Construction and validation of a photographic guide for the validated Investigator's Global Assessment of Chronic Hand Eczema (IGA-CHE) scale

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Conclusions

- The photo-guide is a reliable tool for assessing the morphological severity of CHE
- The photo-guide can be used as part of a comprehensive evaluation of disease using the IGA-CHE scale in clinical research and practice

Objectives

- To develop a supplemental photographic guide of the IGA-CHE scale to support clearer communication, better clinical understanding, and more accurate recognition of Chronic Hand Eczema (CHE)

Background

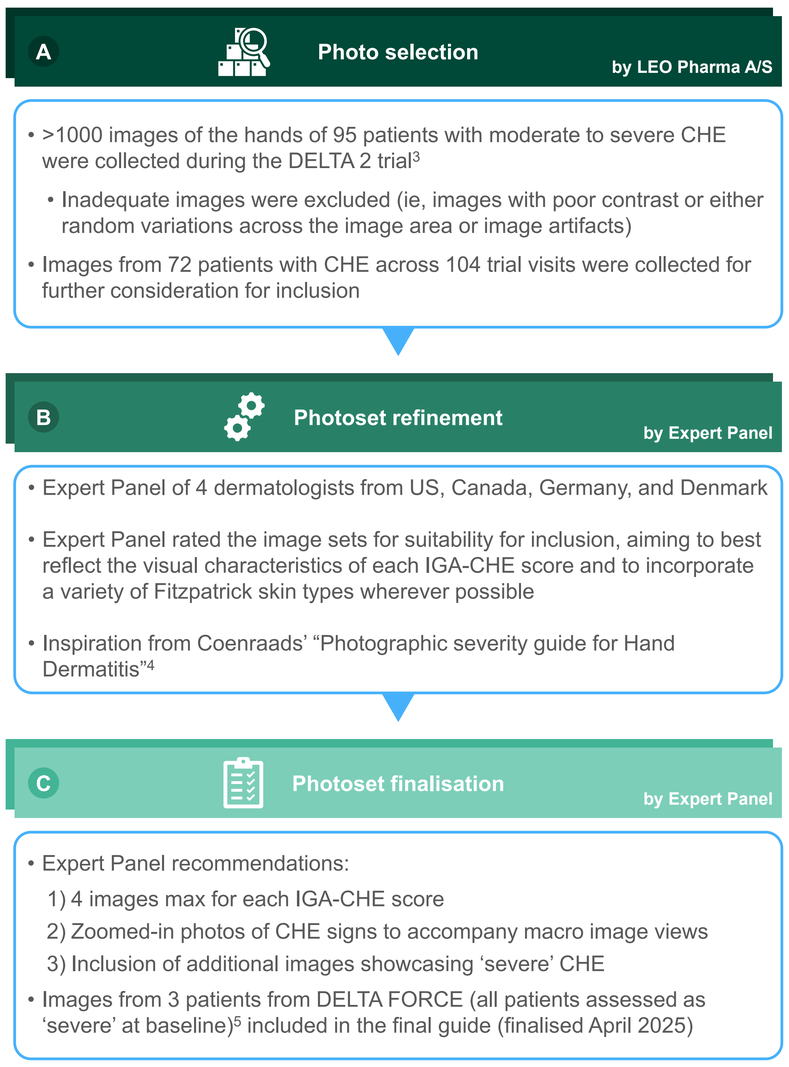
- CHE, a chronic inflammatory skin disease that significantly impacts patients' QoL, is defined as hand eczema that lasts >3 months or recurs ≥2 times per year[1]
- The IGA-CHE is a measure of CHE global disease severity, based on evaluation of clinical signs of erythema, scaling, lichenification /hyperkeratosis, vesiculation, oedema, and fissures[2]
  - IGA-CHE treatment success (defined as an IGA-CHE score of 0 ['clear'] or 1 ['almost clear'] with ≥2-step improvement from baseline to week 16) is a stringent regulatory endpoint and was the primary efficacy endpoint in the DELTA 1 and DELTA 2 trials of delgocitinib cream in patients with moderate to severe CHE[3]
- A supplemental photographic guide is needed to illustrate this heterogeneous skin disease in order to capture the wide range of presentations and enable standardised severity assessment

