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Psychometric Evaluation of the Urticaria Activity Score in Chronic Spontaneous Urticaria

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KEY FINDINGS & CONCLUSIONS

- Analysis of initial pooled data from two clinical trials showed strong psychometric properties for the weekly scores derived from the UAS (UAS7, ISS7, and HSS7)
- Test-retest reliability between weeks 2 and 4 was good and convergent and responsiveness correlations with other study measures were generally as expected
- Scores discriminated between groups defined by symptom severity, HRQOL, disease control, and rescue medication use; changes in scores discriminated between groups defined as improved, not changed, or worsened in symptom severity and HRQOL
- The UAS7, ISS7, and HSS7 are reliable, valid, and able to detect change in adults with CSU inadequately controlled by H1-antihistamines

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INTRODUCTION

- The Urticaria Activity Score (UAS) is a diary-based patient-reported outcome (PRO) measure assessing itch severity and number of hives; the weekly UAS (UAS7) is the criterion standard for assessing disease activity in chronic spontaneous urticaria (CSU)[1]
- The twice-daily UAS administered as part of the Urticaria Patient Daily Diary (UPDD) is frequently used to assess outcomes in CSU clinical trials[2,3]

OBJECTIVE

- The objective of this study was to assess the reliability, validity, and responsiveness of the UAS7, weekly Itch Severity Score (ISS7), and weekly Hives Severity Score (HSS7)

METHODS

- Analyses were conducted using initial data from two double-blind, placebo-controlled trials of remibrutinib in adults (aged ≥ 18 years) with inadequately controlled CSU (REMIX-1 [NCT05030311] and REMIX-2 [NCT05032157])
  - The initial data included UAS scores from n = 889 at baseline, 882 at week 2, 872 at week 4, and 743 at week 12
  - Data were pooled across studies and treatment arms
- Study measures included the UPDD, Patient Global Impression of Severity (PGIS), Patient Global Impression of Change (PGIC), Dermatology Life Quality Index (DLQI), Urticaria Control Test 7-day recall version (UCT7), Work Productivity and Activity Impairment Questionnaire V2.0 for Chronic Urticaria (WPAI-CU), and EQ visual analog scale (VAS)
- Evaluations of the UAS7 (0-42), ISS7 (0-21), and HSS7 (0-21) (higher scores indicate greater urticaria activity) included floor and ceiling effects, test-retest reliability intraclass correlation coefficients (ICCs), convergent/divergent and responsiveness correlations, and analysis of variance (ANOVA) to evaluate hypothesized differences between known and change groups

RESULTS OBJECTIVE

Participant Baseline Characteristics

- The analysis sample included 889 participants (448 in REMIX-1 and 441 in REMIX-2)
- Mean (standard deviation [SD]) age at baseline was 43.4 (14.3) years, 66.3% were female, 55.5% were White, and 83.9% identified as not Hispanic or Latino

UAS7, ISS7, and HSS7 Scores

- There were no problematic floor (worst score) or ceiling (best score) effects at baseline for either the UAS7 (10% and 0%, respectively) or the ISS7 (12% and <1%, respectively); for the HSS7, there was no ceiling effect (0%), but a slight floor effect (24%)

Test-Retest Reliability

- For UAS7, ISS7, and HSS7, ICCs for scores between weeks 2 and 4 were 0.85 for participants with no change on PGIS and 0.87 for participants with no change on PGIC, indicating good reliability
- Lower ICCs were observed using scores at baseline and week 2 (0.50-0.68, indicating moderate reliability)

Convergent/Divergent and Responsiveness Correlations

- Correlations at baseline and week 12 generally supported the validity of the UAS7, ISS7, and HSS7 (**Table 1**; correlations at week 2 were similar to week 12)
  - Moderate to high correlations with measures of related concepts (PGIS, DLQI, and UCT7) and generally weaker correlations with measures of more distal concepts (WPAI-CU and EQ VAS)
- Longitudinal correlations showed similar patterns to the cross-sectional correlations (**Table 1**; change correlations at week 2 were similar to week 12)

