Overview About the burden of Alopecia Areata And a Local Data in our Region

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Alopecia Areata As Auto Immune Disease

Alopecia Areata Is an Autoimmune Disease1

- Alopecia areata is characterized by nonscarring hair loss, which occurs most commonly on the scalp, but eyebrows, eyelashes, facial and body hair can also be affected[1]
- Pathogenesis is thought to be related to loss of immune privilege of the hair follicle[2-4]
- Histopathologic hallmarks include peribulbar inflammation and hair follicle miniaturization[5]
- Course is unpredictable, with periods of hair loss and spontaneous hair growth, or rapidly progressive hair loss leading to extensive and persistent absence of hair on the scalp, face, or body[1,6]

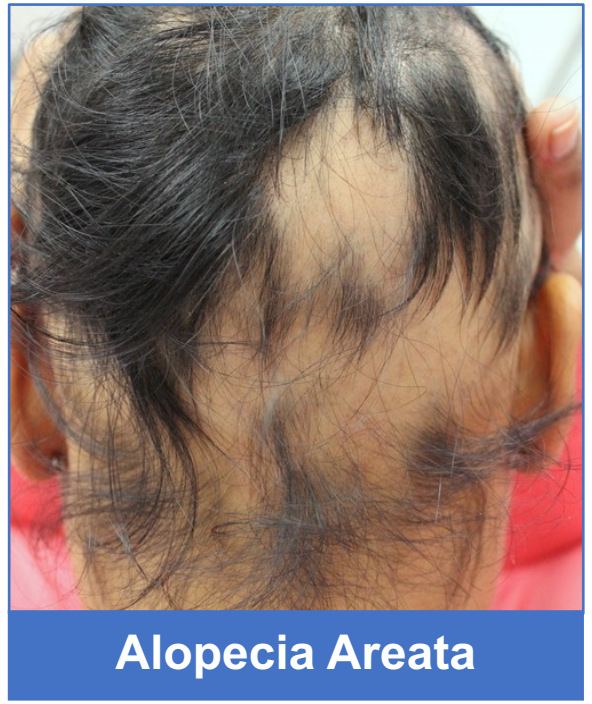

Image supplied with permission by the Canadian Hair Loss Foundation.

1. Pratt CH, et al. *Nat Rev Dis Primers*. 2017;3:17011. doi:10.1038/nrdp.2017.11. **2.** Ito T. *Clin Dev Immunol*. 2013;2013:348546. doi:10.1155/2013/348546. **3.** Ito T, et al. *Exp Dermatol*. 2014;23(11):787-791. **4.** Paus R, et al. *J Investig Dermatol Symp Proc*. 2018;19(1):S12-S17. **5.** Darwin E, et al. *Int J Trichology*. 2018;10(2):51-60. **6.** Cranwell WC, et al. *Australas J Dermatol*. 2019;60(2):163-170.

Alopecia Areata Encompasses a Spectrum of Hair Loss[1]

Patchy Alopecia Areata[1]	Alopecia Totalis[1,2]	Alopecia Universalis[1,3]
One or multiple patches of hair loss (conjoined or separate)	Total or near-total loss of hair on the scalp	Total or near-total loss of hair on the entire body

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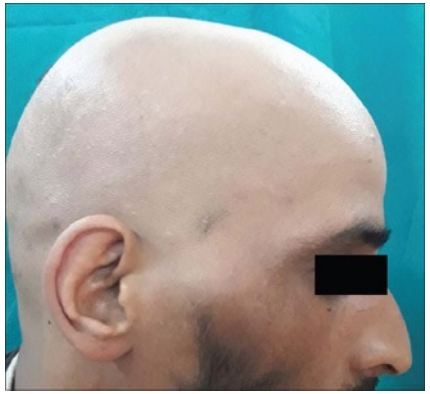
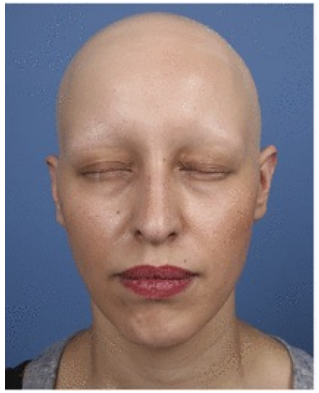


From Rehman F, et al. *Int J Trichology*. 2019;11(2):49-57. © 2019 International Journal of Trichology, licensed under CC BY-NC-SA 4.0



From Leussink VI, et al. *Neurol Neuroimmunol Neuroinflamm.* 2018;5(3):e454. doi:10.1212/NXI.0000000000000454. Copyright © 2018 The Author(s). Published by Wolters Kluwer Health, Inc. on behalf of the American Academy of Neurology, licensed under CC BY-NC-ND 4.0.

