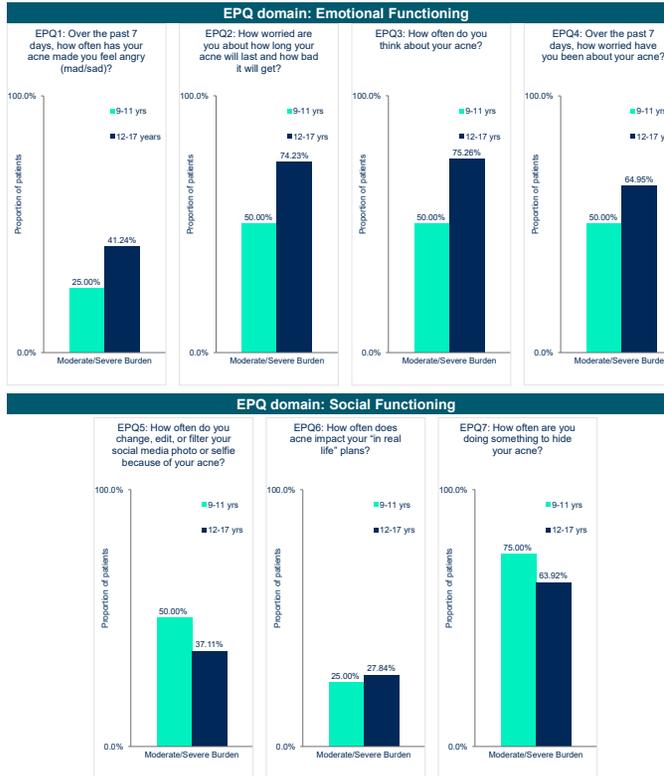
- Evaluate patient self-perceived AV symptoms and impact of AV on emotional/social functioning and ADL, among pediatric patients with AV in community practices across the U.S.

METHODS

- Single-arm, prospective cohort study (PROSES: NCT04820673) was conducted with moderate-to-severe non-nodular AV patients ≥ 9 yrs 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 (>12 yrs) and caregivers (for patients 9-11 yrs) 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)); 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 for pediatric age strata (Grp1: age 9-11 yrs, Grp2: age 12-17 yrs) were analyzed, as observed.

RESULTS

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



Note: Survey responses for pediatric patients 9-11 years old (N=4), were from caregivers of these patients. Survey responses for pediatric patients 12-17 years (N=97) were from patients themselves.
 Moderate to severe (high) burden/impact refers to a score of 2/3/4 for the EPQ items, as follows:
 • EPQ1, EP3, EPQ5, EPQ6, EPQ7, EPQ8, EPQ11: Some of the time (2), most of the time (3), all of the time (4)
 • EPQ2, EPQ4, EPQ9: Somewhat (2), moderately (3), extremely (4)
 • EPQ10: Somewhat (2), quite a bit (3), very much (4)

RESULTS

- 101 pediatric patients with data at week-12 were included in the final analyses.

Table 1: Pediatric Patient Demographics

Demographic	Group	N=101
Age, mean years		14.84
Gender, %	Male	49.17
	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
Academic Accomplishments, %	Pre-K – 5 th grade	3.45
	6 th grade – 8 th grade	19.83
	9 th grade – 12 th grade	73.26
	High school Diploma / Degree / Vocational School	2.59
U.S Region (home location), %	Freshmen in College	0.86
	Northeast	2.97
	Midwest	24.75
	West	11.88
	South	60.40

Table 2: ASIS Domain Scores at Baseline Depicting Moderate to Severe AV Burden

ASIS Domain	Group 1: 9-11 years (N=4)	Group 2: 12-17 years (N=97)
Signs	2.00	1.92
Impact	1.78	1.70
Emotional Impact	2.00	2.02
Social Impact	1.13	0.77

CONCLUSIONS

- Moderate to severe AV burden and psychosocial impact was observed in this prospective cohort of pediatric patients with AV in the U.S., at the beginning of PROSES study.
- Emotional impact and social impact of AV were more pronounced across the pediatric age groups.