

Validity, reliability, and interpretability of the Brazilian urticaria control test

Sérgio Duarte Dortas Junior, M.D.,¹ Solange Oliveira Rodrigues Valle, M.D.,² Karsten Weller, M.D.,³ Marcus Maurer, M.D.,³ and Omar Lupi, M.D.⁴

ABSTRACT

Background: The urticaria control test (UCT) is a patient-reported outcome measure designed to determine the current level of disease control in patients with chronic urticaria (CU). Recently, a Brazilian UCT was developed, but its validity and reliability are unknown.

Method: The clinimetric properties of the Brazilian UCT short form (UCTsh) and its long form (UCTlg) were determined in 130 patients with CU. In parallel, the urticaria activity scores (UAS) that covers 7 days (UAS7) and 28 days (UAS28) were used to assess disease activity. Subsequently, the results were analyzed statistically to determine the validity, reliability, and interpretability of the Brazilian UCT versions.

Results: A total of 107 female (82%) and 23 male patients with CU completed both versions of the Brazilian UCT. Both of the Brazilian UCT versions showed excellent internal consistency reliability. In addition, the Brazilian UCT results showed strong correlations with UAS7 and UAS28 results, which indicated high levels of convergent validity. The test-retest reliability was examined in a subsample of 27 patients with CU and was found to be excellent. Notably, the results of both Brazilian UCT versions correlated extensively, which suggested that the UCTsh can replace the UCTlg without changing the UCT results.

Conclusion: The Brazilian UCT is a valid and reliable tool for assessing disease control. To facilitate the use of the Brazilian UCT in global studies and to put a stronger focus on the specificity, we propose that the same cutoff values for well-controlled disease should be used as identified in the original publication of the UCT, i.e., ≥ 12 points for the UCTsh.

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Urticaria is a condition characterized by the development of wheals (hives), angioedema, or both. According to its clinical course it is classified as acute (lasting <6 weeks) or chronic (lasting ≥ 6 weeks).¹ Chronic urticaria (CU) is a frequent and debilitating disease, which considerably affects patient's quality of life.^{2–5} Currently, there are no reliable biomarkers to assess the disease status in patients with CU. Consequently, the use of patient-reported outcomes is crucial when evaluating and monitoring disease activity, disease control, and quality-of-life impairment in CU. Validated instruments, such as the weekly urticaria

activity score (UAS7), the angioedema activity score, the CU quality-of-life questionnaire, the angioedema quality-of-life questionnaire, and the urticaria control test (UCT) are available for this purpose.^{1,6,7}

The UCT was developed and validated to determine the level of disease control in all forms of CU.^{8,9} It was originally developed in German. Two forms of the UCT are available; the long form UCT (UCTlg) (8 questions) and the short form UCT (UCTsh) (4 questions). Because the results of both UCT forms have been found to correlate extensively, the more convenient UCTsh is primarily used, both, in clinical trials and routine patient care.⁸ Brazilian versions of both the UCTsh and the UCTlg were previously developed. Here, we reported results on their validity, reliability, and screening accuracy.¹⁰

METHODS

Patients

To perform the UCT validation, the sample size was calculated by considering a Cronbach α of at least 0.8 and statistically difference from a Cronbach α of 0.7 (least acceptable), which is a total of 130 patients. Brazilian patients with CU ($N = 130$) who attended the Urticaria Outpatient Clinic of the Urticaria Center

From the ¹Serviço de Imunologia, Hospital Universitário Clementino Fraga Filho (HUCFF-UFRJ), Rio de Janeiro, Rio de Janeiro, Brasil, Universidade Iguaçu (UNIG), Nova Iguaçu, Rio de Janeiro, Brazil, ²Serviço de Imunologia, Hospital Universitário Clementino Fraga Filho (HUCFF-UFRJ), Rio de Janeiro, Rio de Janeiro, Brazil, ³Department of Dermatology and Allergy, Charité – Universitätsmedizin Berlin, Berlin, Germany, and ⁴Serviço de Imunologia, Hospital Universitário Clementino Fraga Filho (HUCFF-UFRJ), Rio de Janeiro, Rio de Janeiro, Brazil
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Address correspondence to Sérgio D. Dortas Junior, M.D., Hospital Universitário Clementino Fraga Filho (HUCFF-UFRJ), Rua Rodolpho Paulo Rocco, 255 room 09E10 - Ilha do Fundão, Rio de Janeiro, Brazil, 21941-590
E-mail address: sdortasjr@gmail.com

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of Reference and Excellence (GA²LEN UCARE, www.ga2len-ucare.com)¹¹ at the immunology service of a university hospital participated in this study. Patients were enrolled after informed consent was obtained and in order of arrival at the outpatient clinic until the determined sample size was reached.