Other AA presentations include[1]:

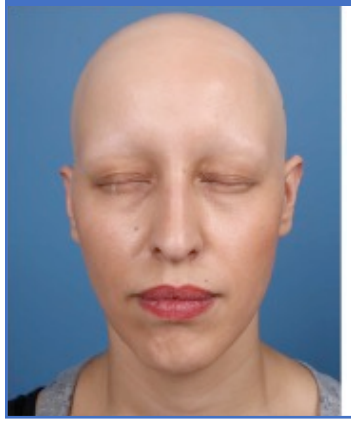
- **Alopecia incognita:** diffuse, abrupt hair loss without nail involvement
- **Ophiasis:** hair loss observed in a band along the circumference of the head
- **Sisaipho:** extensive hair loss except around the periphery of the scalp

1. Pratt CH, et al. *Nat Rev Dis Primers*. 2017;3:17011. doi:10.1038/nrdp.2017.11. **2.** Rehman F, et al. *Int J Trichology*. 2019;11(2):49-57. **3.** Leussink VI, et al. *Neurol Neuroimmunol Neuroinflamm.* 2018;5(3):e454. doi:10.1212/NXI.0000000000000454.

Although Alopecia Areata Most Often Occurs on the Scalp, Any Hair-Bearing Skin May Be Affected[1]

- Eyebrows and eyelashes may be affected in addition to the scalp or alone[1]
- Some patients also experience nail abnormalities (eg, fine stippled pitting and/or roughening of the nail plate with longitudinal striations)[1]

Loss of hair from areas other than the scalp has been reported to have a functional impact[2,3]:



- Water, sweat, sand, and other debris may get into eyes more easily without eyebrows/eyelashes
- Loss of nose hair may contribute to rhinorrhea and sneezing

Up to 64% of patients with AA in one survey reported nail involvement[4]

Image supplied with permission by DermNet New Zealand.

1. Pratt CH, et al. *Nat Rev Dis Primers.* 2017;3:17011. doi:10.1038/nrdp.2017.11. **2.** US Food and Drug Administration. https://www.fda.gov/media/112100/download. Published March 2018. Accessed Feb 15, 2022. **3.** Leussink VI, et al. *Neurol Neuroimmunol Neuroinflamm.* 2018;5(3):e454. doi:10.1212/NXI.0000000000000454. **4.** Roest YBM et al. *Acta Derm Venereol.* 2018;98(2):212-217.

Alopecia Areata Disease Burden

Worldwide

- Global prevalence of AA is ~2%[1]
  - AA prevalence appears to have increased since 2000 and significant regional differences have been reported[1]
- Estimated incidence of AA from hospital-based studies around the world range from 0.6% to 3.8%[2–5]
- AA prevalence is significantly higher in children than in adults (1.92% vs. 1.47%, $p<0.0001$)[1]

US

- Lifetime incidence of AA from US population studies has been reported in the range 1.7–2.1% (data from 1975–1989 and 1990–2009)[6,7]
  - In a recent (2017) large cross-sectional survey (US), self-reported lifetime prevalence was 2.51%[8]
- Estimated point prevalence of AA in the US has been reported to be 0.1–0.2% (data from 1971–1974); however, from recent data (2017) the self-reported point prevalence is 1.14%[8,9]

AA, alopecia areata.
1. Lee HH, et al. *J Am Acad Dermatol*. 2020;82(3):675–82. 2. Guzmán-Sánchez DA, et al. *Int J Dermatol*. 2007;46(12):1308–10. 3. Price VH. *J Invest Dermatol*. 1991; 96(5):68S.
4. Sharma VK, et al. *Int J Dermatol*. 1996;35(1):22–7. 5. Tan E, et al. *Int J Dermatol*. 2002;41(11):748–53. 6. Mirzoyev SA, et al. *J Invest Dermatol*. 2014;134(4):1141–2.
7. Safavi KH, et al. *Mayo Clin Proc*. 1995;70(7):628–33. 8. Benigno M, et al. *Clin Cosmet Investig Dermatol*. 2020;13:259–66. 9. Safavi K. *Arch Dermatol*. 1992;128(5):702.

Demographics

GENDER

- Although hospital-based studies show conflicting results, population studies show no difference in the incidence of AA by gender[1–3]
  - However, females have been reported to have higher rates of extensive AA, comorbid nail involvement and concomitant autoimmune disease[4,5]

AGE

- Onset of AA may be at any age, but it develops in most patients (83–88%) before the age of 40 years[3]

RACE

- AA can affect people of any race/ethnicity[6]
  - In a US study, AA was reported to occur more frequently in African American patients, followed by Caucasian patients then Asian patients[6]
  - In a UK study, non-white patients were more likely to present with AA than white patients, especially Asian patients[7]

AA, alopecia areata.

1. Mirzoyev SA, et al. *J Invest Dermatol*. 2014;134(4):1141–2. 2. Safavi KH, et al. *Mayo Clin Proc*. 1995;70(7):628–33. 3. Villasante Fricke AC, Miteva M. *Clin Cosmet Investig Dermatol*. 2015;8:397–403.
4. Tan E, et al. *Int J Dermatol*. 2002;41(11):748–53. 5. Lundin M, et al. *J Drugs Dermatol*. 2014;13(4):409–13. 6. Lee H, et al. *J Am Acad Dermatol*. 2020;83(4):1064–70. 7. Harries M, et al. *Br J Dermatol*. 2021 Jul 6. doi: 10.1111/bjd.20628. Epub ahead of print.

