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A Concordance Study between Patient Acceptable Symptom State (PASS) and Disease Activity in Chronic Spontaneous Urticaria

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ABSTRACT

Introduction: The Patient Acceptable Symptom State (PASS), a patient-reported outcome measure, has demonstrated correlations with disease severity in various conditions, including psoriasis and scleroderma. However, the clinical relevance of PASS in the context of chronic spontaneous urticaria (CSU) remains to be fully elucidated.

Objectives: This study aimed to determine the prevalence of PASS among CSU patients, identify potential predictors, and establish the weekly urticaria activity score (UAS7) threshold for PASS.

Methods: Demographic and clinical data from CSU patients were prospectively collected. PASS attainment was assessed using a single-item questionnaire. Logistic regression analysis and interaction effects analysis were employed to identify predictors associated with achieving PASS (PASS-Y) or failing to achieve PASS (PASS-N). The UAS7 threshold corresponding to PASS was determined through receiver operating characteristic (ROC) curve analysis.

Results: A total of 161 CSU patients were enrolled in this study. Among them, 70.5% exhibited non-severe disease activity (UAS7<28) and achieved PASS-Y. Logistic regression analysis revealed a

significant association between UAS7 scores and PASS status (AOR=1.105, *P*<0.001). Female patients with severe disease activity (UAS7≥ 28) were significantly less likely to achieve PASS-Y compared to their male counterparts (AOR=3.514, *P*=0.042). ROC analysis identified a UAS7 threshold of 21.5 for predicting PASS, with an area under the curve (AUC) of 0.821.

Conclusions: In patients with CSU, PASS demonstrates a strong correlation with UAS7 scores and is straightforward to implement. It may serve as a valuable complementary tool to UAS7 in clinical settings, facilitating a rapid, patient-centered assessment of disease activity.

Introduction

Chronic spontaneous urticaria (CSU) is characterized by recurrent episodes of wheals (hives), angioedema, or a combination of both, persisting for more than six weeks without identifiable external triggers [1,2]. It is estimated that approximately 1–3% of the general population is affected by CSU [3]. The condition predominantly affects individuals aged 20 to 40 years and significantly impairs quality of life, affecting work and academic performance, mental health, and sleep quality [4,5]. Notably, the impact on daily functioning in CSU patients is comparable to that observed in patients undergoing coronary artery bypass surgery [6].

Current clinical guidelines emphasize the importance of incorporating patient-reported outcome measures (PROMs) to monitor disease progression and treatment response. The Weekly Urticaria Activity Score (UAS7) is widely recommended as the standard PROM for quantifying disease activity in CSU [2,7]. Given the fluctuating nature of CSU symptoms, this validated instrument ranges from 0 to 42, with higher scores indicating greater disease severity and greater impairment of quality of life [8]. A clinically meaningful therapeutic response in CSU is typically defined as either a UAS7 reduction of ≥11 points [9] or a Urticaria Control Test (UCT) of ≥12 points [10].

PASS is a patient-reported tool that evaluates perceived health status and focuses on the patient's subjective assessment of treatment effectiveness. Achieving PASS indicates that the patient perceives their condition to be adequately controlled [11]. PASS is assessed through a single binary question regarding the patient's satisfaction with their current symptom status. It reflects the patient's perception of well-being and serves as a simple yet meaningful indicator of treatment success. The relationship between PASS and disease activity scores or other PROMs has been investigated in several conditions, including rheumatoid arthritis [12], ankylosing spondylitis [13,14], psoriatic arthritis [15], scleroderma [16], and lichen planus [17]. However, to date, no study has specifically examined the clinical significance of PASS in patients with CSU.

Objective

While UAS7 primarily evaluates the core symptoms and signs of CSU, namely wheals and pruritus, other aspects of patient well-being, such as discomfort (e.g., burning, stinging, or pain) and emotional disturbances (e.g., anxiety or depression), also warrant comprehensive assessment. As a holistic evaluation tool, PASS may complement UAS7 by capturing broader dimensions of disease impact. The objectives of this study were to determine the prevalence of PASS among CSU patients, identify potential predictors of PASS achievement, evaluate the ability of UAS7 to distinguish between PASS and non-PASS states, and establish the UAS7 threshold that best differentiates between these states.

