Cutaneous Lupus Activity Investigator's Global Assessment–Revised (CLA-IGA-R) Content Validity: Cutaneous Lupus Erythematosus (CLE) Patient Qualitative Study

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OBJECTIVES

- To explore the lived experience of CLE from the patient's perspective.
- To confirm whether all key signs and symptoms experienced by patients with CLE are captured by the CLA-IGA-R, a clinician-reported three-item scale in development for measuring CLE disease activity severity.

CONCLUSIONS

- This study highlighted the wide range of skin-related lupus signs and symptoms experienced by patients with CLE.
- The key signs and symptoms (erythema, scale, edema/infiltration, erosion, crusting, and hair loss) experienced by patients are captured in the CLA-IGA-R.
- These data support the content validity of the CLA-IGA-R, and thus its use as a measure of CLE disease activity.

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Synopsis

- CLE is a chronic condition that causes a range of potentially disfiguring skin manifestations, which vary in severity and presentation.[1]
- The CLA-IGA-R is an emerging clinician-reported outcome measure of CLE disease activity severity, developed with clinician input.
- The CLA-IGA-R consists of three separate items:[2,3]
  1. **Erythema.**
  2. **Other Morphological Characteristics (OMC)**: scale, edema/infiltration, and secondary changes (comprising erosion, crusting, and vesicles).
  3. **Follicular Activity.**
- The CLA-IGA-R assesses disease severity based on descriptions of each characteristic, where Erythema is considered to be the primary characteristic.
- Qualitative interviews with patients are an important step in assessing the content validity of a measure; the results of these are presented here.

Methods

- In total, 15 US patients with a clinical diagnosis of CLE were enrolled and their demographic and clinical characteristics were collected using standardized forms.
- Patients were invited to take part in qualitative, semi-structured, face-to-face interviews, approximately 60 minutes each.
- For assessment of the patients' CLE signs and symptoms:
  - Patients were first asked to discuss all their CLE signs and symptoms in their own words.
  - If not spontaneously mentioned, the interviewer then asked the patient if they experienced a selection of signs and symptoms from a pre-specified list.
- All interviews were audio-recorded and transcribed verbatim; transcripts were then coded and subjected to thematic analysis[4] by two independent researchers.
  - Saturation analysis was performed by dividing the 15 patients into three equal sets.
- Clinicians were asked to complete the CLA-IGA-R for all patients.

Results

Patient Characteristics

- The 15 study patients had an average age of 43.8 years, were mostly women (n=13), and were predominantly Black/African American (n=9).
- The median time from CLE diagnosis was 10 years, and 80% (n=12) of patients self-reported having mild, moderate, or severe skin-related lupus signs.
- Six patients had a diagnosis of subacute CLE and eight had a diagnosis of chronic CLE, including five with discoid lupus.
  - Information on the CLE subtype was missing for one patient.
- Of the 11 patients with available CLA-IGA-R ratings, 45.5% were rated 'moderate' and none 'clear' for both Erythema and OMC; 9.1% were rated 'severe' for Erythema and none were rated 'severe' for OMC.

Patient-reported Skin-related Lupus Signs (Figure 1) and Symptoms

- **Erythema:** all participants (n=15) reported skin discoloration (red, pink, or purple), with 13 describing it spontaneously; erythema was typically identified as the first sign of a lupus rash.
- **Scale:** dry, ashy, or scaly skin was mentioned by most participants (n=13), with nine reporting it spontaneously.
- **Edema/infiltration:** swelling, swollen, or bumpy skin was noted by 12 participants.
- **Open wounds** (n=11) and **crusting/scabbing** (n=8): associated with more severe rashes, typically occurring at the end of the rash timeline.
- **Little blisters:** reported by six participants.
- **Hair loss:** both current and past scalp hair loss due to CLE were reported by 14 participants, with six describing this spontaneously.
- **Pain and itching:** skin pain (n=9) and itch (n=7) were reported, though only one interview included probing questions on these symptoms.
- **Scarring:** spontaneously mentioned by seven participants; no probing questions were asked because scarring is not part of the CLA-IGA-R.
- Saturation was supported because no new skin-related CLE disease activity signs were reported in the last group of interviews.

Skin-related Lupus Concepts

- Participants described CLE signs and symptoms that closely aligned with the CLA-IGA-R items, providing qualitative support for these measures.
  - Example patient statements illustrating these symptoms are shown in **Figure 2**.

