

THE PATIENT-REPORTED BURDEN OF ALOPECIA AREATA BY CURRENT SEVERITY: A REAL-WORLD STUDY IN THE UNITED STATES

Russel Burge,¹ Peter Anderson,² Jennifer Austin,² James Piercy,² Laure Manuel,² Emily Edson-Heredia,¹ Jill McCollam,¹ Maryanne Senna³

¹Eli Lilly & Company, Indianapolis, USA; ²Adelphi Real World, Bollington, UK; ³Massachusetts General Hospital, Boston, Massachusetts, USA

BACKGROUND

- Alopecia Areata (AA) is an autoimmune non-scarring disease, associated with recurrent hair loss in patients that can be linked to a poor health-related quality of life (HRQoL) [1].
- Unlike in clinical trials, the use of patient-reported outcomes (PROs) is limited in real world practice [2]. Research shows how implementing PROs in real world healthcare practice can improve the overall care the patient receives [3].
- In addition, use of PROs in clinical practice can enhance patient centred healthcare through insights into patient's disease experience and outcome expectations, promoting empathy and advancing shared decision making between physician and patient [4,5].
- Previous research shows evidence of a significant disease burden for AA patients [6,7]. However, research into the effects of differing AA severity levels on patient-reported disease burden, and the impairment of patients' work productivity, is limited.
- This study builds on previous research by enhancing understanding of the patient-reported emotional, symptomatic, and functional burden of AA as well as work/activity impairment. Furthermore, the study contributes to understanding how this burden of the disease varies for AA patients when stratified by severity.

KEY RESULTS

Figure 1. Skindex-16 scores by physician-rated current AA severity

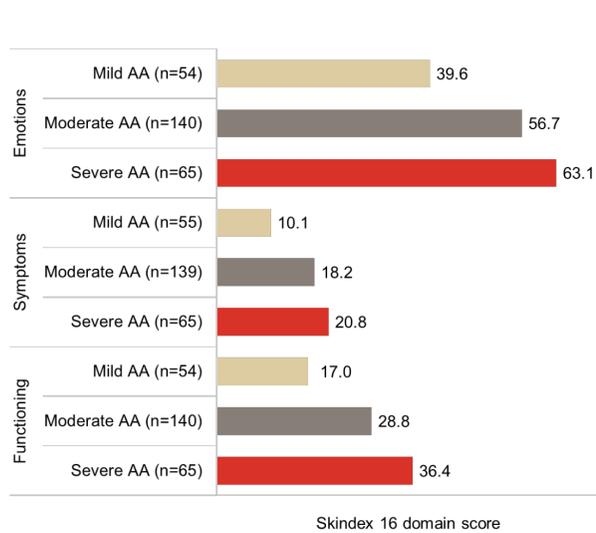


Figure 2. WPAI scores (percentage of total time impaired) by physician-rated current AA severity

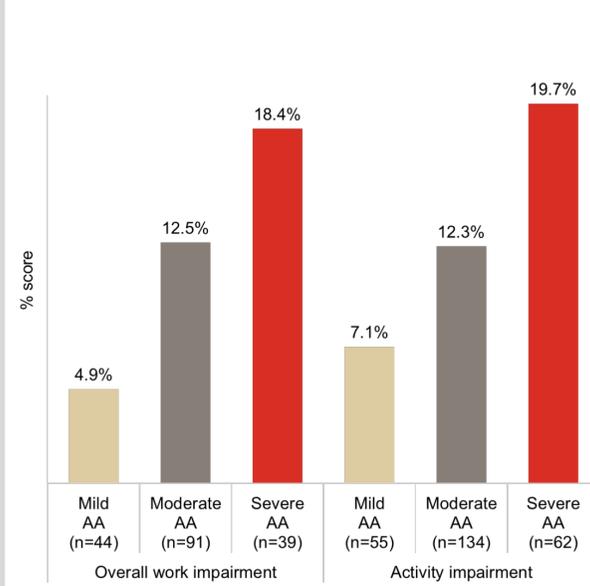
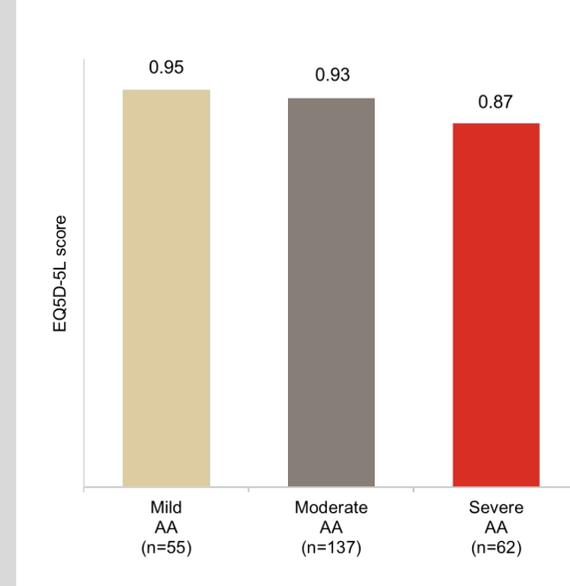


Figure 3. EQ5D-5L scores by physician-rated current AA severity



OBJECTIVE

- To utilise real-world evidence to understand patient-reported burden of AA by physician-rated assessment of patients' current AA severity.