Alopecia Areata May Occur as an Acute or Chronic Disorder[1]

Alopecia areata can be acute and self-limiting (ie, 1 to 5 patches that resolve within 6 to 12 months)

- However, these patients may experience a relapse of alopecia areata in the future

Alopecia areata can also be chronic, defined as duration of disease >1 year

- It may present as multiple patches that relapse and remit over many years, or progress to total hair loss of the scalp, or universal loss of every terminal hair on the body

Cranwell WC, et al. *Australas J Dermatol*. 2019;60(2):163-170.

Certain Factors Are Associated With a Poor Prognosis in Alopecia Areata[1,2]

- Negative prognostic factors include:
  - Increased disease severity (extent of scalp hair loss) at onset[3]
  - Familial or personal history of alopecia areata or autoimmune/atopic disease[4,5]
  - Younger age of onset[4]
  - Nail involvement[2,4]
  - Rapid progression of hair loss[6]
  - Disease duration of ≥1 year[1,4]
- Patients with alopecia areata that persists for >1 year are more likely to develop additional areas of hair loss[7]
  - Remission might occur spontaneously in patients with <1 year disease duration and limited patchy hair loss [1]
- Long-standing, extensive alopecia areata has a high treatment failure rate[1]

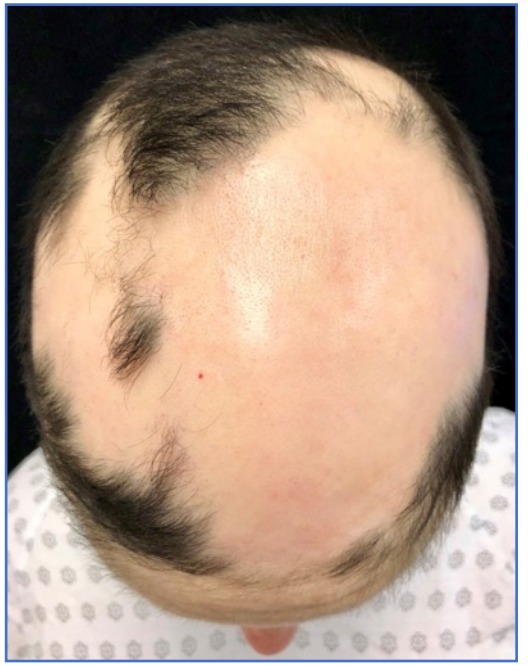


Photo courtesy of Dr Brett King.

1. Pratt CH, et al. *Nat Rev Dis Primers*. 2017;3:17011. doi:10.1038/nrdp.2017.11. **2.** Villasante Fricke AC, Miteva M. *Clin Cosmet Investig Dermatol*. 2015;8:397-403. doi:10.2147/CCID.S53985. **3.** Tosti A, et al. *J Am Acad Dermatol*. 2006;55(3):438-441. **4.** Akhyani M, et al. *Iran J Dermatol*. 2011;14:6-11. **5.** Goh C, et al. *J Eur Acad Dermatol Venerol*. 2006;20(9):1055-1060. **6.** Cranwell WC, et al. *Australas J Dermatol*. 2019;60(2):163-170.

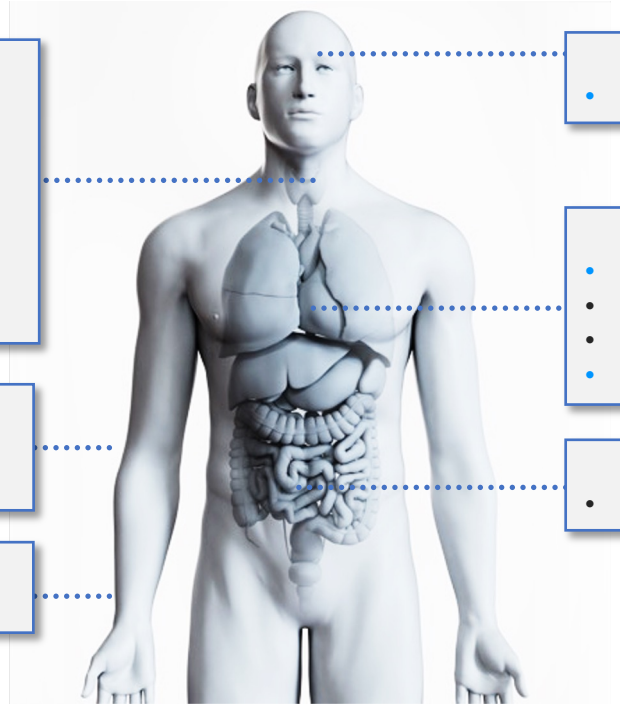
Alopecia Areata Is Associated With Multiple Comorbid Conditions[1]

