Brief report

Validity, reliability, and sensitivity to change of the traditional Chinese Urticaria Control Test (UCT) in Hong Kong

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Background: Uncontrolled chronic urticaria (CU) can severely affect physical and psychosocial health as well as quality of life. Patient-reported outcome measures are crucial for measuring disease control. The Urticaria Control Test (UCT) is recommended by guidelines to monitor CU and guide clinical management. However, the traditional Chinese version of the UCT has not yet been validated.

Objective: We sought to validate the traditional Chinese UCT among Chinese CU patients in Hong Kong.

Methods: Patients with CU were enrolled at a Urticaria Centre of Reference and Excellence (aka UCARE) in Hong Kong and completed the traditional Chinese UCT. The internal consistency, test–retest reliability, construct validity, convergent validity, known-group validity, and sensitivity to change of the traditional Chinese UCT were evaluated.

Results: We recruited 162 CU patients (80.9% female; age 50 ± 14 years) with a mean (median) ± standard deviation baseline UCT score of 8.8 (8) ± 4.7. Overall, Chinese UCT showed excellent internal consistency (Cronbach α and McDonald ω = 0.948), as well as test–retest reliability (intraclass correlation coefficient = 0.916 [95% confidence interval = 0.866-0.953]). Exploratory factor analysis revealed a unidimensional structure and confirmed its construct validity. Strong correlation between UCT and the 7-day urticaria activity score (UAS7) attested to its convergent validity ($\rho = -0.699$, $P < .001$). Its known-group validity was supported by significantly different UCT scores among patient subgroups with different disease activity. The Chinese UCT also demonstrated good sensitivity to change, as reflected by the significant correlation between changes in UCT and UAS7 scores ($\rho = 0.491$, $P < .001$).

Conclusion: The traditional Chinese UCT is a valid, reliable, and sensitive-to-change instrument among Hong Kong Chinese with CU. (J Allergy Clin Immunol Global 2024;3:100290.)

Key words: *Chinese, chronic, control, patient-reported outcome measures, spontaneous, urticaria, validation*

INTRODUCTION

Chronic urticaria (CU) is defined by recurrent hives and/or angioedema for longer than 6 weeks.[1] Affecting about 1% of the world's population, CU is often mistaken as being a trivial illness, although patient symptoms are often beyond skin deep. Uncontrolled CU can lead to devastating physical and psychosocial impairment, and it is often severely detrimental to patient well-being. Subjective patient elements and comorbidities—including interference with daily life, sleep disturbances, sexual dysfunction, and anxiety and depression—can significantly affect health-related quality of life but often remain underappreciated.[2]

To measure more holistic patient outcomes, regional and international urticaria guidelines recommend a stepwise treatment approach based on patient-reported outcome measures (PROMs).[1,3] Among them, the Urticaria Control Test (UCT) is one of the questionnaires of choice. The UCT is a 4-item questionnaire that evaluates urticaria control, covering the aspects of physical symptoms, quality of life, treatment efficacy, and overall disease control. Its score ranges from 0 to 16, with a higher score reflecting better disease control.[4] Since its development in 2014, the UCT has been translated and validated in different languages and patient populations. Although a simplified Chinese version was validated in Beijing (China), the performance of the traditional Chinese version of the UCT and among other Chinese populations remains unknown.[5] Traditional Chinese (using traditional characters), which is the original form of written Chinese, is the norm for many Chinese populations (such as in Hong Kong, Macau, and Taiwan as well as in overseas communities), who often cannot understand simplified characters. This study aimed to address this gap and validate the traditional Chinese-language version of the UCT among Hong Kong Chinese.

All consecutive adult patients newly diagnosed with CU were prospectively recruited at the Urticaria Clinic of the Hong Kong West Cluster (HKWC) between July 2022 and June 2023. Only patients who met the diagnostic criteria of CU according

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Received for publication December 31, 2023; revised February 6, 2024; accepted for publication March 5, 2024.

Available online June 12, 2024.

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2772-8293

https://doi.org/10.1016/j.jacig.2024.100290

Abbreviations used
CU: Chronic urticaria
HKWC: Hong Kong West Cluster
PROM: Patient-reported outcome measure
UAS7: Seven-day urticaria activity score
UCT: Urticaria control test

to the 2022 international EAACI/GA^{2}LEN/EuroGuiDerm/APAAACI urticaria guideline were recruited.[1] Patients who had stand-alone angioedema (without hives) or who could not read traditional Chinese were excluded. HKWC is an accredited Urticaria Centre of Reference and Excellence (aka UCARE) and is the only referral center offering dedicated specialist care for CU in the territory.[6]

This study was approved by the institutional review board of the University of Hong Kong/Hospital Authority HKWC. Informed consent was obtained from all patients.

