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Exploring the Burden of Chronic Inducible Urticaria and the Meaningfulness of Treatment Using In-Trial Interviews

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CONCLUSIONS

- Symptom improvement can have meaningful and important benefits on the lives and well-being of people affected by chronic inducible urticaria (CIndU).
- Heterogeneity in symptom experience highlights the importance of assessing the most bothersome symptom (MBS) when evaluating the effectiveness of new treatments.
- Symptom improvement following a provocation test is perceived as reflecting real-world experiences.

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BACKGROUND

- Chronic inducible urticaria (CIndU) is a debilitating disease characterized by the occurrence of itchy wheals (hives) and/or angioedema experienced over a period longer than 6 weeks.[1,2]
- Common subtypes of CIndU include symptomatic dermographism, cold urticaria, and cholinergic urticaria, each defined by their primary trigger.[3]
- Qualitative interviews embedded in clinical trials provide rich insights into the burden of disease and the meaningfulness of change from the patient perspective.[4]

OBJECTIVES

- To explore the lived experience of CIndU, impact of treatment, and meaningfulness of change in patients participating in a clinical trial.

METHODS

- The RemIND trial is a multinational, phase 3, basket study of remibrutinib in participants with CIndU (symptomatic dermographism, cold urticaria, and cholinergic urticaria) inadequately controlled by H1-antihistamines.
- Qualitative, semi-structured interviews were conducted with a subsample of trial participants from sites in Argentina, Canada, France, Germany, Spain, and the United States.
- Interviews were conducted after the 24-week, double-blind, placebo-controlled treatment period to capture CIndU experiences, perceived changes during the trial, and feedback on meaningful change on key patient-reported outcome measures (the Urticaria Symptoms Daily Diary [USDD], Patient Global Impression of Severity [PGIS], and Patient Global Impression of Change [PGIC]).
- Thematic analysis[5] was used to analyze the interview data.

RESULTS*

Interview Participant Characteristics

- A total of 74 trial participants completed the interviews (12 with symptomatic dermographism, 26 with cold urticaria, and 36 with cholinergic urticaria).
- Participants were aged 18 to 78 years; most were female (n = 40/74, 54.1%), White (n = 53/74, 71.6%), and identified as not Hispanic or Latino ethnicity (n = 46/74, 62.2%).
- Overall symptom severity at baseline varied, with participants reporting mild to very severe symptoms on the PGIS.

Pre-Trial Experiences of CIndU

- Interview participants reported heterogeneous pre-trial symptom experiences.
  - The most common pre-trial symptoms were hives (n = 74/74, 100.0%), itch (n = 73/74, 98.6%), burning (n = 63/74, 85.1%), pain (41/74, 55.4%), swelling (31/74, 41.9%), and redness (n = 23/74, 31.1%).
  - Itch was the symptom most frequently identified in the interviews as the most bothersome symptom (MBS) (n = 52/72, 72.2%), followed by burning (n = 12/72, 16.7%), and pain (n = 6/72, 8.3%).
  - The MBS was described as the most uncomfortable, persistent, and difficult-to-treat symptom, causing the greatest social discomfort and disruption to sleep and daily activities. For several participants (n = 15/59, 25.4%), the MBS was not the most severe symptom.

*"**It is what really wipes me out**, and has, kind of, given me this chronic issue with **fatigue**, because when you have these reactions and are in **pain so much every day**, you know, and have no chance to recuperate." (ColdU005)*

*"Because **it's so intense and it lasts a long time**. It's relentless. Without the medication, **it was just relentless. It would just not go away**." (SDermD001)*

- Trigger avoidance and symptom management were reported to have widespread, detrimental impacts on functioning and daily life.
  - Impacts reported included physical discomfort, disruption of daily activities and sleep, impaired physical and social functioning, impaired work/school productivity and/or attendance, and emotional distress.

*"So, I **started changing my schedules and adapting, avoiding exposure** to the cold; that was quite complicated, let's say. **I had to reorganize my life**..." (ColdU002)*

*"It was to the point where it was just so **uncomfortable**, that I didn't want to do anything. **I didn't want to go to work. I didn't want to go to the gym.** I didn't want to, yeah, really do anything." (CholU024)*

*"It's **embarrassing** in front of others. The thought of patches appearing on your face the moment you step outside **restrains your desire to leave home and adds stress** to daily life." (ColdU024)*

*"It would be, **I can't sleep**, I'm itching, I need to take a cold shower." (CholU023)*

Perceived Changes With Treatment

- 54 of the 74 interview participants (72.9%) reported improvement in symptoms.

