Real-World Assessment of Disease Characteristics and Clinical Outcomes in Alopecia Areata in a Global Noninterventional Observational Cohort (ADAAGIO)

Keith L. Davis, MA,[1] Andrew Messenger, MD, FRCP,[2] Sergio Vañó Galván, MD, PhD,[3] Helen Tran, PharmD,[4] Lynne Napatalung, MD, MA,[4,5] Kent A. Hanson, PharmD,[4] Ernest H. Law, PharmD, PhD[4]

[1] RTI Health Solutions, Research Triangle Park, NC, United States; [2] University of Sheffield, Sheffield, United Kingdom; [3] Trichology Unit of the Ramón y Cajal University Hospital and the Trichology and Hair Transplant Unit of Pedro Jaén Group Clinic, University of Alcalá, Madrid, Spain; [4] Pfizer, Inc., New York, NY, United States; [5] Icahn School of Medicine at Mount Sinai, New York, NY, United States

OBJECTIVE

- To describe patient characteristics, treatment patterns, and clinical outcomes of patients with alopecia areata (AA) with ≥ 50% hair loss of the scalp.

CONCLUSIONS

- This large, multinational retrospective cohort study highlights the wide array of treatment classes that may be applied in patients with AA with extensive hair loss in a real-world setting.
- Although patients in this study experienced a substantial absolute Severity of Alopecia Tool (SALT) score reduction, few patients achieved and subsequently sustained a clinically meaningful response of SALT ≤ 20.
- These findings highlight the potential suboptimal effectiveness of traditional treatment options that were utilized in this population.

CONTACT INFORMATION

Keith L. Davis, MA
Head, Health Economics
RTI Health Solutions
kldavis@rti.org

BACKGROUND

- AA is a chronic, relapsing autoimmune disease characterized by nonscarring hair loss that affects people of all ages, races, and genders.
- AA primarily affects the scalp but can also affect nails, eyelashes, eyebrows, and other hair follicles, presenting a high patient burden including psychosocial impacts.
- A range of medications with varying effectiveness are used to treat AA; however, few are supported by robust clinical evidence.
- There remains limited evidence on prevailing treatments, disease characteristics, and clinical outcomes of patients with AA in routine practice, particularly for those with extensive hair loss; this study sought to address this evidence gap.

METHODS

Study Design

- This was a retrospective chart review study conducted in the United Kingdom, France, Spain, and Germany. (Figure 1 presents the study design schema.)
- Chart reviews were performed by dermatologists from a multinational healthcare provider (HCP) research panel covering all major geographic regions in each country and from varying practice types (e.g., academic hospitals, community clinics).

Patient Selection Criteria

Inclusion Criteria

- Physician diagnosis of ≥ 50% hair loss of the scalp, including alopecia totalis (AT) or alopecia universalis (AU); the **study index date** was defined as date of de novo or progression to ≥50% scalp hair loss and was required to occur between 1 January 2015 and 31 December 2019.
- ≥ 6 months of available postindex follow-up (i.e., time to last clinic visit).
- ≥ 12 years of age at the index date; a target quota was applied to ensure that ≥ 20% of the patient sample included adolescents aged 12-17 years.
- Received continued active treatment for AA at the index date or initiated new active treatment for AA within 60 days after the index date.
- Had ≥ 1 additional visit following the index date in which the percentage of scalp hair loss was recorded.

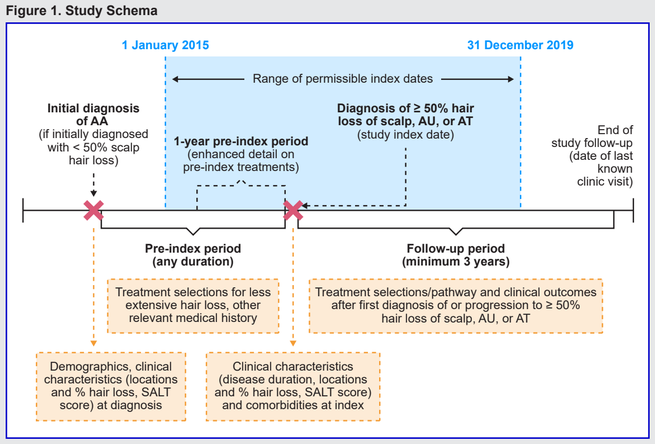
Exclusion Criteria

- Other types of alopecia or other diseases that can cause hair loss.
- Other scalp diseases that could interfere with assessment of hair loss/regrowth.