All eligible patients assessed their disease control and activity using the UCT (see Fig E1 in the Online Repository available at www.jaci-global.org) and the 7-day urticaria activity score (UAS7), respectively. We classified patients' disease activity into 5 classes with the UAS7 as follows: no disease activity (0), minimal disease activity (1-6), mild disease activity (7-15), moderate disease activity (16-27), and severe disease activity (26-42).[7] Patient demographic and clinical characteristics (age at clinic visit, sex, concomitant angioedema, relevant triggers of exacerbation, concomitant autoimmune diseases, suspected food or drug allergy, and history of hospital visits due to CU) were analyzed.

We assessed the internal consistency of the Chinese UCT by Cronbach α and McDonald ω. The UCT's test–retest reliability was tested among patients whose UAS7 differed no more than 2 points based on the intraclass correlation coefficient. We also examined the factor structure of the Chinese UCT by exploratory factor analysis with maximum likelihood for its construct validity. Factors were extracted according to the scree plot. Questions with factor loadings that did not exceed 0.40 were excluded.

For convergent validity, we reviewed the Spearman correlation between UCT and UAS7. UCT scores were then successively compared between groups by independent *t* test for known-group validity.

The sensitivity to change of the Chinese UCT was analyzed by Spearman correlation between improvements in its score and improvements in UAS7 of patients attending their follow-up visits. Patients without a second UCT and UAS7 score (for the same visit) were excluded in this part. Longitudinal PROM scores were also compared by paired *t* test.

Unless otherwise specified, categorical and continuous variables are expressed as number (percentage) and mean (median) ± standard deviation, respectively. All statistical analyses were performed by SPSS Statistics 28.0 software (IBM, Armonk, NY). Two-sided $P < .05$ was considered statistically significant.

RESULTS AND DISCUSSION

A total of 162 patients with CU were enrolled onto this study (Table I). All patients were of Han Chinese origin (the majority ethnicity, comprising >90% of Chinese) and resided in Hong Kong; a total of 131 (80.9%) were women, and the average age was 50 ± 14 years. Among them, 94 (58.0%) reported concomitant angioedema, and 26 (16.0%) could identify relevant triggers. At baseline, the average UCT and UAS7 score was 8.8 (8) ± 4.7 and 13.5 (12) ± 12.1, respectively. Detailed distribution of UCT scores and individual items are shown in Fig 1 and Table II, respectively. There were no significant differences in baseline UCT scores among patients of different age; sex; smoking status; suspected food or drug allergy; and presence of concomitant angioedema, potential CU triggers, concomitant autoimmunity, or history of hospital visits for CU (all $P < .05$).

TABLE I. Clinical characteristics of patients

Characteristic	No. (%)
Total	162 (100.0)
Female sex	131 (80.9)
Smoking	
Active smoker	10 (6.2)
Ex-smoker	10 (6.2)
Nonsmoker	142 (87.7)
Concomitant angioedema	94 (58.0)
Relevant triggers of CU exacerbation*	26 (16.0)
Autoimmune comorbidity†	16 (9.9)
Suspected drug allergy	69 (42.6)
Suspected food allergy	21 (13.0)
History of hospital visits related to CU	75 (46.3)

Mean ± standard deviation age of patients was 50 ± 14 years.
*Stress (n = 4), food (n = 4), and drugs (n = 4) were the top 3 identified triggers of CU exacerbation.
†Graves disease (n = 6), Sjögren syndrome (n = 2), and Kikuchi disease (n = 2) were the top 3 autoimmune comorbidities.