Methods

Study Design and the Patients

CSU patients were prospectively enrolled from the Urticaria Center of Reference and Excellence (UCARE) at the Department of Dermatology of Xiangya Hospital, Central South University, between August 2023 and December 2023. The inclusion criteria consisted of patients diagnosed with CSU as determined by an experienced dermatologist who specializes in CSU. In addition, participants had to be at least 18 years old. The individuals who were unable to participate in the study due to various reasons, those with psychiatric disorders or other severe, uncontrolled systemic diseases, those with other skin diseases such as psoriasis or atopic dermatitis that could influence the results, and pregnant or lactating women were excluded. This study strictly adhered to the Declaration of Helsinki and was reviewed and approved by the Ethics Committee of Xiangya Hospital, Central South University (Ethics No. 202308636). All the patients signed informed consent.

Data Collection

The demographic characteristics assessed included age, sex, height (in centimeters), weight (in kilograms), educational attainment (categorized as primary or junior school, high

school, or college and above), marital status (classified as married, unmarried, or divorced), smoking and drinking habits, and body mass index (BMI), which was categorized as non-overweight, overweight, obese, or severely obese [18]. Clinical characteristics included disease duration of chronic spontaneous urticaria (CSU), presence or absence of angioedema, disease activity, family history of allergic diseases (including atopic dermatitis, chronic urticaria, allergic rhinitis, asthma, et cetera), and treatment history. Disease activity was evaluated using the weekly urticaria activity score (UAS7). A UAS7 score of 0 indicated no disease activity, a score between 1 and 6 indicated mild activity, a score between 7 and 27 indicated moderate activity, and a score of 28 or higher indicated severe activity [19]. During the clinical visit, patients were asked the question: "Imagine the symptoms of urticaria and their impact on your well-being over the past week. Would you be willing to tolerate this for the upcoming months?" If the patient responded with "acceptable," this indicated that the Patient Acceptable Symptom State (PASS) had been achieved (referred to as PASS-Y). Conversely, a response of "not acceptable" was considered as not achieving PASS (referred to as PASS-N) [15]. This question was adapted from the widely accepted and validated PASS format, which has been extensively utilized in studies of chronic immune-mediated diseases [12-17]. The recall period of "the past week" was selected to align with the fluctuating nature of CSU symptoms and to ensure consistency with the assessment window of the UAS7.

Statistical Analysis

The sample size for this study was determined using Power Analysis and Sample Size software (2021), yielding a minimum required sample size of 139. Continuous data that did not follow a normal distribution were summarized using the median and interquartile range (IQR), where IQR is defined as the range between the 25th percentile (P_{25}) and the 75th percentile (P_{75}). Categorical variables are presented as frequencies and percentages. The Mann-Whitney U test was applied to compare differences in continuous variables between groups, whereas the chi-square test or Fisher's exact test was used for categorical variables. Logistic regression analysis was conducted to examine the association between PASS and disease activity scores as well as the clinical characteristics of patients with CSU. The strength of these associations was expressed using odds ratios (OR) and 95% confidence intervals (CI). Adjusted odds ratios (AOR) were calculated after controlling for potential confounding factors. Interaction effects were assessed using the likelihood ratio test. The receiver operating characteristic (ROC) curve was employed to identify the optimal threshold of PASS in relation to UAS7 scores, with the threshold selected based on the maximum Youden index to ensure high sensitivity and specificity. All statistical tests were two-sided, and a *p*-value of less than 0.05 was considered statistically significant unless otherwise stated. Data were analyzed using SPSS Statistics 26 (IBM) and R software (version 4.4.1), and ROC curves were plotted using GraphPad Prism version 10.0.0.

Results

Demographic and Clinical Characteristics of the Participants

A total of 184 patients met the inclusion criteria, with 23 excluded due to refusal to participate, resulting in a final cohort of 161 participants for analysis. The demographic and clinical characteristics of all enrolled patients are summarized in Table 1. Among the CSU patients, 74 (46.0%) reported having achieved PASS status (PASS-Y), whereas 87 (54.0%) did not achieve PASS status (PASS-N).

