



HAIR DISORDERS

DEVELOPMENT AND CONTENT VALIDATION OF A CLINICALLY MEANINGFUL PATIENT-REPORTED OUTCOME (PRO) FOR SCALP HAIR ASSESSMENT

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Introduction: Valid outcome measures, including patient-reported outcome (PRO) measures, are required to evaluate new alopecia areata (AA) treatments.

Objective: To develop a content-valid and clinically meaningful PRO measure to assess the extent of AA scalp hair loss with scoring complementary to the AA Investigator Global Assessment (AA-IGA).

Materials and Methods: Qualitative semi-structured interviews with patients with AA who had experienced $\geq 50\%$ scalp hair loss informed the development of a novel 5-level PRO measure. Two rounds of patient interviews collected patients' input with an interim analysis and modifications of the PRO following the first 30 interviews.

Results: Adults (Round1: n=25; Round2: n=15) and adolescents aged 15–17 (Round1: n=5) in North America participated. Patients were able to assess and self-report their current scalp hair status using assessments of percentage coverage. Round1 input included insights on the 5 scalp hair loss levels and prompted PRO modifications to improve usability and conceptual relevance: 'scalp hair loss' was rephrased as 'total area of your scalp missing hair', a response level was renamed and instructions stipulated the use of mirrors to perform the assessment and clarified that areas of vellus hairs are considered as missing hair. With these modifications, all Round2 patients understood the item wording and responded without difficulty. Most (12/15; 80%) fully agreed with the five-level response scale, and deemed the response levels to be distinct and meaningful gradations (No missing hair, 0%; Limited area, 1–20%; Moderate area, 21–49%; Large area, 50–94%;





Nearly all or all missing, 95–100%). Achievement of 0–20% scalp hair loss was deemed a treatment success by 34/35 patients queried.

Conclusions: The Scalp Hair Assessment PRO is a content-valid and clinically meaningful assessment of scalp hair loss that reflects patients' perspectives and expectations, and provides a key clinical outcome assessment to evaluate new AA treatments.

