

Reliability, validity, and responsiveness of the Rhinitis Control Assessment Test in patients with rhinitis

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Background: The Rhinitis Control Assessment Test (RCAT) is a brief, patient-completed tool to evaluate rhinitis symptom control.

Objective: We sought to test the reliability, validity, and responsiveness of RCAT and to estimate a cut-point score and minimal important difference (MID).

Methods: A total of 402 patients 12 years of age and older with allergic or nonallergic rhinitis were enrolled in a noninterventional study. Patients completed the RCAT (6 items; score range, 6-30) and had Total Nasal Symptom Scores (TNSSs) measured at baseline and 2 weeks later. Physicians completed a global assessment of rhinitis symptom control (Physician's Global Assessment) and disease severity. Internal consistency, test-retest reliability, convergent validity, known-groups validity, and responsiveness were evaluated. The MID was determined by using distribution- and anchor-based methods. Content validity of the RCAT was assessed in individual interviews with a separate group of 58 adult patients. **Results:** Internal consistency and test-retest reliability of RCAT scores were 0.77 and 0.78, respectively. Convergent validity correlation between RCAT and TNSS scores was 0.57, and that between RCAT and Physician's Global Assessment scores was 0.34. Mean RCAT scores differed significantly ($P < .001$) across patient groups, differing in TNSS ($F = 72.7$), Physician's Global Assessment score ($F = 28.6$), and disease severity ($F = 34.1$) in the hypothesized direction. Results suggested a cut-point score of 21 or less can be used to identify patients who are

experiencing rhinitis symptom control problems. The preliminary estimate of the MID was 3 points. Patients found RCAT items comprehensive, easy to understand, and relevant. **Conclusion:** The RCAT demonstrated adequate reliability, validity, and responsiveness and was deemed acceptable and appropriate by patients. This tool can facilitate the detection of rhinitis symptom control problems, and its brevity supports its usefulness in clinical care. (J Allergy Clin Immunol 2012;■■■:■■■-■■■.)

Key words: Allergic rhinitis, nonallergic rhinitis, rhinitis control, patient-reported outcome, Rhinitis Control Assessment Test

Allergic rhinitis is a highly prevalent condition. Approximately 20% of the US population has allergic rhinitis,¹ and the effect of this condition is substantial. Patients with allergic rhinitis report problems sleeping, increased fatigue, headache, impaired cognition, and psychological distress.^{2,3} In addition, the symptoms of allergic rhinitis have been shown to compromise the ability to perform at work or school.^{4,5} With such substantial consequences, it is important to effectively manage allergic rhinitis, particularly during those times of the year when the nasal disease is at its peak.

Patients with rhinitis can have both allergic rhinitis and nonallergic rhinitis (NAR) or NAR alone. A study conducted in a large managed care organization found not only that NAR is relatively common (21% of the population studied) but also that it might affect patients' health status and health services use in the general population.⁶

Many patients with rhinitis are initially evaluated and treated in the primary care setting or practices in which allergy testing is not routinely conducted. In rhinitis specialists' offices allergen sensitivities are usually documented; however, in either setting there has not been a standardized instrument available to evaluate disease control. Using a disease control assessment tool has proved successful in asthma care, in which brief, validated, patient-based assessment tools have demonstrated the ability to categorize patients into categories of well-controlled, not well-controlled, and poorly controlled asthma. Furthermore, these tools have been used to monitor the effectiveness of treatments in controlling asthma over time.⁷⁻¹⁰

Recent studies have documented the development and initial validation of the Rhinitis Control Assessment Test (RCAT), a patient-based tool that measures rhinitis symptom control.^{11,12} The RCAT was developed to identify patients whose nasal symptoms, ocular symptoms, or both might warrant a change in management strategy, referral to an allergy specialist, or both. The RCAT has 6 items that include nasal congestion, sneezing, watery eyes, sleep problems caused by rhinitis, activity avoidance, and rhinitis symptom control. Responses are measured on 5-point Likert-type scales. RCAT scores range from 6 to 30, with higher scores indicating better rhinitis control (Fig 1). Of the potential RCAT items generated by patient and physician focus groups, 6

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Abbreviations used

MID: Minimal important difference
 NAR: Nonallergic rhinitis
 PAR: Perennial allergic rhinitis
 PRO: Patient-reported outcome
 RCAT: Rhinitis Control Assessment Test
 ROC: Receiver operating characteristic
 SAR: Seasonal allergic rhinitis
 TNSS: Total Nasal Symptom Score

were selected by using quantitative methods that were most predictive of rhinitis control problems, as determined by a treating physician.^{11,12} The purpose of the current article is to evaluate the content validity of the 6-item RCAT and to describe the reliability, validity, responsiveness, screening accuracy, and minimal important difference (MID).