No statistically significant difference was observed between the PASS-Y and PASS-N groups in terms of age, sex, education level, marital status, smoking and drinking habits, BMI, disease duration, presence of angioedema, or family history of allergic disorders ($P>0.05$). However, UAS7 scores showed a statistically significant difference between the two groups. The median (interquartile range) UAS7 score in the PASS-Y group was significantly lower than that in the PASS-N group ($P<0.001$). Furthermore, there was a notable difference in disease activity levels between the two groups ($P<0.001$). Patients with lower UAS7 scores were more likely to achieve PASS-Y, whereas those with higher UAS7 scores were less likely to do so. Specifically, 28.4% of CSU patients with mild disease activity (UAS7 <7) considered their disease status acceptable, compared with 52.7% of those with moderate disease activity (7≤UAS7<28) and 18.9% of those with severe disease activity (UAS7 ≥28).

Disease Activity is Associated with PASS Status in Patients with CSU

Table 2 presents the results of univariate and multivariable logistic regression analyses examining factors associated with PASS status. Univariate logistic regression analysis revealed a significant association between UAS7 scores and PASS status (OR=1.105, 95% CI: 1.070–1.140, $P<0.001$). After adjusting for age, sex, and UAS7, multivariable logistic regression analysis indicated that higher UAS7 scores were significantly associated with a greater likelihood of rejecting the current disease status (AOR=1.105, 95% CI: 1.070–1.141, $P<0.001$).

To further investigate the relationship between disease activity and PASS status in CSU patients, a subgroup analysis was conducted based on disease activity levels determined by UAS7 scores. As shown in Table 3, patients in the

Table 1. Comparison of demographic and clinical characteristics between PASS-Y and PASS-N group in CSU patients.

	Total N=161	PASS-Y N=74	PASS-N N=87	Z-score/χ^2	*P*-value
Age (years), median (IQR)	35.0(28.0,50.0)	33.5(26.0,48.0)	37.0(29.0,51.0)	-1.393[a]	0.164
Sex (Female), N (%)	95(59.0)	40(54.0)	55(63.2)	1.338[b]	0.239
Education, N (%)				-0.544[a]	0.586
Primary and junior high school	35(21.7)	13(17.6)	22(25.3)		
High school	40(24.8)	21(28.4)	19(21.8)		
College and above	86(53.4)	40(54.0)	46(52.9)		
Marital status, N (%)				0.076[b]	0.783
Unmarried/divorced	44(27.3)	21(28.4)	23(26.4)		
Married	117(72.7)	53(71.6)	64(73.6)		
Smoking habits, N (%)	27(16.8)	12(16.2)	15(17.2)	0.030[b]	0.862
Drinking habits, N (%)	45(28.0)	23(31.1)	22(25.3)	0.667[b]	0.414
BMI (kg/m2), median (IQR)	22.6(20.3,25.6)	22.2(20.6,25.7)	22.7(20.2,25.1)	-0.047[a]	0.962
<18.5, N (%)	12(7.5)	5(6.8)	7(8.0)	-0.131[a]	0.896
18.5-23.9, N (%)	94(58.4)	44(59.5)	50(57.5)		
24-27.9, N (%)	44(27.3)	19(25.7)	25(28.7)		
≥28, N (%)	11(6.8)	6(8.1)	5(5.7)		
Duration of disease (years), median (IQR)	0.8(0.3,3.0)	0.7(0.3,3.0)	1.0(0.4,2.0)	-0.886[a]	0.375
<0.5, N (%)	66(41.0)	35(47.3)	31(35.6)	-1.041[a]	0.298
0.5-2, N (%)	38(23.6)	14(18.9)	24(27.6)		
2-10, N (%)	51(31.7)	22(29.7)	29(33.3)		
>10, N (%)	6(3.7)	3(4.1)	3(3.4)		
UAS7 score, median (IQR)	23.0(14.0,35.0)	14.0 (6.0,21.0)	34.0(22.0,42.0)	-7.042[a]	<0.001
<7, N (%)	26(16.2)	21(28.4)	5(5.7)	-6.647[a]	<0.001
7-27, N (%)	59(36.6)	39(52.7)	20(23.0)		
≥28, N (%)	76(47.2)	14(18.9)	62(71.3)		
Angioedema, N (%)	10(6.2)	3(4.1)	7(8.0)	1.094[c]	0.296
Family history of allergic diseases, N (%)	39(24.2)	19(25.7)	20(23.0)	b	1.000
Treatment, N (%)				3.665[d]	0.456
No	12(7.5)	4(5.4)	8(9.2)		
Antihistamines	129(80.1)	63(85.1)	66(75.9)		
Omalizumab	3(1.9)	1(1.4)	2(2.3)		
Corticosteroids	14(8.7)	4(5.4)	10(11.5)		
Chinese traditional medicine	3(1.9)	2(2.7)	1(1.1)		

