

Burden of Chronic Hand Eczema: a Snapshot of Patient Reported Outcomes Collected at Screening in a Phase 2b Trial with Delgocitinib

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Introduction

- Hand eczema is a multifactorial inflammatory skin disorder related to skin barrier dysfunction and altered immune response. Chronic hand eczema (CHE) is defined as hand eczema persistent for >3 months or relapses twice or more per year.¹
- Few studies have characterized CHE burden using generic and disease-specific patient-reported outcome (PRO) measures.

Objective

- Here we describe the burden of CHE, by disease severity, on patients' quality of life (QoL) using two PROs measured at screening: (1) Dermatology Life Quality Index (DLQI); and (2) EuroQoL 5-dimension health questionnaire 5-level (EQ-5D-5L).

Materials and methods

- Patients' perspectives of the burden of their CHE were obtained at screening of a phase 2b, randomised, dose-ranging clinical trial (NCT03683719) of adult patients with mild to severe CHE conducted from November 2018 through April 2020 (Denmark, Germany, US)²
- Data were collected at screening before discontinuation of ongoing therapy and initiation of investigational medical product.
- The screening period had a minimum duration of 1 week and a maximum duration of 4 weeks.
- The PROs assessing disease burden were stratified by patient disease severity using the Investigator's Global Assessment for CHE (IGA-CHE).
 - IGA-CHE is a 5-point scale assessing the severity of CHE: 0 = 'clear', 1 = 'almost clear', 2 = 'mild', 3 = 'moderate', 4 = 'severe'.

Patient reported outcomes

- DLQI:** A dermatology-specific 10-item validated questionnaire assessing impact of disease on QoL over the last week. Domains include dermatology-related symptoms and feelings, daily activities, leisure, work or school, personal relationships, and treatment. Item scores range from 0 to 3 and the total score is the sum of the 10 items with a maximum score of 30. A high DLQI score is indicative of poor QoL.³
- EQ-5D-5L:** A standardized, self-administered questionnaire as a generic measure of health status today.⁴ The questionnaire includes two sections:
 - The EQ-5D descriptive system which includes 5 dimensions (mobility, self-care, usual activity, pain/discomfort, and anxiety/depression) with scores ranging from 1 to 5. Dimension scores are converted into a single Index score anchored on a 0-1 scale with low scores indicative of extreme problems.
 - The EQ vertical visual analogue scale (VAS) records the patient's self-rated health ranging from 0 ('the worst health you can imagine') to 100 ('the best health you can imagine').

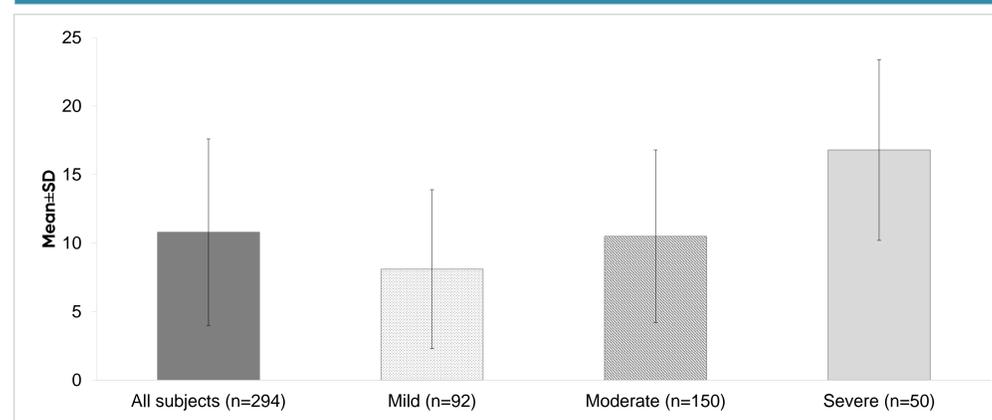
Results

- 305 patients with mild to severe CHE were screened. Patients were primarily aged 18 to 64 years (88.9%), were female (61.3%), and identified as White (97.0%) (Table 1).
- The mean DLQI total score (SD) among all patients completing the DLQI (n=294) was 10.8 (6.8), indicating a very large effect on patients' lives (Figure 1).⁵ Symptom burden increased with disease severity (mean DLQI for mild = 8.1 (5.8), moderate = 10.5 (6.3), severe 16.8 (6.6)).
- The DLQI item with the greatest impact was 'skin feeling itchy, sore, painful, or stinging' (2.1 (0.8)), indicating 'a lot' of itchy, sore, painful or stinging skin during the last week (data not shown).
- On the EQ-5D-5L, the dimension most affected was pain/discomfort with a mean domain score of 2.3, indicating slight to moderate problems related to these symptoms (data not shown).
- The mean EQ-5D-5L index score for patients at screening (n=293) was 0.7 (0.2) and mean VAS score was 72.7 (19.3).
- Patients with severe CHE (n=50) on average had the lowest EQ-5D-5L index and VAS scores (mild = 0.8 (0.2) and 75.0 (18.7), moderate = 0.7 (0.2) and 75.0 (17.1), severe = 0.5 (0.3) and 61.5 (23.0), respectively) (Figure 2).