METHODS**Study designs and samples**

The qualitative study to assess the content validity of the RCAT items consisted of individual interviews with 58 patients. Participants were (1) 18 years of age or older, (2) given a diagnosis of either allergic rhinitis or NAR based on clinical history and responses to skin prick tests, (3) experiencing rhinitis symptoms within the past 12 months, (4) taking either over-the-counter or prescription medications to treat their rhinitis symptoms, and (5) able to provide informed consent and read and understand English. Content validity was assessed through patient interviews conducted by 2 experienced interviewers with a standard interview guide. Patients were asked to describe their rhinitis symptoms and identify the symptoms that were most bothersome. After these questions, patients were asked to provide feedback on the 6 RCAT items while describing their thought process out loud. Interviewers then asked questions about the way in which patients interpreted the items and thoughts about potential responses.

The longitudinal validation study was a no-treatment study conducted at 29 investigational sites in the United States. All investigators were allergists, otolaryngologists, or both. Central (Great Lakes College of Clinical Medicine Institutional Review Board) or local institutional review board approval was obtained. The study consisted of 2 clinician visits occurring 15 to 29 days apart. Included participants (1) provided written informed consent; (2) were treatable on an outpatient basis; (3) had not seen a specialist regarding rhinitis symptoms in at least 3 years; (4) were at least 12 years of age; (5) received a diagnosis of noninfectious seasonal allergic rhinitis (SAR), perennial allergic rhinitis (PAR), or NAR based on a clinical history and skin test results; (6) were able to comply with study procedures; and (7) were literate. Participants were excluded if there was (1) evidence of rhinitis medicamentosa, (2) bacterial or viral respiratory tract infection at the time of the study visit, (3) a physical impairment that prevented the subject from participating, (4) clinical evidence of a *Candida* species infection, (5) severe obstruction of nasal passages caused by a deviated septum or nasal polyp, (6) a positive or inconclusive pregnancy test result for female patients, (7) evidence of acute or chronic sinusitis, (8) a history of psychiatric disease or dementia, or (9) use of allergy medications within 3 days before visit 1.

Data from qualified participants who had a Total Nasal Symptom Score (TNSS) of 2 or greater at visit 1 were included in the analysis. The TNSS is a daily symptom severity score that rates nasal congestion, rhinorrhea, nasal itching, sneezing, and postnasal drip on a 0- to 3-point scale. Stratified sampling was used to ensure appropriate sample sizes and equal representation of the 3 rhinitis types across 2 levels of symptom severity (TNSS 0-5 = mild and TNSS 6-15 = moderate/severe), with a goal of 400 eligible subjects: 150 subjects in each of the PAR and SAR groups and 100 subjects in the NAR group, with half of each category of symptom severity in each diagnosis group.

Reliability

The reliability of the RCAT was evaluated by using internal consistency and test-retest reliability methods. For internal consistency, the Cronbach α value¹³ was computed from the 6 RCAT items at both study visits. Test-retest reliability was examined by calculating the intraclass correlation coefficient¹⁴ between RCAT scores at both visits among patients who self-reported no change in their rhinitis symptoms during the visit interval.

Convergent validity

Convergent validity was examined by computing Spearman rank-order correlations between RCAT scores and criterion measures, including TNSSs, patients' ratings of frequency and improvement in symptoms, and physicians' ratings of disease severity and rhinitis control. It was hypothesized that RCAT scores would correlate¹⁴ with each of these criterion measures with a Spearman r value of at least 0.3.

Discriminant validity

Discriminant validity was investigated by using known-groups validity¹⁵ in which criterion groups were defined that differed in ways that affect rhinitis control. We tested the ability of the RCAT to discriminate among groups of patients who differed on each of the criterion measures of physicians' ratings of disease severity (mild, moderate, and severe), TNSSs (mild = 0-5, moderate = 6-10, and severe = 11-15), and physicians' ratings of rhinitis control (uncontrolled = not controlled at all, poorly controlled, somewhat controlled, and controlled = well-controlled or completely controlled) by using mean RCAT scores and ANOVA to test for significant differences. It was hypothesized that the groups of patients with more severe physician-rated disease, higher TNSSs, and uncontrolled rhinitis symptom status would have lower (worse) RCAT scores than patients with less severe disease, lower TNSSs, and controlled rhinitis symptom status.

Responsiveness

The responsiveness of the RCAT was evaluated by analyzing mean changes in RCAT scores between visits across groups of patients who changed on the criterion measures of (1) physicians' ratings of rhinitis symptom control, (2) TNSS severity categories, and (3) self-rating of change in rhinitis symptom control status, as reported at visit 2, by using ANOVA to test for significant differences. It was hypothesized that RCAT scores would increase (improve) among groups of patients whose symptoms improved and decrease among groups of patients whose symptoms worsened on each of the criterion measures.

