Qualitative and Psychometric Evaluation of the ClinRO Measure for Eyebrow Hair Loss and ClinRO Measure for Eyelash Hair Loss in Adults and Adolescents With Severe Alopecia Areata

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OBJECTIVE

- To evaluate the content validity and assess the psychometric properties of the ClinRO Measure for Eyebrow Hair Loss and the ClinRO Measure for Eyelash Hair Loss for use in clinical trials of adults and adolescents with severe AA:
  - Explore whether clinicians understand and can appropriately complete the ClinRO Measure for Eyebrow Hair Loss and ClinRO Measure for Eyelash Hair Loss
  - Assess the reliability, construct validity, and responsiveness of the ClinRO Measure for Eyebrow Hair Loss and ClinRO Measure for Eyelash Hair Loss

CONCLUSIONS

The cognitive debriefing results demonstrated that clinicians understand and can appropriately complete the ClinRO Measure for Eyebrow Hair Loss and the ClinRO Measure Eyelash Hair Loss.

The psychometric evaluation provided evidence of test-retest reliability, intra-rater reliability, construct validity, and responsiveness for the ClinRO measures.

Together, the findings demonstrate that the ClinRO Measure for Eyebrow Hair Loss and the ClinRO Measure Eyelash Hair Loss are suitable, fit-for-purpose, valid, reliable, and responsive measures of eyebrow and eyelash hair loss for use in the clinical assessment of adults and adolescents with severe AA.

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BACKGROUND

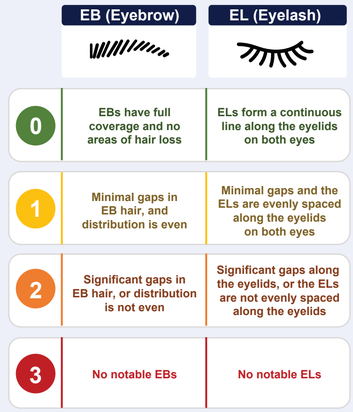
- Alopecia areata (AA) is an inflammatory, autoimmune disorder characterized by nonscarring alopecia (hair loss) on the scalp, face (e.g., eyebrows, eyelashes), and/or body.[1]
- 2 clinician-reported outcome (ClinRO) single-item measures (Figure 1) were developed to evaluate eyebrow and eyelash hair loss severity in patients with AA.[2]

METHODS

Cognitive Debriefing Interviews

- Cross-sectional, semistructured, web-based, individual cognitive debriefing interviews were conducted with clinicians with experience treating adult and adolescent patients with AA.
- Clinicians were asked to provide feedback on the ClinRO measures in turn. Specifically, clinicians were asked to rate 4 example photographs of varying eyebrow/eyelash severity using the respective measure and then were asked follow-up questions focusing on training materials, instructions, item content, and response options.

Figure 1. ClinRO Assessments of Eyebrow and Eyelash Regrowth



Psychometric Analyses

- Psychometric analyses used baseline to Week 24 data from two phase 3 upadacitinib trials in adults and adolescent patients with severe AA (NCT06012240; Up-AA).[3]
- The following psychometric analyses methods were used:

Property	Assessment Method	Timepoints
Test-retest reliability	Weighted kappa coefficients in patients with stable PhGIS-AA (< 0 = poor; 0-0.20 = slight agreement; 0.21-0.40 = fair agreement; 0.41-0.60 = moderate agreement; 0.61-0.80 = substantial agreement; 0.81-1.00 = almost perfect agreement)[4]	Week 8 and Week 12
Intra-rater reliability	Weighted kappa coefficients in patients with stable PhGIS-AA (< 0 = poor; 0-0.20 = slight agreement; 0.21-0.40 = fair agreement; 0.41-0.60 = moderate agreement; 0.61-0.80 = substantial agreement; 0.81-1.00 = almost perfect agreement)[4]	Week 8 and Week 12
Convergent validity	Based on the strength of the correlations (Spearman's rank) between the target ClinRO scores and other measures evaluating overlapping constructs	Baseline and Week 24
Known-groups validity	ANOVAs comparing ClinRO scores across PhGIS-AA severity groups	Baseline and Week 24
(Ability to detect change)	Correlation of change (Spearman's rank) between the target ClinRO scores and supporting measures (< 0.30 = weak or small [negligible]; ≥ 0.30 to < 0.70 = moderate; ≥ 0.70 to < 0.90 = strong or large; ≥ 0.90 = very strong)[5]	Baseline and Week 24
	ANOVAs evaluating mean change in the target ClinRO score by PhGIS-AA response groups (improved, no change, and worsened)	

ANOVA = analysis of variance; PhGIS-AA = Physician Global Impression of Severity-Alopecia Areata.
Notes: PhGIS-AA score (5-point response scale ranging from "none" to "very severe").