Study Variables and Analyses

- Background variables collected or derived were patient demographics, relevant clinical characteristics at the index date (baseline SALT score, AA type [patchy alopecia, AT, or AU], nonscalp sites of hair loss, mental health and atopic comorbidities, and baseline Dermatology Life Quality Index [DLQI] score), and AA treatments received from the index date through last follow-up.
- SALT score was defined as the weighted sum of location-specific percentage scalp hair loss: 40% for vertex percent hair loss, 18% for both the right and left profile percentage hair loss, and 24% for posterior percentage hair loss.
- Specific endpoints measured were:
  - Percentage change from baseline in absolute SALT score at 6-month intervals among patients with SALT measured within +/− 45 days of those timepoints.
  - Achievement of a SALT score of ≤ 20 that was sustained for at least 6 months without regression to SALT > 30.
- Analyses were descriptive and used univariate statistics; Kaplan-Meier methods were used to evaluate time to achieving sustained SALT ≤ 20.

Figure 1. Study Schema



RESULTS

Study Population and Demographics

- A total of 181 dermatologists contributed patient-level chart reviews; 52.5% of these practiced in an academic hospital.
- A total of 741 patients were identified for inclusion; median age at the index date was 27 years (32 years for adults, 15 years for adolescents), and 52.6% of patients were female (Table 1).

Clinical Characteristics

- Nearly two-thirds of patients (65.3%) presented (de novo) with ≥ 50% scalp hair loss at initial AA diagnosis (Table 2).
- Mean (SD) baseline SALT score at index was 63.5 (15.6), with 80.2% of patients having patchy alopecia and 19.8% having AT or AU.
- The most common sites of nonscalp hair loss at index were eyebrows (42.5%), eyelashes (33.5%), and beard (29.5% among males).

Baseline DLQI

- At index, 335 patients (45.2%) had a DLQI score measured; mean (SD) DLQI score was 19.2 (7.2), with 84.5% reporting either a large (DLQI 11-20) or extremely large (DLQI 21-30) impact of AA (Figure 2).
- A larger proportion of adolescents (60.5%) than adults (39.8%) had a baseline DLQI of 21-30 (extremely large effect on life quality).

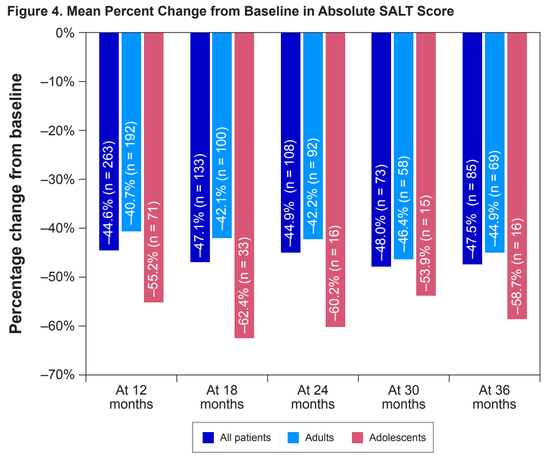
AA Treatments

- Topical corticosteroids were the most common treatment observed from the index date through all available postindex follow-up, with 55.6% of patients receiving ≥ 1 course and a median cumulative postindex exposure of 4 months (Figure 3).
- Intralesional corticosteroids (22.5%), systemic immunosuppressants (22.0%), and oral (17.3%) or topical (19.4%) minoxidil were also common.

SALT Endpoints

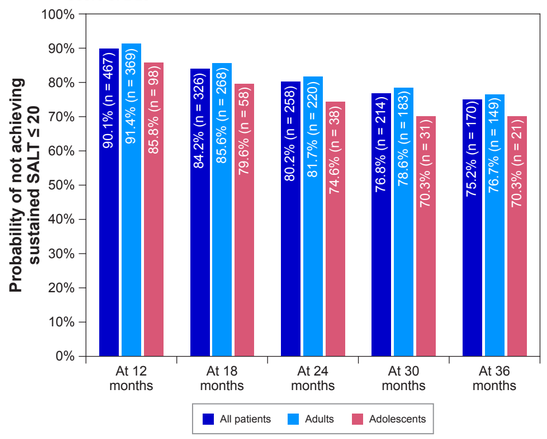
- Among patients with a SALT score measured at 12 months following index, mean (SD) absolute SALT reduction was −44.6% (37.3%) from baseline (Figure 4).
- Mean percent change in SALT score did not vary substantially by timepoint at which measurements were taken.
- At 12 and 24 months postindex, most patients (90.1% at 12 months, 80.2% at 24 months) failed to achieve a SALT score ≤ 20 that was sustained for ≥ 6 months (Figure 5).