All the patients were assessed during a one-time visit. In addition, the first 27 patients were assessed again, after 4 weeks, at a second visit, to determine the test-retest reliability of the UCT versions. During each visit, the participants received appropriate treatment as recommended by the European Academy of Allergology and Clinical Immunology (EAACI), the Global Allergy and Asthma European Network (GA2LEN), the European Dermatology Forum (EDF) and the World Allergy Organization (WAO) guideline.¹ The study was submitted and approved by Comitê de Ética em Pesquisa do Hospital Universitário Clementino Fraga Filho (HUCFF-UFRJ), CAAE 45067715.5.0000.5257.

Clinical Measures

To assess chronic spontaneous urticaria (CSU) disease activity, we used the urticaria activity score (UAS), a prospective diary-type tool. The UAS7 is based on the once-daily assessment of itch intensity and number of hives over a period of 7 days. It sums up the number of wheals and the intensity of pruritus on a four-point scale (0–3), with a minimum and maximum score of 0 and 6 points per day, respectively. Accordingly, the UAS7 ranges from 0 to 42 points. The UAS28 is the sum of the UAS7 scores of 4 consecutive weeks (scores range from 0 to 168 points).

To assess disease control, we used the Brazilian version of the UCT. This version was previously translated and culturally adapted to Brazilian Portuguese by the use of a validated and guideline-recommended approach.¹⁰ The UCT is a retrospective questionnaire (recall period: past 4 weeks) to assess disease control in the patients with CU. The two published forms UCTsh and UCTlg consist of 4 and 8 items, respectively. Each item is scored with 0 to 4 points, which results in 0–16 points for the UCTsh and 0–32 points for the UCTlg, with higher scores indicating higher levels of disease control.

Assessment of the Validity, Reliability, and Interpretability of the Brazilian UCT Versions

Internal Consistency. The Cronbach α coefficient was computed to describe the internal consistency reliability of the Brazilian UCT versions. We used the following, previously suggested interpretation of the Cronbach α coefficient: <0.21, unacceptable; 0.21–0.40, undesirable; 0.41–0.60, minimally acceptable; 0.61–0.80, respectable; >0.80, excellent consistency.¹²

Convergent Validity. To determine the convergent validity of the Brazilian UCT versions, the correlation of their results with the results of the parallel applied UAS7 and UAS28 were computed (Pearson correlation coefficient). Unacceptable, weak, moderate, good, and strong correlations were defined as correlation coefficient values of <0.2, 0.2–0.4, 0.4–0.6, 0.6–0.8, and >0.8, respectively.

Test-Retest Reliability (intraclass correlation coefficient). To determine the test-retest reliability of the Brazilian UCT versions, the first 27 patients included in this study were assessed twice by using the UAS28 and UCTs with a 4-week interval in between. For the sample calculation of test-retest reliability study, we considered question 1 and dichotomized the responses in “yes” (very much + much) and “no” (somewhat + a little + not at all). The sample size initially depended on the frequency of the “yes” response (we considered the possibilities to be 10, 30, or 50%). Then we considered the value of the kappa to be detected (*e.g.*, a kappa >0.7 [0.7, 0.8, or 0.9]) and the null hypothesis (we considered differentiating the kappa found from a minimum kappa of 0.4 [regular agreement]). We considered using the “test power” of 80% (minimum required). Accordingly, the minimum number of patients required for the test-retest study was 27. So only the first 27 subjects were reassessed by using UAS28 and UCT for operational reasons and because of the socioeconomic conditions of patients attending our outpatient clinic. Our patients, in their totality, would have difficulty attending the hospital for 3 consecutive months.

Interpretability. The receiver operating characteristic (ROC) was used to analyze screening accuracy. We used the sensitivity and specificity values for each UCT value to determine the best cutoff for UCT questionnaires in diagnosing a person with CU. Thus, the best cutoff was one that optimized sensitivity and specificity statistics. We opted to use UAS7 scores of ≤ 6 and > 6 , which were used to categorize the disease control as “controlled” and “not controlled,” respectively, as suggested by Stull *et al.*¹³

RESULTS

Patient Characteristics

The Brazilian UCT versions (UCTsh and UCTlg) were completed by 106 female patients (82%) and 23 male patients with CU at the Chronic Urticaria Outpatient Clinic of the Immunology Service of HUCFF-UFRJ (mean $\pm$ standard deviation [SD] age, 46.0 ± 2.5 years (Table 1). Fifty-two percent of the patients presented with isolated CSU, whereas 45.4% and 2.3% had CSU

Table 1 Patient sample characteristics

Patients, no.	130
Gender, <i>n</i> (%)	
Women	107 (82.3)
Men	23 (17.7)
Age, mean $\pm$ SD (range), y	46.0 $\pm$ 2.5 (18–83)
Form of chronic urticaria, <i>n</i> (%)	
CSU	65 (50.0)
CSU + CIndU	62 (47.7)
CIndU	3 (2.3)

SD = Standard deviation; CSU = chronic spontaneous urticaria; CIndU = chronic inducible urticaria.