Common Comorbidities Observed in Multiple Studies of Individuals With Alopecia Areata

Autoimmune
- **Thyroid disease** (14.6% to 18.8%)[1,2,a]
- Diabetes mellitus (11.1%)[1]
- Psoriasis and psoriatic arthritis (6.3%)[1]
- Systemic lupus erythematosus (4.3%)[1]
- Vitiligo (2.8%)[1]
- Rheumatoid arthritis (3.9%)[1]
- Inflammatory bowel disease (2.0%)[1]

Atopy
- Allergic rhinitis, asthma, and/or eczema (38.2%)[1]
- **Eczema** (14.2%)[2,a]

Other Skin
- Contact dermatitis and other eczema (35.9%)[1]



Mental Health
- **Depression** or **anxiety** (25.5%)[1]

Cardiovascular/Blood
- **Vitamin D deficiency** (39.0%)[2,a]
- Hyperlipidemia (24.5%)[1,b]
- Hypertension (21.9%)[1,b]
- **Anemia** (16.8% to 19.6%)[1,2,a]

Gastrointestinal
- Gastroesophageal reflux disease (17.3%)[1,b]

[a]More common in individuals with AA than in healthy controls.[2] [b]According to study authors, this may be related to steroid use for the treatment of alopecia areata.[1]

Based on multiple studies, thyroid disease, eczema, vitamin D deficiency, and anemia are common in alopecia areata, and there may be psychiatric (eg, depression and anxiety) and other autoimmune comorbidity associated with alopecia areata.[1,2]

1. Huang KP, et al. *JAMA Dermatol.* 2013;149(7):789-794. **2.** Conic RZ, et al. *J Am Acad Dermatol.* 2017;76(4):755-757.

Quality of Life (QoL) and its Assessment

Patients with AA consistently demonstrate impaired health-related QoL (HRQoL)[1]

- Up to 77% of adult AA patients reported impaired HRQoL based on results from a DLQI survey[2]
  - DLQI scores of AA patients were similar to those seen in patients with other chronic skin diseases such as AD and psoriasis[1]
  - However, the DLQI is not appropriate for AA patients because it has item wording asking about “skin” rather than “hair” and includes a question on skin symptoms[3,4]
  - A proprietary PRO assessment tool (AAPPO) was developed to measure the extent of hair loss, emotional symptoms and activity limitations in AA patients[3]

Click to add text

- Meta-analysis of studies using the generic SF-36 measure showed the greatest impairments of HRQoL in AA patients in the domains of role-emotional, mental health and vitality[5]
- Scalp involvement, anxiety and depression are predictors of lower HRQoL[5]

AA, alopecia areata; AAPPO, Alopecia Areata Patient Priority Outcomes; AD, atopic dermatitis; DLQI, Dermatology Life Quality Index; HRQoL, health-related quality of life; PRO, patient-reported outcome; QoL, quality of life; SF-36, Short Form-36.

1. Liu LY, et al. *J Am Acad Dermatol*. 2016;75(4):806–12.e3. 2. Liu LY, et al. *J Am Acad Dermatol*. 2018;79(3):556–8.e1. 3. Winnette R, et al. *Dermatol Ther (Heidelb)* 2021;11(2):599–613. 4. Finlay AY, Khan GK. *Clin Exp Dermatol*. 1994;19(3):210–6. 5. Rencz F, et al. *Br J Dermatol*. 2016;175(3):561–71.

Impact of AA on the Lives of Family Members

AA can have a significant negative impact on the HRQoL of family members[1,2]

- Family members of AA sufferers have been shown to have impaired HRQoL[1]
  - In family members of AA sufferers, emotional distress is a frequent finding and often severe[1]
- Poor FDLQI scores of AA family members may be significantly associated with depression[1]
- Families of children with AA have worse FDLQI scores than families of adults with AA[1]
- Medical costs of AA treatment may be a source of stress for patients and their families[1]
- Patients themselves describe the emotional impact of AA not only on themselves but also on their family members[2]

"Sadness, anxiety, and deep feelings of helplessness have impacted not only [my daughter], but our entire family"[2]

AA, alopecia areata; FDLQI, Family Dermatology Life Quality Index; HRQoL, health-related quality of life.

1. Liu LY, et al. *J Am Acad Dermatol*. 2018;79(3):556–8.e551. 2. U.S. Food and Drug Administration. The Voice of the Patient: Alopecia Areata. March 2018. Available at: https://www.fda.gov/files/about%20fda/published/Alopecia-Areata--The-Voice-of-the-Patient.pdf. [Last accessed August 2021].