In terms of reliability, the Chinese UCT showed excellent internal consistency for clinical application (Cronbach α and McDonald ω = 0.948). Its intraclass correlation coefficient reached 0.916 (95% confidence interval = 0.866-0.953), implying excellent test–retest reliability. In favor of construct validity, exploratory factor analysis suggested a 1-factor structure for the traditional Chinese UCT, able to explain up to 86.55% of the total variance. In this model, the factor loadings of all 4 questions were above 0.40 (Table II). Spearman correlation between UCT and UAS7 demonstrated significant and strong correlations ($\rho = -0.699$, $P < .001$), supporting the convergent validity of UCT (Table III). The known-group validity of the Chinese UCT was verified by significant differences of UCT scores among patients with different disease activity levels, as shown in Table III and Fig 2. The sensitivity of change analysis included 104 patients with available follow-up PROM scores. Compared to their first clinic visits, both their UCT and UAS7 scores demonstrated significant improvements, as follows: UCT: 8.4 (8) ± 4.6 vs 11.1 (12) ± 4.6 ($P < .001$); and UAS7: 15.5 (14) ± 12.1 vs 8.5 (4) ± 10.7 ($P < .001$). On average, UCT improved by 2.7 (2) ± 5.0 points, whereas UAS7 scores improved by 7.0 (4) ± 11.6 points, showing a moderate correlation in between ($\rho = 0.491$, $P < .001$) and an established sensitivity to change for the Chinese UCT.

This study demonstrated the validity, reliability, and sensitivity to change of the traditional Chinese UCT, thus paving the way for further clinical studies among more diverse patient populations in the future. Similar to reports for other populations, we found significant correlations between disease activity (assessed by UAS7) and disease control (measured by UCT) among Chinese CU patients.[8-15] This supports the convergent validity and sensitivity to change of the UCT, justifying the use of this PROM in

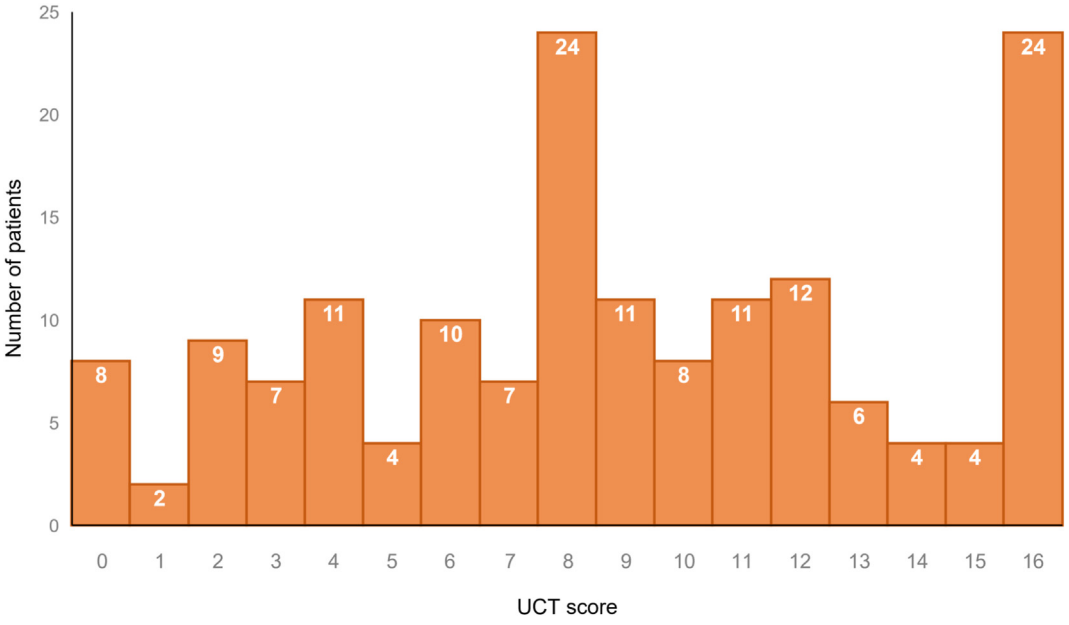

FIG 1. Distribution of baseline UCT scores.

TABLE II. Score distributions and factor loadings of the 4 items in UCT

Characteristic	Q1 (physical symptoms)	Q2 (quality of life)	Q3 (treatment efficacy)	Q4 (overall control)
Score distribution				
Mean (median) ± standard deviation	2.0 (2) ± 1.3	2.3 (2) ± 1.4	2.4 (2) ± 1.3	2.2 (2) ± 1.2
0 points (worst)	23 (14.2)	23 (14.2)	17 (10.5)	16 (9.9)
1 point	31 (19.1)	23 (14.2)	22 (13.6)	28 (17.3)
2 points	52 (32.1)	48 (29.6)	47 (29.0)	58 (35.8)
3 points	28 (17.3)	27 (16.7)	39 (24.0)	32 (19.8)
4 points (best)	28 (17.3)	41 (25.3)	37 (22.8)	28 (17.3)
Factor loading	0.913	0.942	0.893	0.872

The points are number (percentage); N = 162.