Figure 4. Mean Percent Change from Baseline in Absolute SALT Score



Note: SALT score change from baseline to each timepoint following index reported only among patients with a follow-up SALT score measurement within +/- 45 days of the timepoint of interest. Cohort denominator shown in parentheses inside data bar.

Figure 5. Kaplan-Meier Landmark Probabilities of Failing to Achieve Sustained SALT Score of ≤ 20



Note: Numbers in parentheses on each data bar are number still at risk at each timepoint.

Table 1. Patient Demographics

	All patients		Age group: Adults		Age group: Adolescents	
Total patients, n, %	**741**	**100%**	**570**	**100%**	**171**	**100%**
Country, n, %						
United Kingdom	220	29.7%	160	28.1%	60	35.1%
France	97	13.1%	92	16.1%	5	2.9%
Germany	210	28.3%	160	28.1%	50	29.2%
Spain	214	28.9%	158	27.7%	56	32.8%
Age at study index date, years						
Mean, SD	29.5	13.1	33.9	11.7	14.8	1.4
Median	27		32		15	
Min, max	12	81	18	81	12	17
Sex, n, %						
Female	390	52.6%	293	51.4%	97	56.7%
Male	346	46.7%	274	48.1%	72	42.1%
Nonbinary	5	0.7%	3	0.5%	2	1.2%
Race/ethnicity, n, %						
African/Black	50	6.8%	37	6.5%	13	7.6%
East Asian[a]	41	5.5%	32	5.6%	9	5.3%
South Asian[b]	29	3.9%	22	3.9%	7	4.1%
Middle Eastern	35	4.7%	30	5.3%	5	2.9%
Multi-race/ethnicity	33	4.5%	24	4.2%	9	5.3%
White/Caucasian	546	73.7%	424	74.4%	122	71.4%
Other/unknown	7	0.9%	1	0.2%	6	3.5%

SD = standard deviation.
[a] East Asia defined as Mainland China, Hong Kong, Macau, Taiwan, Japan, Mongolia, North Korea, and South Korea.
[b] South Asia defined as India, Pakistan, Bangladesh, Nepal, Bhutan, the Maldives, and Sri Lanka.

Table 2. Clinical Characteristics

	All patients		Age group: Adults		Age group: Adolescents	
Total patients, n, %	741	100%	570	100%	171	100%
At initial AA diagnosis, patient presented with ≥ 50% scalp hair loss, n, %						
Yes (diagnosis date = index date)	484	65.3%	366	64.2%	118	69.0%
No (diagnosis date < index date)	257	34.7%	204	35.8%	53	31.0%
AA type at the study index date, n, %						
Patchy alopecia	594	80.2%	450	79.0%	144	84.2%
Alopecia totalis	100	13.5%	79	13.9%	21	12.3%
Alopecia universalis	47	6.3%	41	7.2%	6	3.5%
SALT score at the study index date						
Mean, SD	63.5	15.6	64.1	15.8	61.4	14.7
Median	56		57		55	
Min, max	50	100	50	100	50	100
Other sites of hair loss/involvement at the study index date, n, %						
Eyebrows	315	42.5%	243	42.6%	72	42.1%
Eyelashes	248	33.5%	191	33.5%	57	33.3%
Beard (males only)	102	29.5%	85	31.0%	17	23.6%
Extremities	82	11.1%	63	11.1%	19	11.1%
Torso	72	9.7%	63	11.1%	9	5.3%
Pubic areas	82	11.1%	66	11.6%	16	9.4%
No body hair loss at any location	492	66.4%	374	65.6%	118	69.0%
Nail involvement	106	14.3%	85	14.9%	21	12.3%
Mental health comorbidities present/ongoing at index, n, %						
Anxiety	131	17.7%	97	17.0%	34	19.9%
Obsessive-compulsive disorder	17	2.3%	14	2.5%	3	1.8%
Sleep disorder	24	3.2%	22	3.9%	2	1.2%
Depression	56	7.6%	50	8.8%	6	3.5%
Other mental health comorbidity[a]	18	2.4%	16	2.9%	2	1.2%
Atopic comorbidities present/ongoing at index, n, %						
Atopic dermatitis	47	6.3%	38	6.7%	9	5.3%
Allergic rhinitis	57	7.7%	43	7.5%	14	8.2%
Asthma	38	5.1%	27	4.7%	11	6.4%
Other atopic diseases not otherwise specified	6	0.8%	2	0.4%	4	2.3%

[a] Other mental health comorbidity includes bipolar disorder, alexithymia, schizophrenia, attention deficit disorder, and personality disorder.