Screening accuracy

The accuracy of the RCAT as a tool for screening patients with rhinitis symptom control problems was assessed by means of logistic regression and receiver operating characteristic (ROC) curve analyses by using visit 1 data and the criterion measure of the physician's rating of rhinitis symptom control. Patients were categorized either as having control problems if the physician's rating was "not controlled at all," "poorly controlled," or "somewhat controlled" or having controlled rhinitis if the physician's rating was "well controlled" or "completely controlled." A separate analysis was conducted for each cut-point score from 14 to 25 on the RCAT scale. Results were summarized in terms of sensitivity, specificity, percentage of patients correctly classified, positive and negative predictive values, and the area under the ROC curve.

MID

Distribution-based and anchor-based approaches were used to determine the MID of the RCAT. For the distribution-based approach, the score equivalents of $\frac{1}{2}$ SD (moderate effect size) and 1 SEM were considered as MIDs of the RCAT. The score equivalents of $\frac{1}{2}$ SD¹⁶ and 1 SEM^{17,18} have both been considered thresholds for determining the MID on patient-reported outcome (PRO) tools.

The anchor-based approach examines the relationship between scores on the target instrument (RCAT) and some independent measure (anchor).¹⁹

1. During the past week, how often did you have nasal congestion?

Never	Rarely	Sometimes	Often	Extremely often
☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

2. During the past week, how often did you sneeze?

Never	Rarely	Sometimes	Often	Extremely often
☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

3. During the past week, how often did you have watery eyes?

Never	Rarely	Sometimes	Often	Extremely often
☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

4. During the past week, to what extent did your nasal or other allergy symptoms interfere with your sleep?

Not at all	A little	Somewhat	A lot	All the time
☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

5. During the past week, how often did you avoid any activities (for example, visiting a house with a dog or cat, gardening) because of your nasal or other allergy symptoms?

Never	Rarely	Sometimes	Often	Extremely often
☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

6. During the past week, how well were your nasal or other allergy symptoms controlled?

Completely	Very	Somewhat	A little	Not at all
☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

FIG 1. The RCAT.

Clinically relevant benchmarks likely to be conceptually related to the RCAT were used as anchors: (1) TNSS; (2) the physician's rating of rhinitis control; (3) the physician's rating of rhinitis severity; and (4) the patient's self-report of change in rhinitis symptom control. Differences in mean RCAT scores were computed between groups that differed on each criterion measure at baseline, and differences in mean changes in RCAT scores were computed between groups of patients that differed in the level of change on each criterion measure.

RESULTS

Patient samples

Table I provides demographic characteristics of patients who participated in the qualitative study to evaluate the content validity of the RCAT. The majority were female (67%) and white (74%), with a mean age of 48 years (range, 20-71 years). All patients had at least a high school education, and 77% had annual incomes of less than \$75,000. Most patients self-reported allergic rhinitis (64%).

Table I also provides demographic characteristics of participants in the longitudinal study. Four hundred forty-nine patients were screened for the study, and 402 patients with rhinitis were randomized (12% screen failure rate) and administered the RCAT survey at visit 1 (150 with PAR, 152 with SAR, and 100 with NAR), of whom 396 (99%) also completed the survey at visit 2 (147 with PAR, 150 with SAR, and 99 with NAR). The average age was 37 years (SD, 15 years), and the majority of patients were female (66%) and white (81%). There were no significant differences in age, sex, or race across disease types. The mean baseline TNSS for the 402 randomized patients was 7.26 (SD, 3.24).

Content validity

Overall, patients found the RCAT items to be "relevant," "concise," and "easy to understand." Most patients found the

1-week recall period appropriate for assessing the symptoms they experienced. All patients believed that they could accurately remember their rhinitis symptoms over the past week. The majority of patients found the response options of the RCAT items easy to understand and noted that each option was distinct from the adjacent options. Patients believed that the RCAT items appropriately covered most of the symptoms they experienced. However, roughly two thirds of the patients believed that several important symptoms, including itchy eyes, headache, and itchy throat, were not captured by the RCAT. Lastly, during the cognitive debriefing, patients indicated that all RCAT items were clear and easy to understand and relevant to their condition, and all patients interpreted the items similarly.

Reliability

The internal consistency reliability of the RCAT in the total sample was 0.77 at visit 1 and 0.84 at visit 2 (Table II) and was very similar across the 3 disease types. The test-retest reliability of the RCAT among patients who indicated no change in their rhinitis condition between visits 1 and 2 was 0.78 for the total sample (Table II). By disease type, test-retest reliability was highest among patients with PAR (0.84) compared with that among patients with SAR (0.78) and patients with NAR (0.72).

Convergent validity

Correlations between the RCAT and the other criterion measures (total TNSS and individual symptom scores, the patient's global rating of severity, and physicians' ratings of severity and control) were generally in the 0.3 to 0.6 range in the total sample and by disease type (Table III). The correlation between the RCAT and the physician's rating of rhinitis control for patients with SAR was smaller (0.24) compared with the other measures.