Methods

Construction of the IGA-CHE photo-guide

- A consensus group of CHE experts reviewed photographs from investigator assessments in DELTA 2 (NCT04872101; **Figure 1A**)
- To form the Photo-guide, an Expert Panel selected images that best represented each IGA-CHE score (0 = 'clear'; 1 = 'almost clear'; 2 = 'mild'; 3 = 'moderate'; 4 = 'severe')[2] (**Figure 1B**)
- The Expert Panel recommended developing a final Photo-guide that showcased diverse morphological presentations across CHE subtypes, skin colours, and ages, and enabled future use of printed copies of the guide, which lack digital zoom (**Figure 1C**)

Figure 1 Construction of the IGA-CHE photo-guide

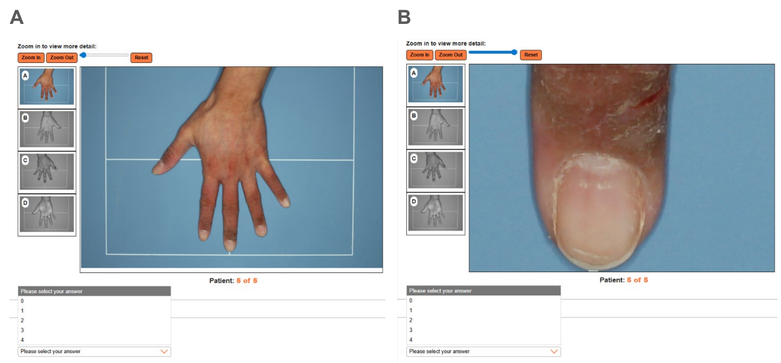


Validation of the IGA-CHE photo-guide by dermatologists

- An online validation survey was sent to 25 dermatologists (raters) across 9 countries*
- Survey requested that raters evaluate 44 patient photosets from 39 patients in DELTA trials§ per IGA-CHE using a printed copy of the Photo-guide (**Figure 2**)
- Raters were trained on the use of IGA-CHE before completing the validation survey
- Each rater completed the survey twice over 3 days, with 1 day in between
- The order of patient photos was altered between surveys to limit bias

*France, Germany, Spain, Italy, Switzerland, US, Canada, South Korea, China.
§DELTA 2 (NCT04872101); DELTA FORCE (NCT05259722).

Figure 2 Example photoset validated by dermatologists. (**A**) Full size (**B**) 100% zoom



Analysis of reliability of the IGA-CHE Photo-guide

- The IGA-CHE scores from the validation survey were analysed*
- Interclass correlation coefficient was estimated using a variance components model
  - Inter- and intra-rater variability were also calculated
- Inter-rater variability was assessed with Kendall's concordance estimator

*Data analyses were conducted using SAS v9.4 (SAS Institute Inc, Cary, NC, USA).

Results

Evaluation of the IGA-CHE photo-guide

- HCPs generally agreed on the severity grade of the photosets, with minimal variation between results from the first (Day 1) and second (Day 3) surveys (**Figure 3**)
  - Examples of mixed and near-uniform ratings are shown in **Figure 4A** and **Figure 4B**, respectively
  - The Expert Panel assessed the photoset in **Figure 4A** as "almost clear" (ie, "barely perceptible" erythema only). Variability in IGA-CHE scoring may reflect differences in raters' computer display settings, affecting colour depth and perception of erythema severity. Therefore, raters may classify erythema as absent (clear), "barely perceptible" (almost clear), or "slight but definite" (mild). When erythema is perceived as more than "barely perceptible" but no additional signs required for a "mild" classification are present, variability between IGA-CHE scores of 1 and 2 is expected
- The intraclass correlation coefficient for the validation surveys was 0.78, indicating most raters had consistent scores per image
- Kendall's concordance for the surveys on Day 1 and Day 3 was 0.85 and 0.84, respectively, indicating high consistency between raters
- The final IGA-CHE photo-guide was a short document, presenting images of hands affected by CHE at varying severities, illustrating all IGA-CHE scale scores (**Figure 5**)