Table 2 Urticaria control test (UCT) internal consistency

UCT	Cronbach α
Short form	0.904
Long form	0.949

Table 3 Urticaria control test (UCT) convergent validity with urticaria activity scores that cover 7 days

UCT	Correlation (<i>r</i>)	<i>p</i>
Short form	−0.762	<0.001
Long form	−0.744	<0.001

associated with chronic inducible urticaria (CIndU) and isolated CIndU, respectively (Table 1).

The Brazilian UCT Versions Showed Excellent Internal Consistency

The internal consistency of the Brazilian UCTs, as assessed by the Cronbach α , was 0.904 and 0.949 for the UCTsh and UCTlg, respectively, which indicated excellent internal consistency reliability (Table 2).

Brazilian UCT Versions Showed High Levels of Convergent Validity

There was a strong and statistically significant inverse correlation between the values of both Brazilian UCT versions with UAS7 values ($r = -0.762$, $p < 0.001$ for UCTsh; $r = -0.744$, $p < 0.001$ for UCTlg) (Table 3), which indicated a high level of convergent validity for both UCT versions. The same was true for the correlation of the values of both Brazilian UCT versions with the UAS28 ($r = -0.778$, $p < 0.001$ for UCTsh; $r = -0.771$, $p < 0.001$ for UCTlg) (Table 4).

Table 4 Urticaria control test (UCT) convergent validity with urticaria activity scores that cover 28 days

UCT	Corr (<i>r</i>)	<i>p</i>
Short form	−77.8%	<0.001
Long form	−77.1%	<0.001

Brazilian UCT Showed Excellent Test-Retest Reliability

Among the 27 patients who obtained the Brazilian UCT twice, 4 weeks apart, 20 presented UAS28 scores that did not differ by more than three points, a surrogate for stable disease. Differences between the evaluation and reevaluation of both versions of UCT in seven patients are justified by the therapeutic intervention (doubling or even quadrupling the antihistamines dose) of the attending physician after the patient responds to the first assessment with regard to ethics considerations. The standard of well-controlled disease among this group was 12.7 ± 2.7 . For the assessment of the test-retest reliability of the UCT, patients with stable disease should be used. In the group with stable disease, the first and the second evaluation mean $\pm$ SD UCTsh scores were 10.7 ± 3.6 and 11.3 ± 3.6 , respectively ($p = 0.042$), and the first and the second mean $\pm$ SD UCTlg scores were 21.3 ± 7 and 21.8 ± 7.14 , respectively ($p = 0.256$). In addition, the intraclass correlation coefficient was 0.96 for UCTsh and 0.98 for UCTlg, which indicated excellent reproducibility.

ROC Analyses Showed Excellent Accuracy of Both Versions of the Brazilian UCT

ROC analysis was used to identify the best suitable cutoff value to distinguish patients with well-controlled CU from patients with poorly controlled disease. For the Brazilian UCTsh, UCT scores of ≥ 10 (sensitivity, 83.6%; specificity, 73.0%), ≥ 11 (sensitivity, 77.6%; specificity, 79.4%), or ≥ 12 (sensitivity, 65.7%; specificity, 84.1%) were suitable cutoff values to define well-controlled disease. For the UCTlg, UCT scores of ≥ 24 (sensitivity, 71.6%; specificity, 79.4%), ≥ 25 (sensitivity, 67.2%; specificity, 84.1%), or ≥ 26 (sensitivity, 61.2%; specificity, 88.9%) were found to be potential cutoff values to define well-controlled disease. (Tables 5 and 6; Figs. 1 and 2).

Results of the Brazilian UCT Versions Showed Extensive Correlations

The results of both Brazilian UCT versions correlated extensively ($r = 0.971$, $p < 0.001$), which suggested that the UCTsh may replace the UCTlg and *vice versa* without changing the UCT result to a meaningful extent.