Patients May Also Suffer From Psychosocial Burden of the Disease

- Patients with AA may experience psychosocial impact, low self-esteem, and challenges with relationships, career, and school[1,2]
- Results based on a 25-item quantitative-qualitative online survey with responses from 216 patients[1]

71% of patients experience **impact on self-esteem**

69% of patients **feel anxious** in social situations

"The biggest challenge was the hit to my self-esteem. It impacted me physically and mentally[1]" – **AA Patient**

45% of employed patients reported **missing time from work***

"It has affected me financially. I quit my job because I couldn't handle the stress of wearing a wig all day[1]" – **AA Patient**

51% of patients attending school reported **missing time from school†**

"I looked different, was very insecure and an easy target to make fun of. That year I did have to stay back due to academic failure because I didn't attend school due to bullying[1]" – **AA Patient**

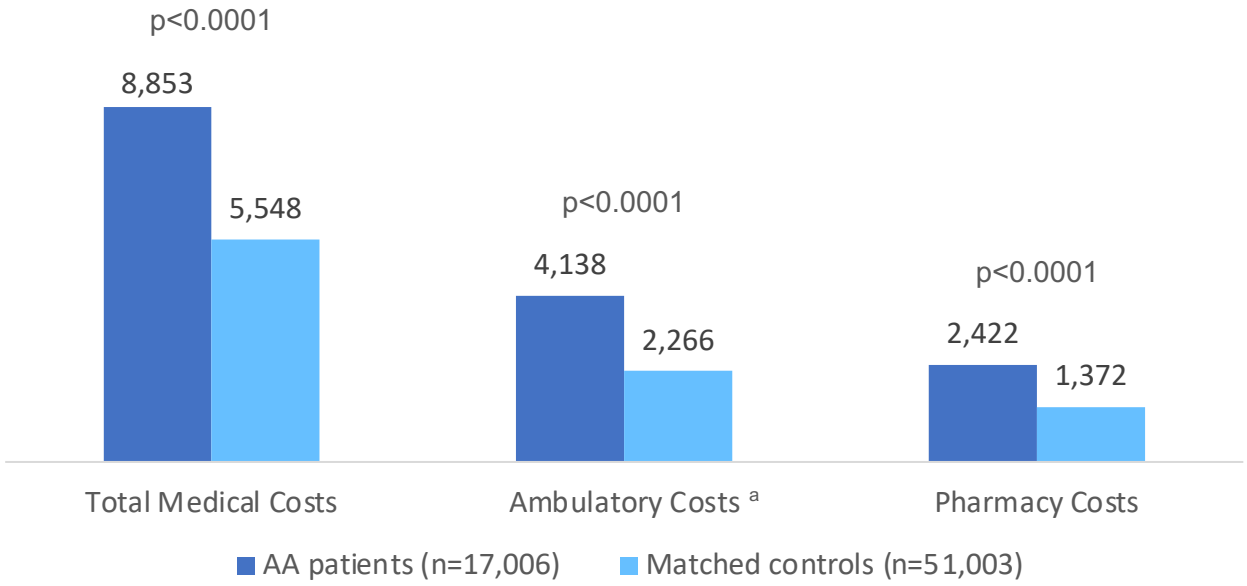
*45% of the 132 responders that were employed † 51% of 47 responders that were attending school.

1. Mesinkovska N, et al. *J Investig Dermatol Symp Proc.* 2020;20:S62-S68. **2.** Aldhouse NVJ, et al. *J Patient Rep Outcomes.* 2020;4(1):76.

Economic Impact of AA

Medical costs are significantly higher in AA patients versus matched controls in a US managed care population

RWE Claims Study: mean all-cause 12-month post-index direct medical costs ($)



- Among AA patients, those with alopecia totalis or alopecia universalis (n=1,482) had significantly higher total medical costs than those with AA only (n=15,524)
  - $12,654 vs. $8,490 (p<0.0001)

AA, alopecia areata; RWE, Real World Evidence; US, United States.
[a]Ambulatory costs refer to non-hospitalized/outpatient costs.
Xenakis J, et al. *Value in health*. 2019;22(Suppl 2):S379.

Assessing Disease Severity of Alopecia Areata

Various Tools Exist to Evaluate Patients With AA Based on Different Considerations1

In clinical practice, there are numerous ways to evaluate scalp hair loss, including[2]

- Visual inspection
- Hair pull test
- Dermoscopy
- Biopsy in rare cases where physical examination and clinical course are insufficient for diagnosis

In addition, a new tool, Alopecia Areata Scale (AASc), has been developed as an option for use in clinical practice to assess disease severity[1]

In AA clinical trials, the Severity of Alopecia Tool (SALT) score is often used to determine the amount of scalp hair loss[1]