Data are expressed as median and interquartile range (IQR) or N (%). [a] Mann-Whitney U test statistic Z-score; [b] Fisher's exact test statistic; [c] Pearson chi-square statistic χ^2; [d] Fisher-Freeman-Halton statistic. BMI, body mass index; PASS, Patient Acceptable Symptom Status; UAS7, the weekly Urticaria Activity Score.

moderate disease activity group (7 ≤ UAS7 < 28) with higher UAS7 scores were more likely to report dissatisfaction with their disease status (AOR=1.147, 95% CI: 1.013–1.298, *P*=0.031). In the severe disease activity group, female patients were significantly less likely to accept their disease status compared to male patients (AOR=3.514, 95% CI: 1.045–11.822, *P*=0.042). Based on the likelihood ratio test, there was no statistically significant interaction effect between sex and either disease activity or disease duration on PASS attainment.

Table 2. Univariate and multivariable regression analysis between demographic and clinical parameters and PASS status.

Characteristics	Univariate analysis		Multivariable analysis	
	OR (95%CI)	*P*-value	AOR (95%CI)	*P*-value
Age	1.017(0.994-1.041)	0.155	1.003(0.974-1.033)	0.832
Sex (ref=male)	1.461(0.777-2.747)	0.239	1.600(0.743-3.442)	0.229
Education				
Primary and junior high school (ref)	-	-	-	-
High school	0.535(0.212-1.348)	0.184	-	-
College and above	0.680(0.304-1.521)	0.348	-	-
			-	-
Marital status Unmarried/divorced(ref) Married	1.103(0.550-2.208)	0.783		
Disease duration	0.985(0.915-1.061)	0.693	-	-
UAS7	1.105(1.070-1.140)	<0.001	1.105(1.070-1.141)	<0.001
Family history of allergic diseases	0.864(0.420-1.779)	0.692	-	-
Treatment				
No (ref)	-	-	-	-
Antihistamines	0.524(0.150-1.826)	0.310	-	-
Omalizumab	1.000(0.068-14.640)	1.000	-	-
Corticosteroids	1.250(0.236-6.633)	0.793	-	-
Chinese patent medicine	0.250(0.017-3.660)	0.311	-	-

Abbreviations: AOR: adjusted odds ratio; CI: confidence interval; OR: odds ratio; PASS: Patient Acceptable Symptom Status (PASS-N versus PASS-Y); UAS7: the weekly Urticaria Activity Score.

The Cutoff Value of the UAS7 Score to Distinguish PASS

Receiver operating characteristic (ROC) curve analysis demonstrated that a UAS7 score of 21.5 served as an effective threshold for distinguishing between CSU patients who achieved PASS-Y and those who did not (PASS-N), indicating the predictive value of the UAS7 score in identifying PASS status. The area under the curve (AUC) was 0.821 (95% CI: 0.755–0.886), with a sensitivity of 0.759 and a specificity of 0.784 (Figure 1).