Figure 1. Frequency of Patient-reported Skin-related Lupus Signs

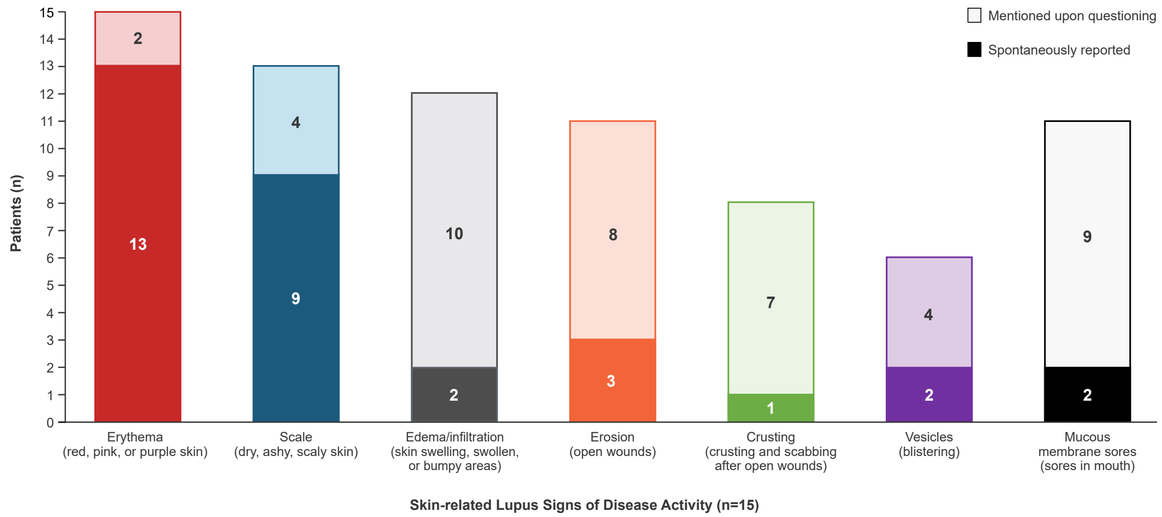

Figure 2. Patient Statements*

Erythema

The ***redness*** is always the ***first thing***

It ***takes months*** for the ***redness to calm down***

When I get them [erythema], ***I feel unattractive***

Other Morphological Characteristics

Scale

My ***skin scales all over*** now … The ***hardening*** keeps getting ***thicker and thicker***

Edema/infiltration

Like ***hives*** that end up ***spreading***

Erosion

It has to be a ***really bad flare*** up to have erosion … It'll start off ***itchy***, and then ***turn into lesions*** depending on the severity

Crusting

Some days it would be on the oozing side … At other times it would be more ***crusty and really angry***

*Patient statements were edited for clarity and readability by removing filler words and informal language, while ensuring that the original meaning and intent remain unchanged.

References 1. Ogunsanya ME, et al. *Int J Womens Dermatol.* 2018;4(3):152–158; 2. Guo LN, et al. *Lupus Sci Med.* 2021;8(1):e000529; 3. Zhang AJ, et al. *Lupus Sci Med.* 2024;11(1):e001165; 4. Braun V and Clarke V. *Qual Res Psychol.* 2006;3(2):77–101. **Disclosures** JFM: consultant for AbbVie, Amgen, AstraZeneca, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Incyte, Janssen, LEO Pharma, Lilly, MoonLake, Novartis, Pfizer, Sanofi-Regeneron, and UCB Pharma, and grant/research support from Amgen, AstraZeneca, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Janssen, Lilly, MoonLake, Sanofi-Regeneron, Sun Pharma, and UCB Pharma; WY, QL, and FZ: employees of Biogen and may hold Biogen stock; CB: former employee of Biogen and may hold Biogen stock; HD and JR: employees of Clinical Outcomes Solutions who were paid to conduct this research as an independent research organization. **Acknowledgments** This study was funded by Biogen (Cambridge, MA, USA) and conducted by Clinical Outcomes Solutions (Folkestone, Kent, UK). Writing and editorial support was provided by Freya Haycox-Ferguson, PhD, of Selene Medical Communications (Macclesfield, UK), funded by Biogen. Poster previously presented at ACR Convergence (October 24–29, 2025 Chicago, IL, USA).