Figure 3 Photoset evaluation by dermatologists

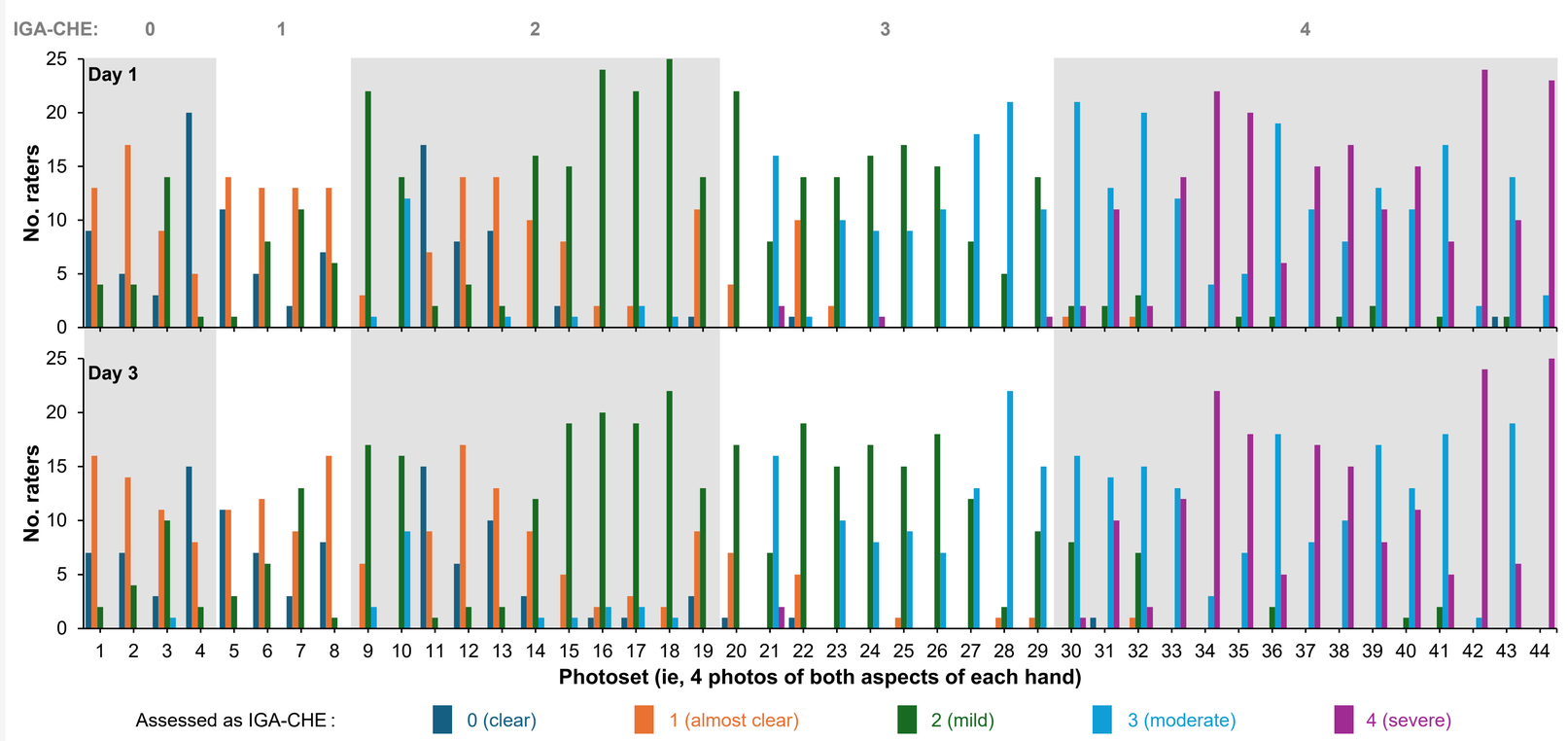
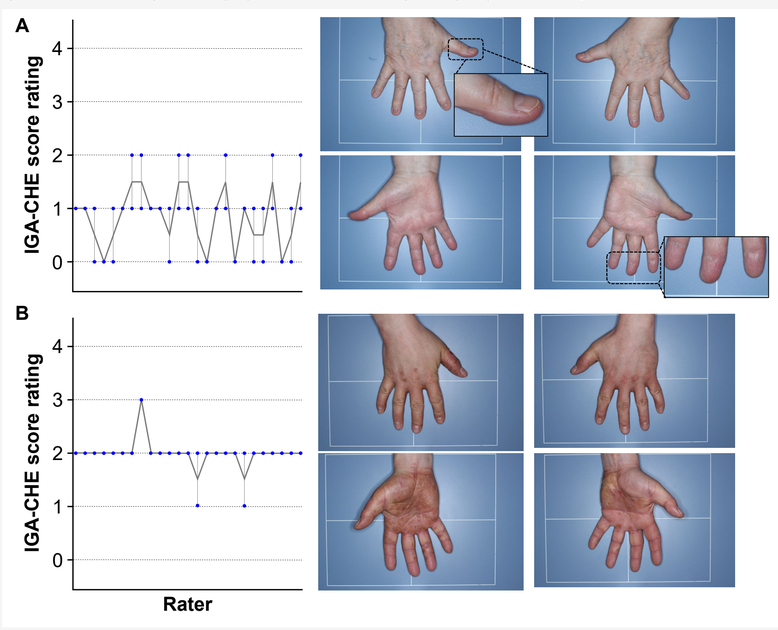
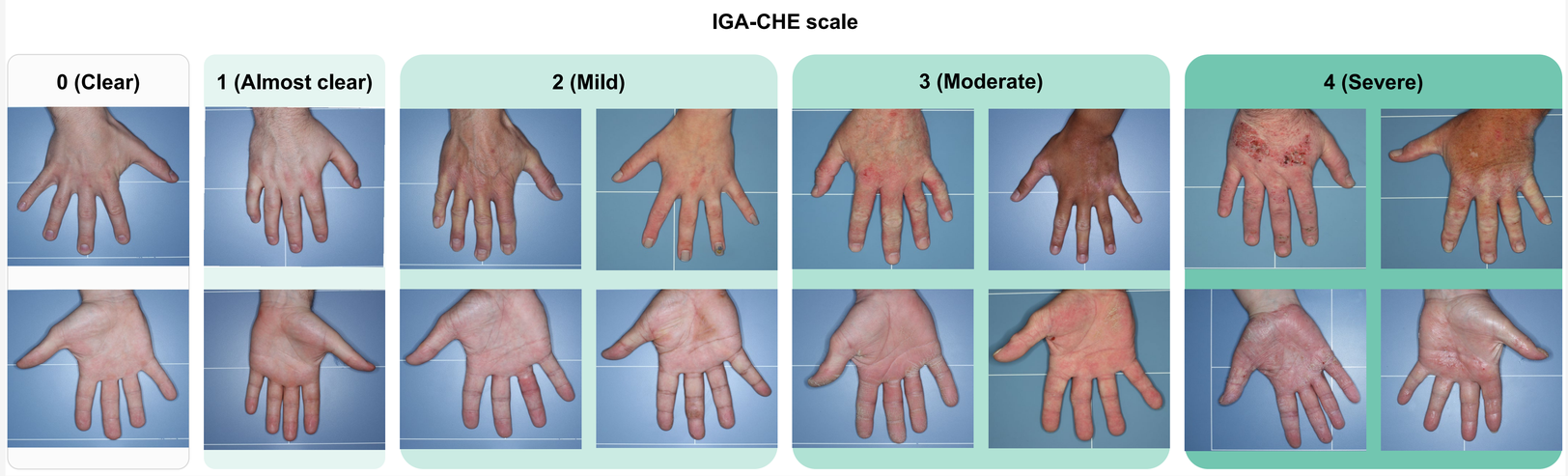


Figure 4 Rater variability of photosets graded as (**A**) IGA-CHE 1 (almost clear) and (**B**) IGA-CHE 2 (mild) by the Expert Panel



Hand images and corresponding zoomed-in views were selected from the respective photosets.

Figure 5 Representative images from the IGA-CHE Photo-guide



Abbreviations CHE, Chronic Hand Eczema; HCP, Healthcare Professional; IGA-CHE, Investigator's Global Assessment of CHE; QoL, quality of life.

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