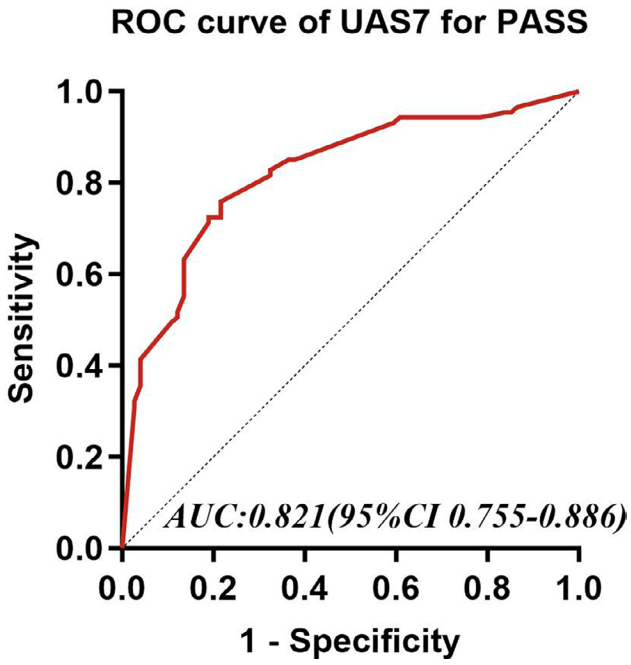

Figure 1. Receiver operating characteristic (ROC) curve of the UAS7 for Patient Acceptable Symptom State (PASS). Optimal cut-off: UAS7=21.5 (Youden index=0.543, sensitivity=0.759, specificity=0.784). The area under the curve (AUC) was 0.821.

Discussion

CSU is a chronic inflammatory condition that can persist for several months or even decades, significantly affecting patients' quality of life, mental health, and work productivity [2]. Moreover, it may contribute to psychological distress, including anxiety and depression [20]. Therefore, when evaluating CSU patients, it is essential to consider not only clinical manifestations but also the broader impact on quality of life and related psychosocial factors. Currently, there is a lack of sensitive, easily applicable laboratory indicators for assessing disease activity and treatment efficacy in CSU patients.

Table 3. Logistic regression and interaction analysis of patient characteristics in different subgroups.

Characteristics	Mild group (UAS7<7)		Moderate group (7≤UAS7<28)		Severe group (UAS7≥28)		Total	Disease duration
	AOR (95%CI)	*P*-value	AOR (95%CI)	*P*-value	AOR (95%CI)	*P*-value	*P* for interaction	*P* for interaction
Age	0.977(0.899-1.061)	0.574	0.983(0.937-1.030)	0.469	1.038(0.993-1.085)	0.098	0.061	0.165
Sex (ref=male)	3.636(0.346-38.232)	0.282	0.625(0.210-1.856)	0.397	3.514(1.045-11.822)	0.042	0.079	0.238
BMI	0.988(0.801-1.219)	0.912	1.057(0.928-1.205)	0.403	0.918(0.770-1.095)	0.342	0.349	0.476
Education							0.446	0.969
Primary and junior high school (ref)	-	-	-	-	-	-		
High school	0.000	0.999	0.970(0.168-5.593)	0.973	2.647(0.248-28.240)	0.420		
College and above	0.300(0.029-3.135)	0.315	1.733(0.387-7.764)	0.472	0.529(0.128-2.192)	0.380		
Marital status	1.600(0.147-17.411)	0.700	1.034(0.299-3.580)	0.957	1.471(0.431-5.018)	0.538	0.957	0.247
Disease duration	1.038(0.760-1.418)	0.817	0.962(0.858-1.079)	0.508	1.289(0.871-1.908)	0.204	0.237	0.426
UAS7	0.786(0.484-1.277)	0.331	1.147(1.013-1.298)	0.031	1.114(0.993-1.249)	0.065	0.221	0.237
Family history of allergic diseases	1.667(0.220-12.617)	0.621	0.848(0.248-2.900)	0.793	1.592(0.316-8.020)	0.573	0.939	0.230

Abbreviations: AOR: adjusted odds ratio; CI: confidence interval; OR: odds ratio; PASS: Patient Acceptable Symptom Status (PASS-N versus PASS-Y); UAS7: the weekly Urticaria Activity Score.