Table 1. Baseline characteristics of screened patients

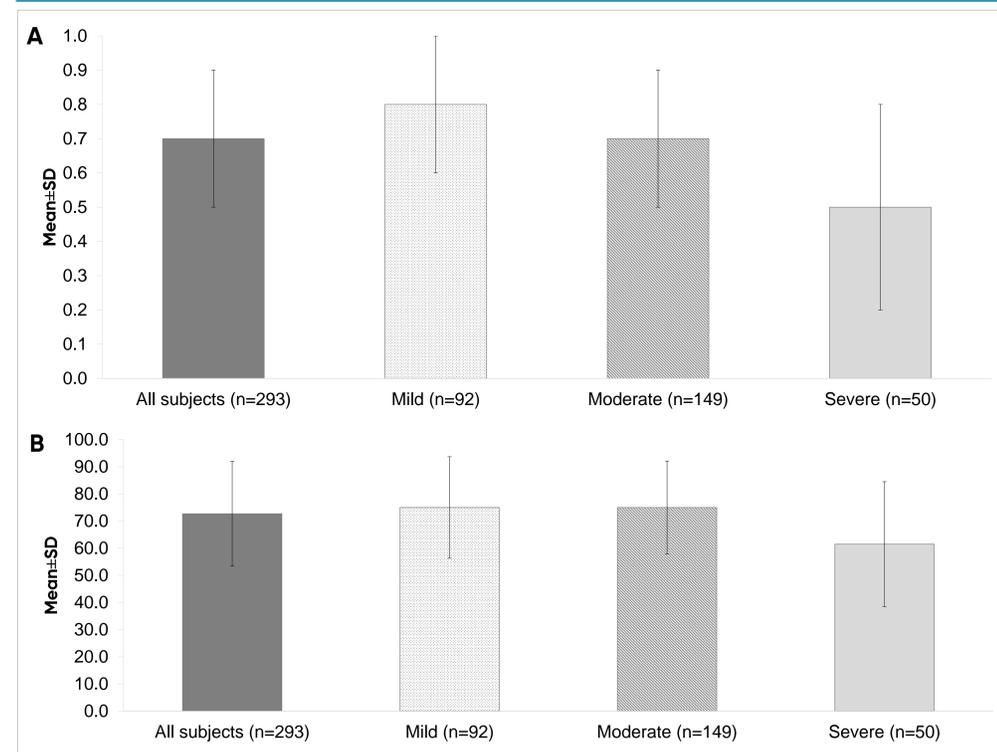
Characteristic	All screened patients (N=305)
Age group, n (%)	
18 – 64 years	271 (88.9)
65 – 84 years	34 (11.1)
Gender, n (%)	
Male	118 (38.7)
Female	187 (61.3)
Race, n (%)	
White	296 (97.0)
Black or African American	1 (0.3)
Asian	5 (1.6)
Other	3 (1.0)
Ethnicity, n (%)	
Hispanic or Latino	10 (3.3)
Not Hispanic or Latino	295 (96.7)
Country, n (%)	
Denmark	72 (23.6)
Germany	208 (68.2)
United States	25 (8.2)

Figure 1. DLQI total score at screening (first assessments) by screening disease severity (IGA-CHE score)



CHE, chronic hand eczema; DLQI, Dermatology Life Quality Index; IGA-CHE, Investigator's Global Assessment for CHE; SD, standard deviation.
 Note. No patients had an IGA-CHE score of 0-Clear at screening visit. The IGA-CHE score is unknown for some patients at screening (n=2). First assessment collected +/- 7 days from first IGA-CHE score is not included.

Figure 2. (A) EQ-5D-5L index score and (B) EQ-5D-5L VAS score at screening (first assessments) by screening disease severity (IGA-CHE score)



CHE, chronic hand eczema; EQ-5D-5L, EuroQoL 5-Dimension Health Questionnaire 5-Level; IGA-CHE, Investigator's Global Assessment for CHE; SD, standard deviation; VAS, visual analog scale.
 Note. No patients had an IGA-CHE score of 0-Clear at screening visit. The IGA-CHE score is unknown for some patients at screening (n=2). First assessment collected +/- 7 days from first IGA-CHE score is not included.

Discussions

- Results of this analysis provide insights into the dimensions of the patient burden associated with CHE in adults receiving different treatments, indicating that CHE has a profound negative impact on patients' QoL assessed by the DLQI and EQ-5D-5L.
- The analysis shows that the burden related to QoL worsens with increasing severity of CHE. Items/domains with the greatest impact are those including questions related to itch and pain.
- Limitations of this study include generalizability; conclusions may not necessarily apply to patients failing to meet the strict inclusion/exclusion criteria of randomized controlled trials or those unwilling to participate in these.
- In conclusion, these findings emphasize the high burden of CHE among adults receiving different treatments, indicating a need for more effective management strategies and treatment options in this disease area.

References

- Agner et al. J Eur Acad Dermatol Venereol 2020;34:4-12.
- Worm et al. BR. J. Dermatol. Accepted 2021.
- Finlay et al. Clin Exp Dermatol 1994;19(3):210-216
- EuroQoL Research Foundation. UserGuide 2019:3
- Hongbo et al. J Invest Dermatol 2005; 125(4):659-664

Disclosures

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