*"The burning was definitely not as strong. I could **tolerate cold** for a longer time without gloves, even though it was cold. I **no longer had the burning in my face**, no wheal formation, no more pain." (ColdU020)*

*"I definitely would not want to miss taking that medication…because the urge to itch, I mean the duration of **this urge to itch has shortened**, I'd say by about half." (CholU025)*

- Most participants (50/54, 92.6%) who reported improvements in their symptoms described meaningful benefits in their daily functioning, participation in daily and social activities, sleep, and emotional well-being.

*"**I can go out with my dog and I can meet my children** in the park again. I can go for a walk, and I can go shopping again, even walk through the chilled section [of the supermarket] without problems. **I have my old life back; it is a big win**." (ColdU018)*

*"It just made a huge difference in my life. **I can work again without worrying** about if I'm going to be itching all day. If, you know, I'm going to be hiving all day. If I'm going to be able to, you know, sleep or work or be comfortable all day. [...] **I feel like I have my life back**." (SDerm001)*

- The symptom considered most bothersome remained the same throughout the trial for most participants (53/56, 94.6%).
- Perceived improvements in symptoms triggered by the provocation tests at the study visits aligned with changes these participants noticed in their everyday life, re-affirmed that treatment was working, provided a tangible indication of progress, and offered the prospect of gaining more freedom in daily life.

*"You can already notice that in everyday life. The tests are only an indication to make the whole thing [symptom improvement] **more tangible and measurable**." (ColdU021)*

*"**You could see live that the medication actually works**." (CholU026)*

* Percentages and denominators reflect the number of participants who provided feedback.

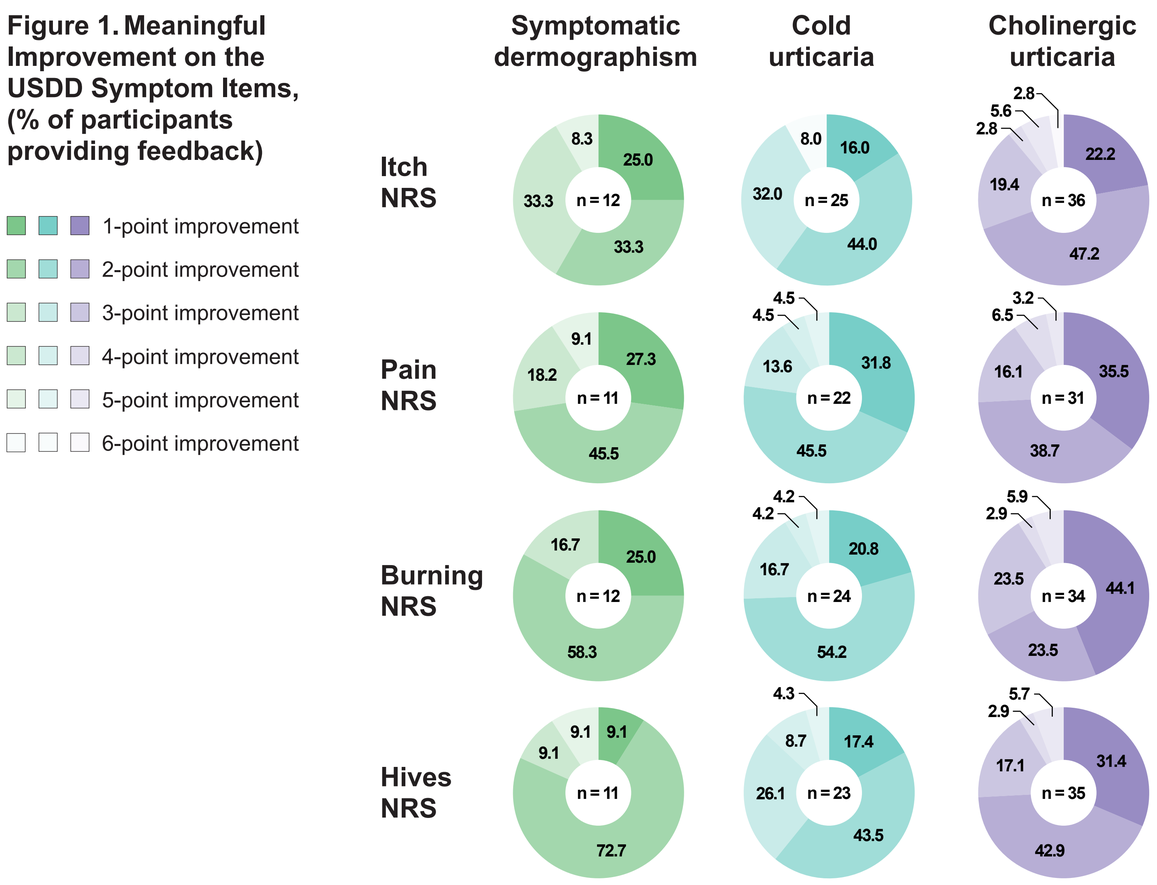
Meaningful Change in Clinical Outcome Assessment Scores