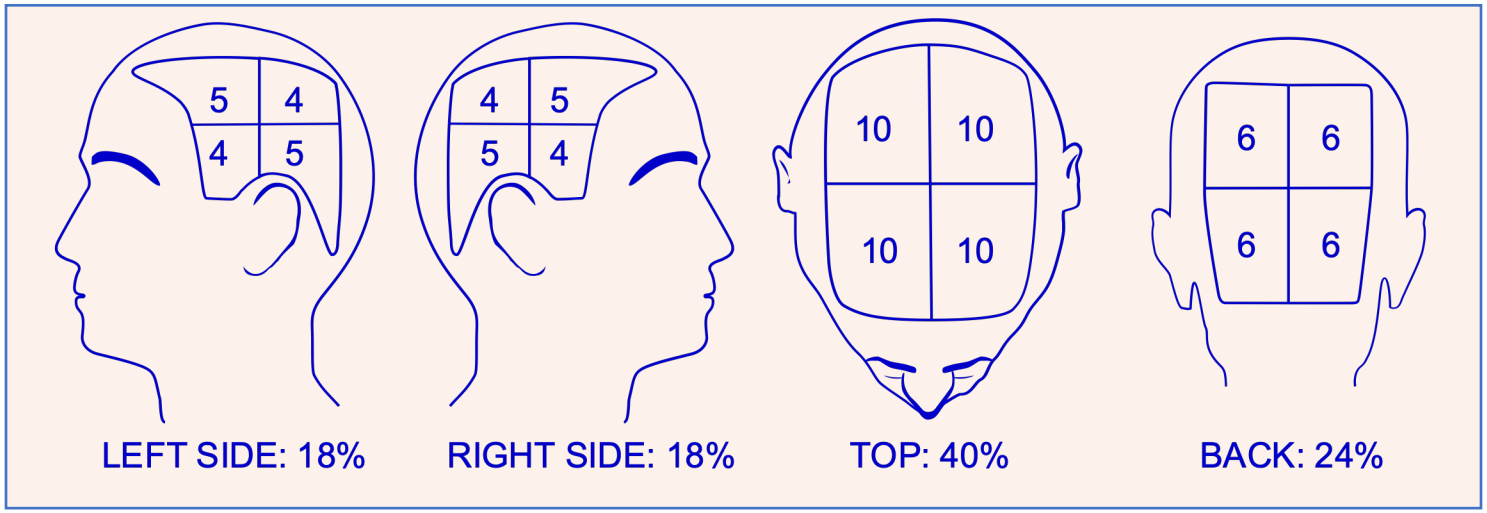
In addition, tools are available to assess eyebrow and eyelash involvement, including eyebrow assessment (EBA) and eyelash assessment (ELA)[1,]

Beyond extent of hair loss, depression, anxiety, and psychosocial impact related to AA may be important in evaluating patients with AA[1]

1. King BA, et al. *J Am Acad Dermatol.* 2022;86(2)359-364. **2.** Cranwell WC, et al. *Australas J Dermatol.* 2019;60(2):163-170..

The Severity of Alopecia Tool (SALT) Score Is One of the Standardized Methods to Assess Scalp Hair Loss

- The SALT score is a clinically validated tool* that assesses disease severity and can aid in tracking treatment response[1]
- The SALT score is determined by visual inspection of the patient's scalp[1]
  - The SALT visual aid is used to determine the percentage area of terminal hair loss



Reprinted from J Am Acad Dermatol. 51/3, Olsen EA, et al. Alopecia areata investigational assessment guidelines—Part II, 440-447, Copyright 2004, with permission from the American Academy of Dermatology, Inc.[1]

*There are other validated tools available to assess scalp hair loss.[2]

1. Olsen EA, et al. *J Am Acad Dermatol*. 2004;51(3):440-447. **2.** Olsen EA, Canfield D. *J Am Acad Dermatol*. 2016;75(6):1268-1270.

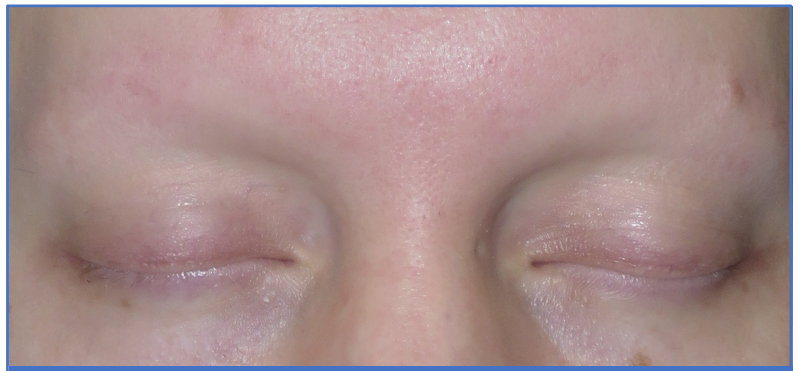
Assessment of Eyebrows

- **Eyebrow assessment scale (EBA)*** is one of the numeric rating scales developed to characterize eyebrow hair loss by visual inspection