CONCLUSIONS

- With increased severity of AA, patients reported greater burden of disease.
- The most impacted domains of HRQoL were emotions as measured by the Skindex-16 and activities outside of work as measured by the WPAI.
- Interventions which can prevent, delay, or reverse the progression to severe disease are likely to have the greatest impact on patients' HRQoL and emotional burden.

METHODS

Key Eligibility Criteria

Physician inclusion criteria

- Physician specialty identified as dermatologist.
- Actively involved in the drug management of adult AA patients (defined as 18 years of age or over).
- Typical monthly workload includes a minimum of 5 adult AA patients including at least 1 mild and 4 moderate or severe AA patients (at least 1 of these being severe).

Patient inclusion criteria

- ≥18 years.
- With a confirmed diagnosis of AA and currently moderate or severe or with a history of moderate/severe AA.
- Not currently involved in a clinical trial for AA.

Data Source

- Data were drawn from the 2019 AA Disease Specific Programme (DSP™), a point-in-time survey obtaining real world evidence from US dermatologists and AA patients between July and September 2019.
- Physicians completed patient record forms (PRFs) for 5 consulting adult AA patients, of which 1 was considered by their physician to have currently mild AA and 4 patients were considered to have either moderate or severe AA (with at least 1 severe patient). The severity of patients was rated subjectively by the physician based on their professional assessment of the patient using both the patient's medical history and observations made during the consultation.
- As well as the physician's subjective opinion of patients' current severity, the PRF captured detailed patient demographics.

Patient-Reported Outcomes

- Each patient was invited to complete a patient self-completed questionnaire (PSC). Using a check box, patients wishing to take part provided informed consent for use of their anonymized and aggregated data for research and publication.
- The PSC included the following PRO tools:
 - Skindex-16 AA: A validated 16-item scale assessing the impact of AA on HRQoL [8,9]. The Skindex-16 has 3 domains which include emotions, symptoms, and functioning. Scores for each domain range from 0 (no effect) to 100 (experience effect all the time). A higher score represents a higher burden of disease.

The Work Productivity and Activity Impairment (WPAI) index:

A 6-item validated PRO tool estimating health-related work productivity in patients. It assesses the effects of their condition over the last 7 days on percentage of time absent from work, percentage of productivity lost, percentage of overall work impairment, and percentage of overall daily activity impairment outside of employment [10]. The impairment to work and activity are calculated as percentages of total time impaired.

The EQ5D-5L:

Includes 5 dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression [11]. These result in a score between -0.594 and 1 with a higher score indicating better health.

- Statistical analysis was conducted using STATA version 16.1 [12]. Statistical analyses across severity groups were conducted using ANOVA testing.
- The DSP methodology has been published and validated [13-15].

RESULTS

- 90 dermatologists completed PRFs for 452 AA patients, of which 261 completed a PSC form and were included in this analysis.
- Among 261 patients who completed a PSC form, physicians considered 56 of the patients to have currently mild AA, 140 to have currently moderate AA and 65 to have currently severe AA. Demographic and clinical characteristics for each AA severity group are shown in Table 1.

Table 1. Patient demographics by AA severity (n=261)

	Mild AA (n=56)	Moderate AA (n=140)	Severe AA (n=65)
% of patient survey sample	21	54	25
mean age, Years (SD)	35.3 (11.6)	39.4 (13.5)	41.6 (14.7)
% male	61	46	48
mean BMI (SD), kg/m ²	25.0 (3.6)	26.1 (4.2)	26.7 (5.2)
% white/Caucasian	84	79	74
% employed	89	69	72

SD: standard deviation

- Figure 1 shows that for Skindex-16, patients reported experiencing significantly higher disease burden with increased physician-reported severity of AA.
- For the emotions domain, mean (SD) scores were 39.6 (26.3) for patients with mild AA, 56.6 (29.8) for patients with moderate AA, and 63.1 (31.9) for patients with severe AA (p<0.0001 across all severity groups).

DISCLOSURES

- RG, EEH, JM are employees of Eli Lilly & Co.; PA, JA, JP, LM are employees of Adelphi Real World; MS is an employee of Massachusetts General Hospital.
- This study was sponsored by Eli Lilly and Company. Medical writing services were provided by Simran Marwaha of Adelphi Real World and was funded by Eli Lilly and Company.

- For the symptoms domain, equivalent mean (SD) scores were mild 10.1 (17.9), moderate 18.2 (22.5), and severe 20.8 (26.2) (p=0.0265 across all severity groups).
- While for the functioning domain, mild, moderate, and severe AA mean (SD) scores were, respectively: 17.0 (23.7); 28.8 (29.3); and 36.4 (33.1) (p=0.0018 across all severity groups).
- Figure 2 shows that overall work and activity impairment due to AA increased with higher physician-rated severity.
- For the overall work impairment domain, mean (SD) scores were 4.9% (11.7%) for patients with mild AA, 12.5% (17.2%) for patients with moderate AA, and 18.4% (20.2%) for patients with severe AA (p=0.0013 across all severity groups).
- For the activity impairment domain, mean scores were 7.1% (14.0%) for patients with mild AA, 12.3% (16.0%) for patients with moderate AA, and 19.7% (23.5%) for patients with severe AA (p=0.0007 across all severity groups).
- Figure 3 shows that for the EQ5D-5L patients reported a lower quality of life with increasing physician-rated severity of AA.
- Mean (SD) EQ5D-5L scores were 0.95 (0.14) for patients with mild AA, 0.93 (0.13) for those with moderate AA, and 0.87 (0.21) for those with severe AA (p=0.0070 across all severity groups).

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