TABLE III. UCT scores according to disease activity categories and correlation between UCT and UAS7

Characteristic	Q1 (physical symptoms)	Q2 (quality of life)	Q3 (treatment efficacy)	Q4 (overall control)	UCT total
Disease activity (UAS7)					
Severe (n = 30)	0.8 (1) ± 0.9	0.8 (1) ± 0.9	0.9 (0.5) ± 1.1	1.0 (1) ± 1.0	3.4 (3) ± 3.2
Moderate (n = 34)	1.4 (1.5) ± 0.9	1.6 (2) ± 1.1	2.1 (2) ± 1.0	1.7 (2) ± 0.9	6.8 (7) ± 3.2
Mild (n = 42)	2.1 (2) ± 0.7	2.5 (2) ± 0.9	2.5 (2.5) ± 0.8	2.3 (2) ± 0.8	9.5 (9) ± 2.7
Minimal (n = 17)	2.9 (3) ± 0.8	3.1 (3) ± 0.8	3.2 (3) ± 0.8	2.9 (3) ± 0.8	12.1 (12) ± 2.8
No (n = 39)	3.1 (4) ± 1.3	3.3 (4) ± 1.2	3.2 (4) ± 1.1	3.1 (4) ± 1.2	12.6 (16) ± 4.6
Spearman correlation					
UAS7 total	−0.665***	−0.664***	−0.634***	−0.634***	−0.699***
UAS7 hives	−0.606***	−0.608***	−0.591***	−0.592***	−0.647***
UAS7 itching	−0.663***	−0.664***	−0.614***	−0.619***	−0.689***

Information is presented as mean (median) ± standard deviation. UAS7 categories were defined as no (0), minimal (1-6), mild (7-15), moderate (16-27), and severe (26-42) disease activity based on UAS7 total scores.
***$P < .001$.

routine clinical practice in our population. As also demonstrated in previous studies, the disease of a majority of CU patients is not satisfactorily controlled before specialist care is sought.[16,17] This emphasizes the importance of access to specialist care and the largely unmet needs of CU patients, especially in regions with limited access to specialist services, referral pathways, and guidance, such as Asia.[18-22] A recent regional consensus document has proposed guidance on the management and referral approaches for patients with severe hives and angioedema, and it will be of interest to investigate how such guidance could affect future care and outcomes in this region.[3]

This study has some limitations. Patient global assessment scores were not available, so we could not directly evaluate the screening accuracy (sensitivity and specificity in identifying