Table 5 Urticaria control test long form (UCTlg) receiver operating characteristic curve

UCTlg	Sensitivity, %	Specificity, %
1.0	100	0.0
3.0	100	6.3
4.5	100	11.1
5.5	100	15.9
6.5	100	17.5
7.5	97.0	20.6
8.5	95.5	22.2
9.5	94.0	25.4
10.5	94.0	28.6
12.0	94.0	33.3
13.5	94.0	36.5
14.5	92.5	41.3
15.5	92.5	42.9
16.5	85.1	49.2
17.5	85.1	55.6
18.5	83.6	58.7
19.5	82.1	65.1
20.5	80.6	66.7
21.5	76.1	73.0
22.5	73.1	76.2
23.5	71.6	79.4
24.5	67.2	84.1
25.5	61.2	88.9
26.5	56.7	90.5
27.5	53.7	93.7
28.5	49.3	95.2
29.5	44.8	96.8
30.5	40.3	100
31.5	35.8	100
33.0	0.0	100

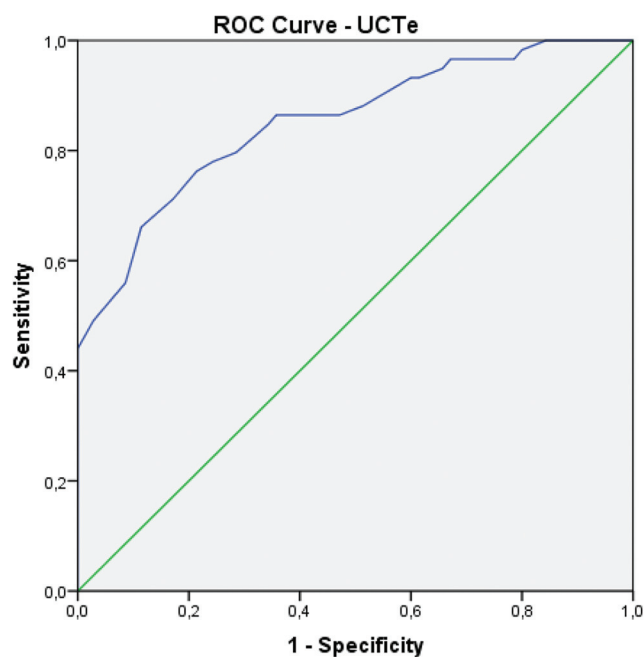
DISCUSSION

The UCT is a simple and easy-to-administer patient-reported outcome measure that was originally developed in German to determine disease control in patients with CU.⁸ The results of our study demonstrated that the recently developed Brazilian UCT versions, *i.e.*, UCTsh and UCTlg, both show high levels of validity and reliability. In addition, the identified possible cutoff values of the Brazilian UCT versions to distinguish well-controlled CU from poorly controlled disease are comparable with the cutoff values found for the original German version of the UCT.

Our study population showed the typical features of patients with CU, the target population of the UCT, *i.e.*, our study population had a higher proportion of female patients (82.2%), and many of the patients with CU had CSU with comorbid CIndUs.

Table 6 Urticaria control test short form (UCTsh) receiver operating characteristic curve

UCTsh	Sensitivity, %	Specificity, %
-1.0	100	0.0
0.5	100	3.2
1.5	100	7.9
2.5	98.5	15.9
3.5	98.5	19.0
4.5	95.5	23.8
5.5	94.0	30.2
6.5	91.0	38.1
7.5	91.0	49.2
8.5	88.1	63.5
9.5	83.6	73.0
10.5	77.6	79.4
11.5	65.7	84.1
12.5	56.7	92.1
13.5	52.2	96.8
14.5	41.8	100
15.5	35.8	100
17.0	0.0	100



Diagonal segments are produced by ties.

Figure 1. Long form urticaria control test (UCTlg), receiver operating characteristic (ROC) curve.

Several epidemiologic studies indicated that the prevalence of CU is at least twice as high in female compared with male patients.¹⁴⁻¹⁶ Another validation study of a patient-reported outcome instrument