Table 1. Correlations Between Study Measures

Measure	Baseline			Week 12			Change from baseline to week 12		
	UAS7	ISS7	HSS7	UAS7	ISS7	HSS7	UAS7	ISS7	HSS7
PGIS	0.58	0.61	0.43	0.77	0.76	0.72	0.70	0.70	0.63
PGIC	–	–	–	–	–	–	0.65	0.59	0.64
UCT7 total score	−0.50	−0.51	−0.38	−0.73	−0.72	−0.69	−0.68	−0.67	−0.63
DLQI total score	0.50	0.56	0.34	0.67	0.66	0.62	0.57	0.60	0.49
AAS7	0.36	0.41	0.22	0.43	0.46	0.36	0.39	0.43	0.33
EQ VAS	−0.30	−0.32	−0.22	−0.32	−0.34	−0.28	−0.27	−0.28	−0.23
WPAI-CU Absenteeism	0.13	0.19	0.06	0.18	0.21	0.15	0.13	0.15	0.10
WPAI-CU Presenteeism	0.38	0.45	0.24	0.52	0.55	0.45	0.47	0.49	0.40
WPAI-CU Overall Work Impairment	0.37	0.44	0.22	0.53	0.56	0.46	0.46	0.49	0.39
WPAI-CU Activity Impairment	0.34	0.41	0.21	0.57	0.58	0.52	0.48	0.48	0.43
AIS7	0.71	0.79	0.48	0.86	0.89	0.76	0.81	0.84	0.71
SIS7	0.70	0.78	0.49	0.83	0.86	0.73	0.79	0.82	0.69
No. of rescue medication tablets over 7 days	0.20	0.20	0.16	0.30	0.30	0.28	0.21	0.22	0.19
No. of angioedema days over 7 days	0.25	0.30	0.14	0.36	0.38	0.31	0.34	0.36	0.30
No. of days called HCP over 7 days	0.18	0.24	0.08	0.15	0.17	0.12	0.14	0.16	0.12

AAS7: weekly Angioedema Activity Score; AIS7: weekly Activity Interference Score; DLQI: Dermatology Life Quality Index; HCP: healthcare practitioner; HSS7: weekly Hives Severity Score; ISS7: weekly Itch Severity Score; PGIC: Patient Global Impression of Change; PGIS: Patient Global Impression of Severity; SIS7 = weekly Sleep Interference Score; UAS7 = weekly Urticaria Activity Score; UCT7 = Urticaria Control Test 7-day recall version; VAS: visual analog scale; WPAI-CU: Work Productivity and Activity Impairment Questionnaire V2.0 for Chronic Urticaria

Notes: Teal shading indicates correlations that met the a priori hypotheses; blue shading indicates correlations that were higher than hypothesized; grey shading indicates correlations with no associated hypotheses