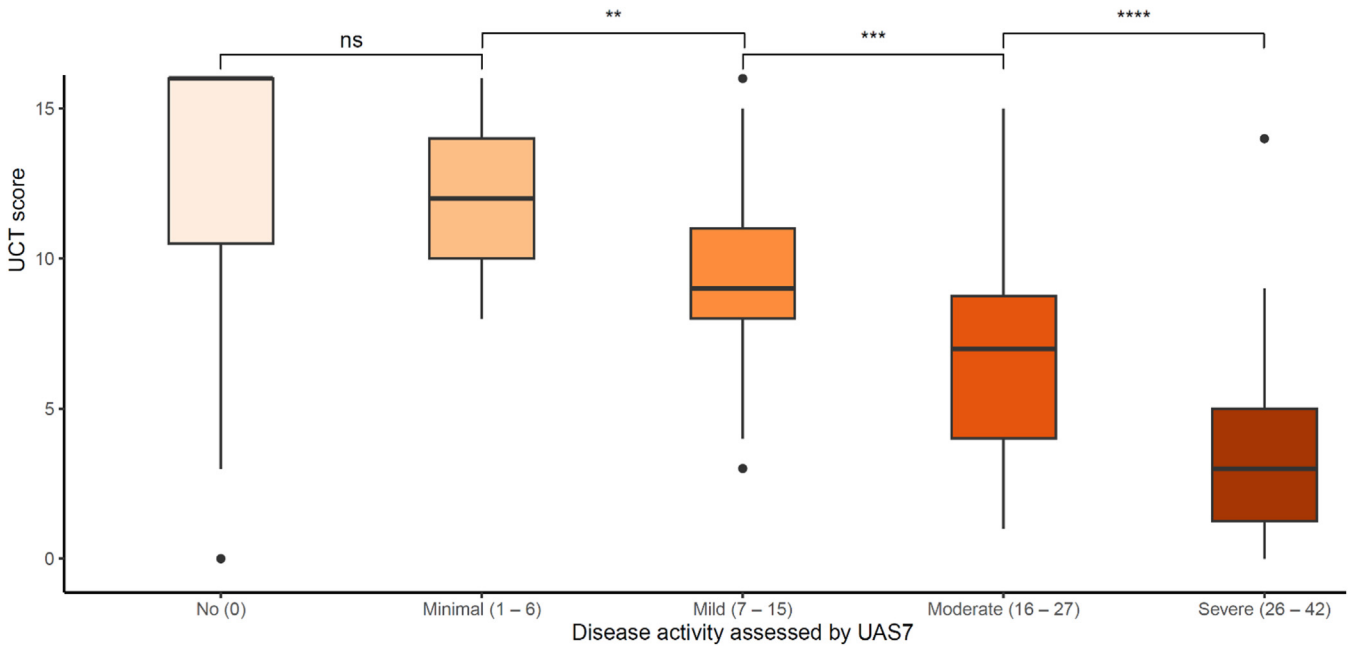

FIG 2. UCT scores according to disease activity category. *$P < .05$, **$P < .01$, ***$P < .001$, ****$P < .0001$; *ns,* Not significant.

well-controlled urticaria) of the traditional Chinese UCT. Similarly, we did not have this anchor to determine the minimal clinically important difference. We also excluded illiterate patients who could not read Chinese, and we did not record clinical details such as reported triggers of urticaria for further analysis. Furthermore, because we are our area's only tertiary-care referral center, as well as an Angioedema Centre of Reference and Excellence (aka ACARE), there was also likely a degree of referral bias, with patients with concomitant angioedema more likely to be referred and recruited.[23] However, we did not notice any significant differences among patients with or without concomitant angioedema. Future studies are underway to include more diverse patient populations (especially with other Chinese-speaking populations) from nonspecialist centers and with other important PROMs (such as the Chronic Urticaria Quality of Life Questionnaire).[24]

In conclusion, the traditional Chinese UCT is a valid, reliable, and sensitive-to-change urticaria-specific PROM. We recommend its routine use to monitor disease control and guide clinical management, as well as to evaluate treatment effectiveness in upcoming clinical trials among more diverse patient populations in the future.

DISCLOSURE STATEMENT

Disclosure of potential conflict of interest: M. Maurer has, outside the present report, been speaker and/or advisor for and/or has received research funding from Allakos, Amgen, Aralez, ArgenX, AstraZeneca, Blueprint, Celldex, Centogene, CSL Behring, FAES, Genentech, GIInnovation, Innate Pharma, Kyowa Kirin, Leo Pharma, Lilly, Menarini, Moxie, Novartis, Roche, Sanofi/Regeneron, Third HarmonicBio, UCB, and Uriach. The rest of the authors declare that they have no relevant conflicts of interest.

This project benefited from the global network of Urticaria Centers of Reference and Excellence (www.ga2len-ucare.com).

REFERENCES

1. Zuberbier T, Abdul Latiff AH, Abuzakouk M, Aquilina S, Asero R, Baker D, et al. The international EAACI/GA^{2}LEN/EuroGuiDerm/APAAACI guideline for the definition, classification, diagnosis, and management of urticaria. Allergy 2022; 77:734-66.
2. Goncalo M, Gimenez-Arnau A, Al-Ahmad M, Ben-Shoshan M, Bernstein JA, Ensina LF, et al. The global burden of chronic urticaria for the patient and society. Br J Dermatol 2021;184:226-36.
3. Li PH, Au EYL, Cheong S-L, Chung L, Fan KI, Ho MHK, et al. Hong Kong–Macau severe hives and angioedema referral pathway. Front Allergy 2023;4: 1290021.
4. Weller K, Groffik A, Church MK, Hawro T, Krause K, Metz M, et al. Development and validation of the urticaria control test: a patient-reported outcome instrument for assessing urticaria control. J Allergy Clin Immunol 2014;133:1365-72.e1-6.
5. Yu M, Chen Y, Liu B, Song X, Zhao Z. The Chinese version of the urticaria control test and validation of its reliability and validity. Chin J Dermatol 2020;53:533-8.
6. Maurer M, Metz M, Bindslev-Jensen C, Bousquet J, Canonica GW, Church MK, et al. Definition, aims, and implementation of GA^{2}LEN Urticaria Centers of Reference and Excellence. Allergy 2016;71:1210-8.
7. Stull D, McBride D, Tian H, Gimenez Arnau A, Maurer M, Marsland A, et al. Analysis of disease activity categories in chronic spontaneous/idiopathic urticaria. Br J Dermatol 2017;177:1093-101.
8. Brzoza Z, Badura-Brzoza K, Maurer M, Hawro T, Weller K. Chronic spontaneous urticaria activity, impact and control as well as their changes are strongly linked, and these links are not affected by angioedema or comorbid inducible urticaria —results from the validation of the Polish urticaria control test. World Allergy Organ J 2022;15:100635.
9. Kocaturk E, Kiziltac U, Can P, Oztas Kara R, Erdem T, Kiziltac K, et al. Validation of the Turkish version of the urticaria control test: correlation with other tools and comparison between spontaneous and inducible chronic urticaria. World Allergy Organ J 2019;12:100009.
10. Kulthanan K, Chularojanamontri L, Tuchinda P, Rujitharanawong C, Maurer M, Weller K. Validity, reliability and interpretability of the Thai version of the urticaria control test (UCT). Health Qual Life Outcomes 2016;14:61.
11. Lee JH, Bae YJ, Lee SH, Kim SC, Lee HY, Ban GY, et al. Adaptation and validation of the Korean version of the urticaria control test and its correlation with salivary cortisone. Allergy Asthma Immunol Res 2019;11:55-67.