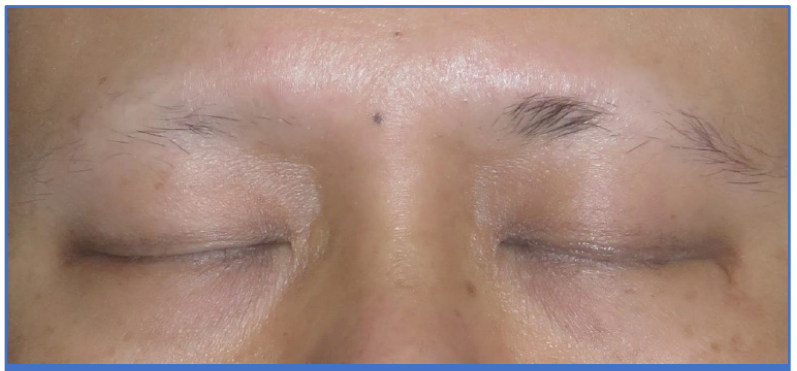
Score	Description
0	**NONE EYEBROW** • No eyebrow hair
1	**MINIMAL EYEBROW** • Normal or decreased density of one or both eyebrows with large gap(s) • Severely decreased density of one or both eyebrows with or without gap(s)
2	**MODERATE EYEBROW** • Normal density of both eyebrows with short gap(s) that does not significantly distort the appearance of the eyebrows, OR • Mildly decreased density of eyebrows with or without short gap(s), OR • Moderately decreased density of eyebrows without short gap(s). There is visual definition of eyebrows at a distance of 3 feet
3	**NORMAL EYEBROW** • Normal density of both right and left eyebrows spanning usual length (ie, from glabella to near temple) and width; there are no gap(s)

***There are other tools to assess eyebrows available, which feature similar scoring but different descriptions**

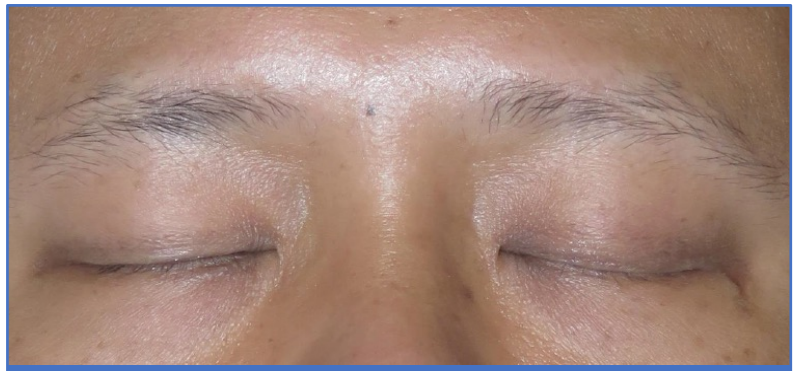
Assessment of Eyebrows (cont'd)*



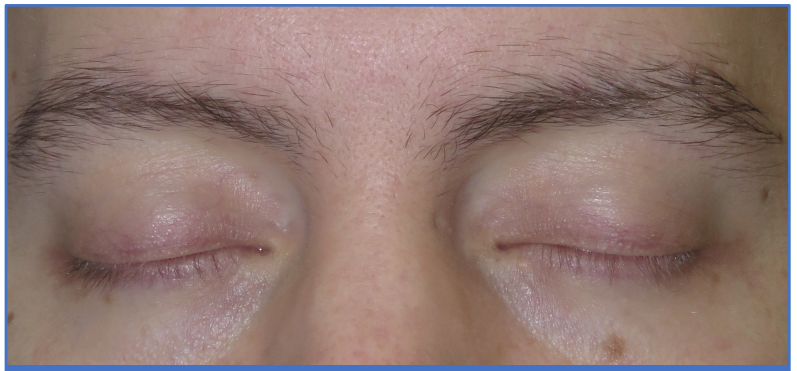
None Eyebrow (EBA = 0)



Minimal Eyebrow (EBA = 1)



Moderate Eyebrow (EBA = 2)



Normal Eyebrow (EBA = 3)

*Patient visuals from study B7981015 (Each patient's consent was provided for use of photograph).
EBA, eyebrow assessment.
Data on file. Pfizer, New York, NY.

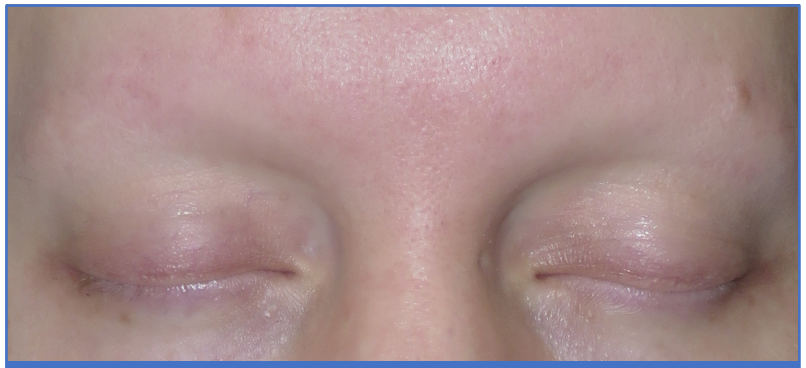
Assessment of Eyelashes

- **Eyelash assessment scale (ELA)*** is one of the numeric rating scales developed to characterize eyelash hair loss