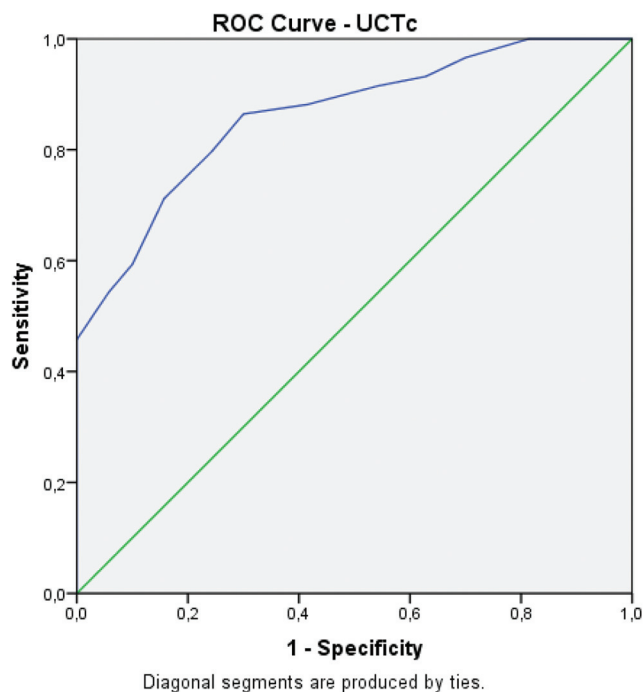


Figure 2. Short form urticaria control test (UCTsh), receiver operating characteristic (ROC) curve.

in CU, performed at the outpatient clinic of the immunology service of HUCFF-UFRJ, had a rate of 86% female patients.¹⁷ In a recent study on the perspective of Brazilian patients on the impact of CU, the disease was also more common in women than in men.⁵

In the original German UCT validation study, the distribution of CU subforms was as follows: 60% with isolated CSU, 23.3% with both CSU and CIndU, and 16.7% with isolated CIndU.³ In our patient population, there was also a predominance of patients with isolated CSU (50.0%). However, the proportion of patients with both CSU and CIndU (47.7%) was higher and the proportion of patients with isolated CIndU was lower (2.3%). These differences may point toward a different distribution of CU subforms in Brazil compared with in Germany. However, we are confident that the population of our study was sufficiently diverse to yield valid results for all patients with CU.

The Brazilian versions of the UCT showed excellent internal consistency reliability, with Cronbach $\alpha > 0.9$ for both the UCTsh and the UCTlg. These values were comparable with the values described in validation studies for other language versions. In the original publication of the German UCT, the Cronbach α of the UCTsh was found to be 0.84.⁸ The Thai UCTsh had a Cronbach α of 0.91,¹⁸ the Arabic UCTsh had a value of 0.82,¹⁹ the Turkish UCTsh had a value of 0.81,⁶ and the Korean UCTsh had a value of 0.87.²⁰

As expected, we found that the values of the Brazilian UCT versions showed strong correlations with urticaria activity, as assessed by the UAS7 and UAS28, *i.e.*, the higher the urticaria activity in the examined patients, the lower their current level of disease control. This indicated that the convergent validity of the Brazilian UCT versions was good. The correlation coefficient was negative because higher scores of the UAS indicated higher urticaria activity, whereas higher scores of the UCT versions indicated higher levels of disease control. In the validation studies of the original questionnaire (German), the Thai version, the Turkish version, and the Korean versions, the UCT showed great reliability.^{6,8,18,19} The Brazilian UCT also showed excellent reliability, with stable UCT values in patients with a stable disease activity and an intraclass correlation coefficient of >0.95 .

With regard to the cutoff value of the UCT to distinguish well-controlled CU from poorly controlled disease, *i.e.*, the lowest UCT value that still indicates well-controlled disease, we found that 25 for the UCTlg and 10.5 for the UCTsh showed the best sensitivity and specificity. In the original validation study of the German UCTsh version, a cutoff value of 12 was suggested.⁸ For the Thai and the Turkish UCTsh, cutoff values were suggested to be ≥ 11 and ≥ 9.5 to ≥ 11.5 respectively. Thus, the cutoff values found in the different validation studies, including the Brazilian study, are highly comparable.^{6,8,18} To facilitate the use of the Brazilian UCT in global studies and to put a stronger focus on specificity rather than sensitivity of the cutoff value, we suggested that a cutoff value of ≥ 12 points is used for the Brazilian UCTsh to identify well-controlled CU (the same cutoff values as identified in the original publication of the UCT) in clinical trials but also in routine patient care.

CONCLUSION

Our results demonstrated that the recently developed Brazilian versions of the UCT are valid and reliable patient-reported outcome measures to assess the current level of disease control in Brazilian patients with CU. The levels of validity and reliability of the Brazilian UCT were high and comparable with other published language versions, and the identified cutoff values to distinguish well-controlled from poorly controlled CU were similar to previously published data. Furthermore, our results demonstrated that the four-item short version of UCT yielded comparable results as the eight-item long version and may, therefore, be preferred over the long version. Our study provided the basis for the future use of the UCT in the Brazilian patients with a CU population and the interpretability of its results. As in other countries, where the UCT is already available, the UCT may serve, in the future, as

a useful tool in daily practice to identify subjects with poorly controlled disease to guide and back treatment decisions as well as to monitor disease control over time. In addition, it may help to facilitate the performance of clinical trials, including the pooling and comparison of UCT data obtained in other countries.

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