12. Dortas Junior SD, Valle SOR, Weller K, Maurer M, Lupi O. Validity, reliability, and interpretability of the Brazilian urticaria control test. Allergy Asthma Proc 2020;41:e61-6.
13. Khoshkhui M, Weller K, Fadaee J, Maurer M, Jabbari Azad F, Emadzadeh M. Evaluation of the reliability and validity of the persian version of urticaria control test (UCT). Iran J Allergy Asthma Immunol 2021;20:423-31.
14. Nakatani S, Oda Y, Washio K, Fukunaga A, Nishigori C. The urticaria control test and urticaria activity score correlate with quality of life in adult Japanese patients with chronic spontaneous urticaria. Allergol Int 2019;68:279-81.
15. Ohanyan T, Schoepke N, Bolukbasi B, Metz M, Hawro T, Zuberbier T, et al. Responsiveness and minimal important difference of the urticaria control test. J Allergy Clin Immunol 2017;140:1710-3.e11.
16. Kan AKC, Wong TTH, Chiang V, Lau CS, Li PH. Chronic spontaneous urticaria in Hong Kong: clinical characteristics, real-world practice and implications for COVID-19 vaccination. Allergy Asthma Immunol Res 2023;15:32.
17. Irani C, Hallit S, Weller K, Maurer M, El Haber C, Salameh P. Chronic urticaria in most patients is poorly controlled. Results of the development, validation, and real life application of the arabic urticaria control test. Saudi Med J 2017;38:1230-6.
18. Maurer M, Weller K, Bindslev-Jensen C, Giménez-Arnau A, Bousquet PJ, Bousquet J, et al. Unmet clinical needs in chronic spontaneous urticaria. A GA^{2}LEN task force report. Allergy 2011;66:317-30.
19. Lee TH, Leung TF, Wong G, Ho M, Duque JR, Li PH, et al. The unmet provision of allergy services in Hong Kong impairs capability for allergy prevention—implications for the Asia Pacific region. Asian Pac J Allergy Immunol 2019;37:1-8.
20. Li PH, Pawankar R, Thong BYH, Mak HWF, Chan G, Chung WH, et al. Disparities and inequalities of penicillin allergy in the Asia-Pacific region. Allergy 2023;78:2529-32.
21. Chu CY, Al Hammadi A, Agmon-Levin N, Atakan N, Farag A, Arnaout RK, et al. Clinical characteristics and management of chronic spontaneous urticaria in patients refractory to H_1-antihistamines in Asia, Middle-East and Africa: results from the AWARE-AMAC study. World Allergy Organ J 2020;13:100117.
22. Cho YT, Pao YC, Chu CY. Unmet medical needs for chronic spontaneous urticaria patients: highlighting the real-life clinical practice in Taiwan. J Eur Acad Dermatol Venereol 2016;30:41-9.
23. Maurer M, Aberer W, Agondi R, Al-Ahmad M, Al-Nesf MA, Ansotegui I, et al. Definition, aims, and implementation of GA^{2}LEN/HAEi Angioedema Centers of Reference and Excellence. Allergy 2020;75:2115-23.
24. Baiardini I, Pasquali M, Braido F, Fumagalli F, Guerra L, Compalati E, et al. A new tool to evaluate the impact of chronic urticaria on quality of life: chronic urticaria quality of life questionnaire (CU-QoL). Allergy 2005;60:1073-8.