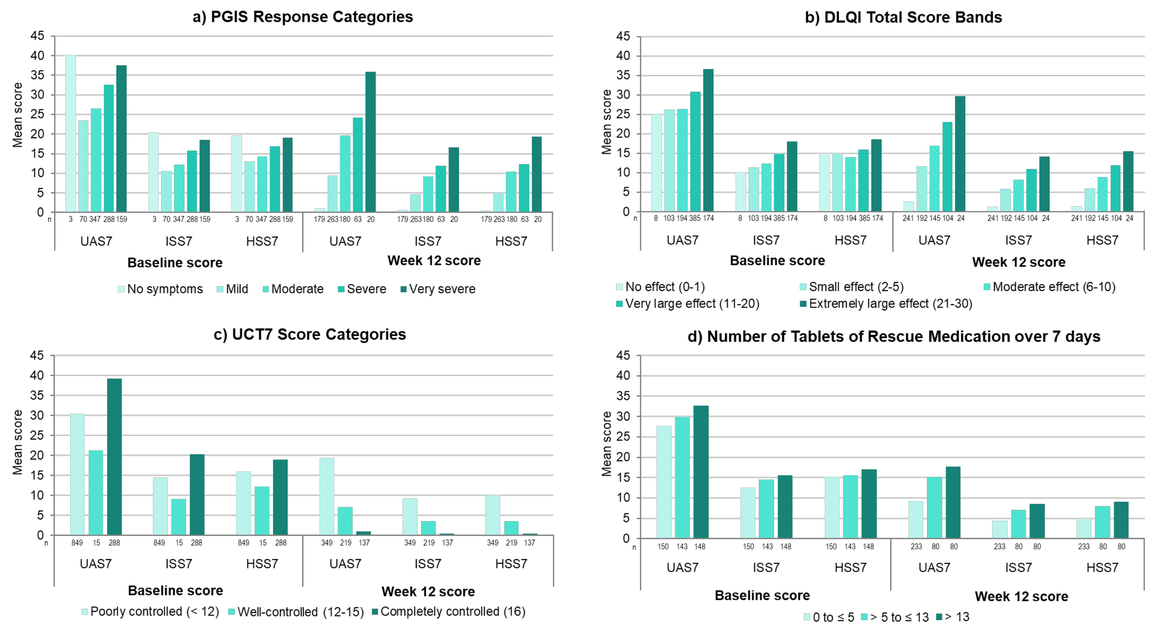
Known-Groups Analysis

- Higher mean UAS7, ISS7, and HSS7 scores were associated with more severe symptoms on the PGIS, worse health-related quality of life (HRQOL) on the DLQI, poorer control on the UCT7, and taking more tablets of rescue medication (**Figure 1**; results at week 2 were similar to week 12)

Change-Groups Analysis

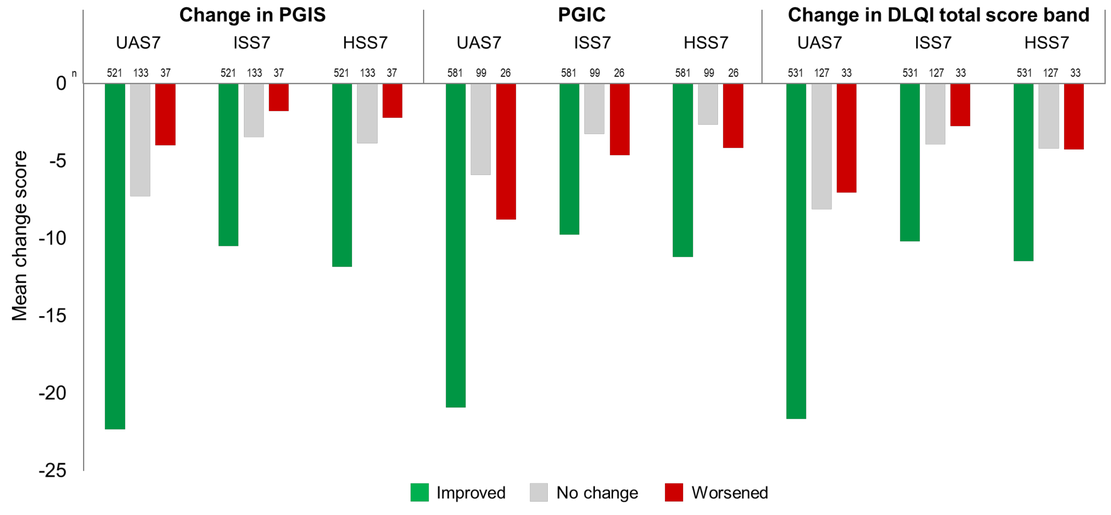
- The highest negative mean changes in UAS7, ISS7, and HSS7 (indicating greatest improvement) were observed for participants who had improved based on the PGIS, PGIC, and DLQI total score bands, compared with participants who had not changed or had worsened (**Figure 2**; results for change at week 2 were similar)

Figure 1. UAS7, ISS7, and HSS7 by Known Groups at Baseline and Week 12



DLQI: Dermatology Life Quality Index; HSS7: weekly Hives Severity Score; ISS7: weekly Itch Severity Score; PGIS: Patient Global Impression of Severity; UAS7: weekly Urticaria Activity Score; UCT7: Urticaria Control Test 7-day recall version.
Notes: ANOVA *P* values all < 0.01; Possible score ranges 0-42 in UAS7, 0-21 in ISS7, and 0-21 in HSS7.

Figure 2. Change From Baseline to Week 12 in UAS7, ISS7, and HSS7 By Change Subgroups in the PGIS, PGIC, and DLQI Total Score Bands



ANOVA: analysis of variance; DLQI: Dermatology Life Quality Index; HSS7: weekly Hives Severity Score; ISS7: weekly Itch Severity Score; PGIC: Patient Global Impression of Change; PGIS: Patient Global Impression of Severity; UAS7: weekly Urticaria Activity Score
Notes: ANOVA *P* values all < 0.0001. Negative change scores indicate improvement

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Disclosures

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