Patient-reported outcome (PRO) serves as a valuable tool for capturing patients' subjective experiences, disease symptoms, and the overall impact of the condition. It facilitates a comprehensive evaluation of the patient's status throughout the treatment process, thereby supporting the selection of optimal, effective therapeutic interventions. Currently, commonly used PRO instruments in chronic spontaneous urticaria (CSU) include the Urticaria Activity Score (UAS), the Urticaria Control Test (UCT), the Dermatology Life Quality Index (DLQI), and the Chronic Urticaria Quality of Life Questionnaire (CU-Q2oL). These tools have demonstrated high reliability and validity in assessing disease activity and treatment efficacy [8,9]. However, their implementation in clinical practice can be cumbersome and time-consuming, which may reduce patient willingness to participate, particularly in China. Additionally, CRUSE (Chronic Urticaria Self Evaluation) is available as a mobile application that allows patients to complete PRO assessments via their smartphones. Nevertheless, its widespread adoption may be limited by constraints related to internet access, device availability, or patient willingness to use digital tools [21].

The Patient Acceptable Symptom State (PASS) is a patient-reported measure that reflects the overall perception of disease symptoms. It closely aligns with real-world clinical scenarios and is straightforward to implement [11,15]. PASS facilitates dermatologists in understanding patients' perspectives and adjusting treatment strategies accordingly. In our study, less than half of the patients (46.0%) reported an acceptable symptom state (PASS-Y). Compared with other dermatological conditions, studies have shown that approximately 71.4% of patients with mild psoriasis perceived their condition as acceptable (PASS-Y) [22], and 71.0% of patients with active diffuse cutaneous systemic sclerosis achieved PASS [16]. This discrepancy may be attributed to the higher disease activity and longer disease duration observed in our cohort. However, most patients with mild or moderate disease activity in our study accepted their symptom status. Interestingly, female CSU patients with severe disease activity were less likely to achieve PASS compared to their male counterparts. Furthermore, the interactions of sex with both disease severity and disease duration were not statistically significant. These results indicate that female sex may be an independent predictor of PASS attainment. Previous studies on psoriasis and ligament reconstruction have similarly indicated that female patients are less likely to achieve PASS [22,23]. Research has also shown that female patients with chronic urticaria tend to experience longer disease duration, more severe symptoms, and a poorer response to treatment [24-26] and are more likely to suffer from comorbidities such as anxiety, depression, and fatigue [27,28]. These factors may partially explain the lower acceptance of symptom status among female patients compared to males.

Receiver operating characteristic (ROC) curve analysis was conducted to determine the optimal UAS7 score threshold for distinguishing between PASS-Y and PASS-N. The threshold was identified as 21.5, which falls within the range of moderate disease activity. This finding is consistent with the majority of existing studies, suggesting that PASS is typically associated with mild-to-moderate disease severity [11,12,15]. However, in the long-term management of chronic diseases, the ultimate goal is to prevent or minimize disease progression. Therefore, the concept of an acceptable symptom state does not equate to complete remission (UAS7=0, UCT ≥12). Clarifying the relationship between these two endpoints is essential to guiding treatment adjustments.

This study has several limitations. First, data were collected from a single large tertiary hospital, which may have introduced potential selection bias. Second, the fluctuating nature of CSU symptoms may affect the consistency of the PASS over time. Third, as the concept of PASS is relatively new, there is currently no consensus on its exact wording or construct validity, which may lead to variability in how patients interpret it. Further multicenter, large-sample studies are needed to confirm the reliability of PASS and evaluate its clinical applicability.

Conclusions

This study demonstrates that the Patient Acceptable Symptom State (PASS) is an effective and straightforward patient-centered tool for evaluating disease acceptance and satisfaction in chronic spontaneous urticaria (CSU), exhibiting good consistency with UAS7. Our findings reveal that more than half of CSU patients find their current disease status unacceptable (PASS-N). Notably, higher disease activity is associated with a lower likelihood of achieving PASS-Y, and female patients exhibit a significantly reduced probability of symptom acceptance in the severe disease activity subgroup (UAS7 ≥ 28). These findings underscore the clinical value of integrating PASS into routine assessments to capture unmet health-related quality of life needs that conventional symptom-based tools may overlook. For patients in the PASS-N state, proactive modification of treatment strategies is recommended to enhance overall patient satisfaction, with special clinical attention warranted for female patients. Future studies are needed to further elucidate the impact of psychosocial determinants, including psychological stress, anxiety, depression, and social support, on patient-perceived disease acceptance.

Ethics Statement: This study was reviewed and approved by the Ethics Committee of Xiangya Hospital, Central South University (Ethics No. 202308636).

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