RESULTS

Cognitive Debriefing Interviews

- Interviews were conducted with 12 clinicians experienced in treating adult and adolescent patients with AA.
- Clinicians reported that they found both ClinRO measures easy to understand and use. Table 1 presents a summary of clinician feedback on the ClinRO Measure for Eyebrow Hair Loss and the ClinRO Measure for Eyelash Hair Loss.

Table 1. Clinician Feedback on the ClinRO Measures for Eyebrow and Eyelash Hair Loss

Section	Summary of findings	Illustrative quotations
Training materials	**ClinRO for Eyebrow Hair Loss** All clinicians (n = 12/12) provided positive feedback, describing the materials as straightforward, helpful, clear and useful.	**ClinRO for Eyebrow Hair Loss** "Very helpful, because they made it very clear and easy to select the correct answer for the eyebrow involvement." *ID03*
	ClinRO for Eyelash Hair Loss All clinicians who commented (n = 11/12) provided positive feedback describing the materials as straightforward, helpful, clear and useful.	**ClinRO for Eyelash Hair Loss** "I think they were helpful. It's important to have a guide." *ID07*
Instructions	**ClinRO for Eyebrow Hair Loss** All clinicians who commented (n = 6/12) reported that the instructions were easy to understand and appropriate.	**ClinRO for Eyebrow Hair Loss** "I should be standing probably around social distance. You know, this clinically appropriate, clinically meaningful distance to make my assessment. So those things are pretty clear, and they pop out. It's a very simple set of instructions." *ID10*
	ClinRO for Eyelash Hair Loss All clinicians who commented (n = 10/12) reported that the instructions were clear.	**ClinRO for Eyelash Hair Loss** "I think the instructions were really clear." *ID09*
Comprehensibility	**ClinRO for Eyebrow Hair Loss** All clinicians (n = 12/12) interpreted the question as intended.	**ClinRO for Eyebrow Hair Loss** "I think it's clear enough for clinicians." *ID07*
	ClinRO for Eyelash Hair Loss All clinicians (n = 12/12) interpreted the question as intended.	**ClinRO for Eyelash Hair Loss** "It's very clear to understand. So I definitely think it's excellent. There's no issue at all with this clinical measure." *ID03*
Response options	**ClinRO for Eyebrow Hair Loss** All clinicians (n = 12/12) were able to successfully use the response options to rate the photo examples based on an overall evaluation of both eyebrows. Clinicians described the response options as clear and straightforward to use.	**ClinRO for Eyebrow Hair Loss** "I think it's very straightforward." *ID04*
	ClinRO for Eyelash Hair Loss All clinicians (n = 11/11[a]) were able to successfully use the response options to rate the photo examples based on an overall evaluation of both sets of eyelashes. Clinicians described the response options as easy, clear, and straightforward to use.	**ClinRO for Eyelash Hair Loss** "I would say that providing answers for the examples given was easy and straightforward. The categories into which each of those examples fall were straightforward and really no ambiguity." *ID01*

ID = clinician participant number.
[a] 1 participant was not asked this question.

Psychometric Evaluation

- The analysis sample comprised 1,399 patients (1,281 adults; 118 adolescents; 59% female; median age, 35 years). The psychometric results for the ClinRO Measures for Eyebrow and Eyelash Hair Loss are presented in Table 2.