Figure 2. Baseline DLQI Score

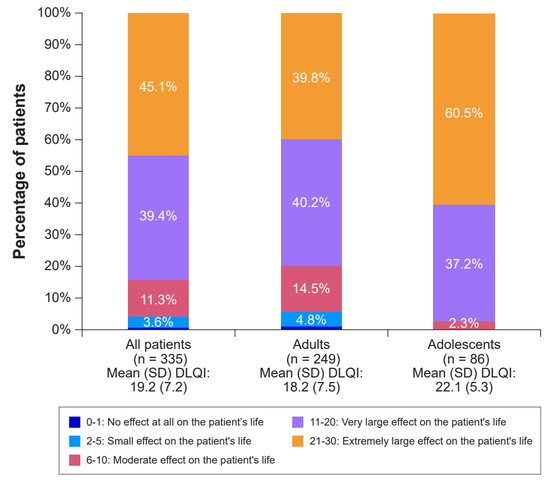
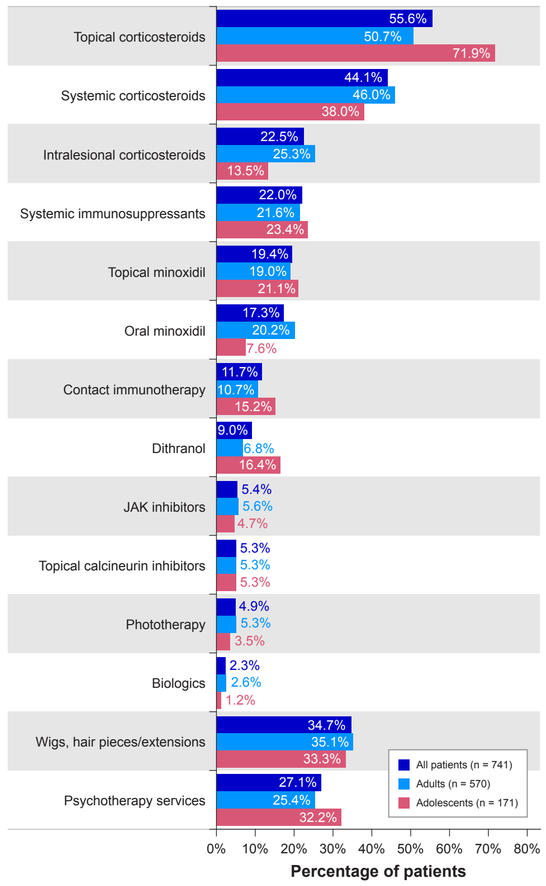


Figure 3. Postindex AA Treatments Received



LIMITATIONS

- Medical records included in this study were from HCPs who were willing to participate; our population thus represents a convenience sample that may not be generalizable to all physicians who treat patients with AA.
- As patients were required to have ≥ 1 postindex follow-up visit, there is potential for immortal time bias; this may further limit the generalizability of the findings.
- Although a minimum 20% sampling quota was applied for adolescents, this quota could not be met for France due to lower-than-expected recruitment.
- Analyses of longer-term clinical endpoints (such as SALT endpoints beyond 18 months postindex) were subject to the limitations of incomplete follow-up and early censoring. The potential for nonrandom censoring may limit the robustness of Kaplan-Meier estimates of these endpoints.

Electronic Poster

An electronic version of this poster may be obtained by scanning this QR code with your smartphone app. Copies of this poster obtained through the QR Code are for personal use only and may not be reproduced without permission from WCH23 and the author of this poster. To request permission or to ask questions about the poster please contact kldavis@rti.org.

DISCLOSURES

This study was funded by Pfizer, Inc.

Presented at: Winter Clinical Dermatology Conference – Hawaii; 12-17 January 2024; Maui, HI