- Most participants (87.0%-100.0%) considered a 1- to 3-point change in the USDD itch, pain, burning, and hives numeric rating scale (NRS) items to reflect meaningful improvement (Figure 1).
  - This level of improvement was considered to represent less frequent and more manageable symptoms, less discomfort, reduced reliance on rescue medication, and being able to engage in a wider range of activities with fewer adjustments.

*[2-point improvement on the USDD Itch NRS] "It's going from a **moderate itch to a mild itch**. […] Moderate to me would be where I would actively try to avoid the trigger in the future. Mild—I wouldn't make as much of an effort to." (ColdU008)*

*[1-point improvement on the USDD Burning NRS] "…it's a little bit **more relief**, actually, you know, in your daily life, that you're, you're feeling **less burning**, you're **not as sensitive**, you're **not as irritable**." (SDerm004)*

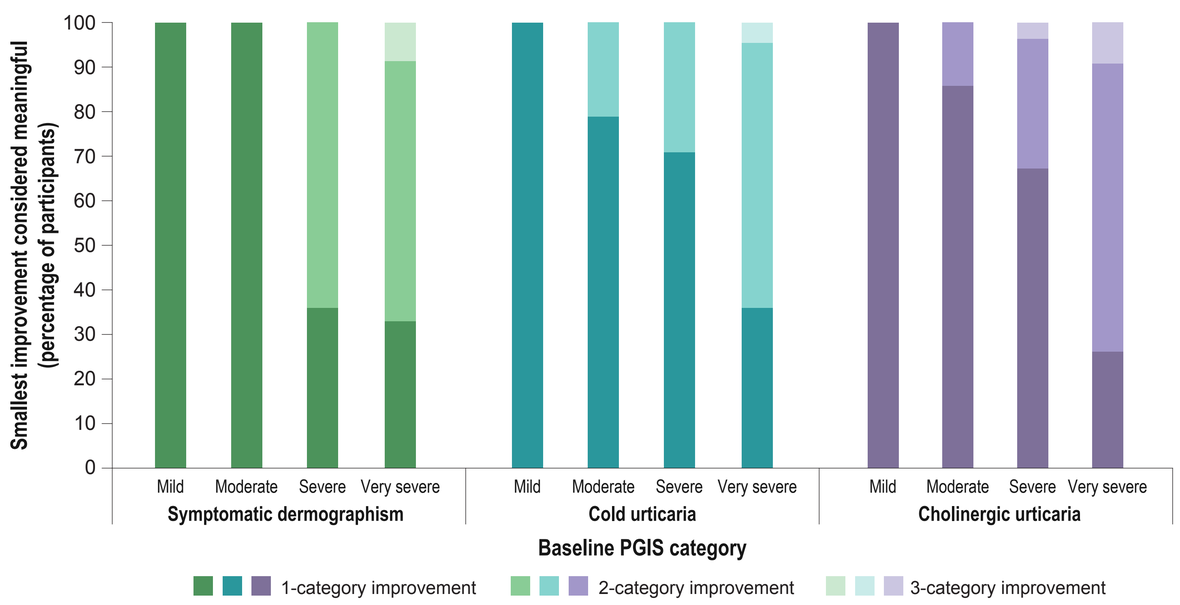
Figure 1. Meaningful Improvement on the USDD Symptom Items, (% of participants providing feedback)



Note: Totals may not add to exactly 100% due to rounding.

- Most participants considered a 1-category improvement from "mild," "moderate," or "severe" on the PGIS to reflect meaningful change; from "very severe," most participants required a 2-category change (Figure 2).

Figure 2. Meaningful Improvement on the PGIS



- Most participants reported "a little better" (n = 33/69, 47.8%) or "a lot better" (n = 31/69, 44.9%) on the PGIC reflected meaningful symptom improvement.

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