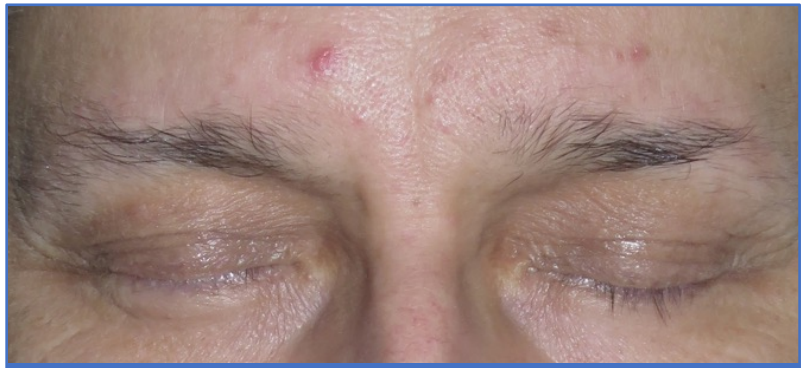
Score	Description
0	**NONE EYELASH** • No eyelashes of both right and left upper and lower eyelashes
1	**MINIMAL EYELASH** • Modestly or severely decreased density of and/or large gap(s) in one or both upper eyelashes
2	**MODERATE EYELASH** • Normal density of both upper eyelashes without gap(s), and decreased density or gap(s) is present in one or both lower eyelashes, OR • Normal density of both upper eyelashes with short gap(s), OR • Mildly decreased density of one or both upper eyelashes with or without short gap(s)
3	**NORMAL EYELASH** • Normal density of both right and left upper and lower eyelashes from near medial canthus to near lateral canthus without any gap(s)

***There are other tools to assess eyelashes available, which feature similar scoring but different descriptions**

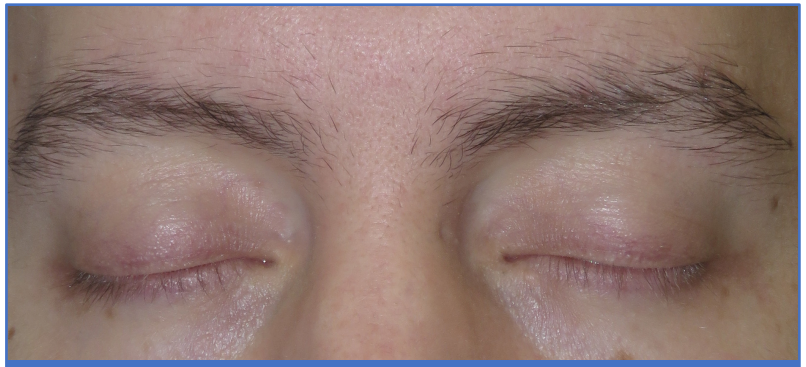
Assessment of Eyelashes (cont'd)*



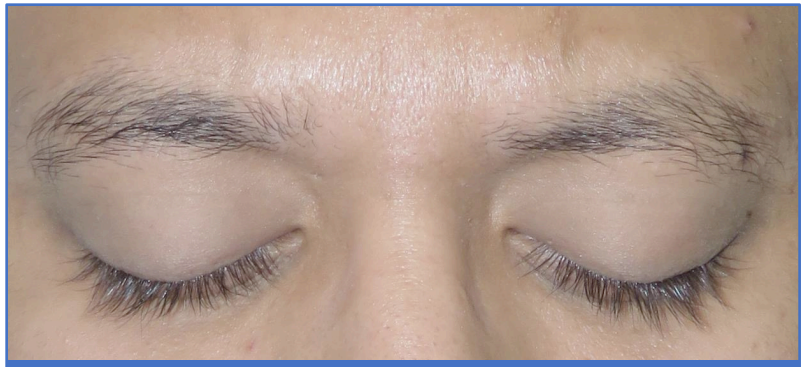
None Eyelash (ELA = 0)



Minimal Eyelash (ELA = 1)



Moderate Eyelash (ELA = 2)



Normal Eyelash (ELA = 3)

*Patient visuals from study B7981015 (Each patient's consent was provided for use of photograph)
ELA, eyelash assessment.

The PGI-C Provides a Measure of Patients' Own Perception of Change in Their AA

- The PGI-C is a self-administered questionnaire that asks the patient to evaluate the improvement or worsening of their AA compared with the start of treatment
- The questionnaire includes 7 responses ranging from "greatly improved" to "greatly worsened"

Patient's Global Impression of Change (PGIC)

Instructions: Please select the box that best describes your experiences since the start of treatment.

1. Since the start of the study, my alopecia areata has:

- ○ Greatly improved
- ○ Moderately improved
- ○ Slightly improved
- ○ Not changed
- ○ Slightly worsened
- ○ Moderately worsened
- ○ Greatly worsened

AA, alopecia areata; PGI-C, Patient's Global Impression of Change.

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