Table 2. Summary of Psychometric Evidence for the ClinRO Measure for Eyebrow Hair Loss and ClinRO Measure for Eyelash Hair Loss

	ClinRO Measure for Eyebrow Hair Loss		ClinRO Measure for Eyelash Hair Loss	
Evaluation	**Adults**	**Adolescents**	**Adults**	**Adolescents**
Test-retest reliability: weighted kappa	0.90	0.92	0.91	0.95
Intra-rater reliability: weighted kappa[a]	0.97	—	0.97	—
Convergent validity: Spearman correlations at baseline, Week 24				
PhGIS-AA	0.53, 0.53	0.65, 0.68	0.49, 0.48	0.58, 0.58
PaGIS-AA	0.46, 0.48	0.46, 0.57	0.43, 0.44	0.44, 0.56
PRO Measure for Eyebrows	0.86, 0.78	0.86, 0.85	0.76, 0.64	0.72, 0.71
PRO Measure for Eyelashes	0.78, 0.64	0.82, 0.72	0.88, 0.77	0.85, 0.82
SALT	0.61, 0.54	0.71, 0.68	0.56, 0.50	0.65, 0.60
Known-groups validity (all *P* < 0.01)[b]				
PhGIS-AA	**Mean (SD)**	**n[c]**	**Mean (SD)**	**n[c]**	**Mean (SD)**	**n[c]**	**Mean (SD)**	**n[c]**
1 = None	0.2 (0.51)	175	0.2 (0.45)	32	0.2 (0.55)	175	0.1 (0.39)	32
2 = Mild	0.6 (0.72)	333	0.2 (0.44)	33	0.5 (0.71)	332	0.2 (0.53)	33
3 = Moderate	1.0 (0.86)	209	0.6 (0.70)	10	0.8 (0.83)	208	0.4 (0.52)	10
4 = Severe	1.1 (1.00)	252	1.1 (1.02)	18	0.9 (1.04)	252	1.1 (1.06)	18
5 = Very severe	2.1 (1.03)	234	2.1 (0.85)	24	1.9 (1.15)	234	1.5 (1.10)	24
PaGIS-AA								
1 = None	0.4 (0.65)	156	0.4 (0.76)	30	0.4 (0.71)	156	0.2 (0.53)	30
2 = Mild	0.6 (0.77)	277	0.2 (0.42)	33	0.4 (0.72)	277	0.2 (0.55)	33
3 = Moderate	0.7 (0.81)	238	0.3 (0.49)	15	0.7 (0.81)	237	0.2 (0.56)	15
4 = Severe	1.1 (1.00)	243	1.4 (1.30)	15	0.9 (0.99)	242	0.9 (0.99)	15
5 = Very severe	2.0 (1.07)	277	1.9 (0.78)	24	1.8 (1.17)	277	1.7 (1.00)	24
Responsiveness: Spearman correlations of changes from baseline to Week 24								
PhGIS-AA	0.48		0.50		0.41		0.35	
PaGIS-AA	0.42		0.45		0.35		0.35	
PaGIC-AA	0.45		0.39		0.38		0.33	
PRO Measure for Eyebrows	0.73		0.80		0.58		0.58	
PRO Measure for Eyelashes	0.62		0.74		0.72		0.78	
Responsiveness (all *P* < 0.01)[b]								
PhGIS-AA	**Mean (SD)**	**n[c]**	**Mean (SD)**	**n[c]**	**Mean (SD)**	**n[c]**	**Mean (SD)**	**n[c]**
Improved	-1.2 (1.05)	821	-1.2 (1.10)	86	-1.0 (1.06)	820	-0.9 (1.16)	86
No change	-0.2 (0.78)	362	-0.3 (0.76)	29	-0.3 (0.79)	361	-0.3 (0.77)	29
Worsened	0.4 (1.23)	20	1.5 (0.71)	2	0.6 (1.19)	20	1.0 (1.41)	2

PaGIC = Patient Global Impression of Change; PaGIC-AA = Patient Global Impression of Change of Alopecia Areata; PaGIS-AA = Patient Global Impression of Severity of Alopecia Areata; PRO = patient-reported outcome; SALT = Severity of Alopecia Tool; SD = standard deviation.
[a] For each ClinRO, intra-rater reliability statistics (i.e., weighted kappa) are computed for each clinician who rated at least 10 participants in each planned subgroup and then summarized over all available clinicians.
[b] *P* values denote the statistical significance of ANOVA tests.
[c] n at Week 24.