TABLE I. Patients' characteristics

Qualitative interview participants (n = 58)		Longitudinal study participants (n = 402)	
Characteristic	No. (%)	Characteristic	No. (%)
Female sex	39 (67)	Female sex	265 (66)
Age (y)		Mean (SD) age (y)	37 (15)
18-24	2 (3)		
25-34	8 (14)		
35-44	15 (26)		
45-54	16 (28)		
55-64	6 (10)		
65-74	11 (19)		
Race		Race	
White	43 (74)	White	321 (81)
Black	6 (10)	Black	70 (18)
Other	7 (12)	Other	4 (2)
Education			
Advanced degree	5 (9)		
College graduate	17 (29)		
Some college	19 (33)		
High school	17 (29)		
Income			
≥\$75,000	9 (16)		
\$55,000-\$74,999	4 (7)		
\$35,000-\$54,999	17 (29)		
\$20,000-\$34,999	14 (24)		
<\$20,000	14 (24)		
Rhinitis type		Rhinitis type	
		PAR	150 (37)
SAR and/or PAR	37 (64)	SAR	152 (38)
NAR	21 (36)	NAR	100 (25)

TABLE II. Internal consistency and test-retest reliability of the RCAT

Disease type	Cronbach α , visit 1	Cronbach α , visit 2	Test-retest* ICC (95% CI)
SAR	0.77	0.85	0.78 (0.75-0.81)
PAR	0.75	0.83	0.84 (0.81-0.87)
NAR	0.79	0.83	0.72 (0.68-0.76)
Total sample	0.77	0.84	0.78 (0.76-0.80)

ICC, Intraclass correlation coefficient.

*Included only patients who indicated no change in their rhinitis condition between visits.

Discriminant validity

Mean RCAT scores differed significantly ($P < .001$) across groups of patients known to differ in TNSSs ($F = 72.7$), physicians' ratings of rhinitis symptom control ($F = 28.6$), and physicians' ratings of disease severity ($F = 34.1$, Table IV). As hypothesized, mean RCAT scores were lowest among patients in the most severe group and highest among patients in the least severe group on each criterion measure. The discriminant validity of the RCAT was reproduced in each type of rhinitis (patients with PAR, SAR, and NAR).

Responsiveness

The responsiveness of the RCAT to changes in the criterion measures is presented in Table V. As shown, mean changes in RCAT scores differed significantly ($P < .001$) across patients,

TABLE III. Convergent validity correlations between RCAT scores and criterion measure scores at baseline

Criterion measure	Rhinitis type			Total
	SAR	PAR	NAR	
TNSS	-0.59	-0.53	-0.54	-0.57
NSS: nasal congestion code item	-0.47	-0.40	-0.39	-0.44
NSS: runny nose item	-0.41	-0.32	-0.27	-0.35
NSS: itchy nose item	-0.44	-0.35	-0.29	-0.39
NSS: sneezing item	-0.42	-0.46	-0.41	-0.44
NSS: postnasal drip item	-0.33	-0.38	-0.31	-0.36
Patient-rated frequency of symptoms	-0.50	-0.43	-0.29	-0.43
Physician's rating of rhinitis severity	-0.38	-0.35	-0.40	-0.38
Physician's rating of rhinitis symptom control	0.24	0.40	0.38	0.34

All correlations are significant at a P value of less than .001.

NSS, Nasal Symptom Score.

differing in their change in TNSS ($F = 50.2$), physician's rating of control ($F = 23.7$), physician's severity rating ($F = 36.5$), and patient's self-assessment of change ($F = 63.3$). As hypothesized, mean changes in RCAT scores increased (improved) significantly among those patients categorized as "improved" on each of the criterion measures. Mean changes in RCAT scores among patients categorized as the "same" or "worse" on each criterion measure were generally small and insignificant. Results were fairly consistent by disease type.

Screening accuracy

Table VI summarizes the performance of the RCAT in screening for rhinitis symptom control problems by using the criterion measure of the physician's rating of rhinitis symptom control. Classification statistics are presented for scores on the RCAT scale between 14 and 25. Scores greater than and less than these cut points are not presented because of poor classification statistics. Lower cut-point scores yielded lower sensitivity and higher specificity (fewer false-positive results), whereas higher cut-point scores yielded higher sensitivity and lower specificity (higher false-positive rate). The highest area under the ROC curve (0.689) was observed at a cut-point score of 21 or less (Fig 2), at which the sensitivity and specificity of the RCAT was 83% and 55%, respectively, and 79% were correctly classified.

MID

The SEM and $\frac{1}{2}$ SD distribution approaches each yielded an MID estimate of roughly 2 points (Table VII). Results of the anchor-based approach yielded estimates ranging from 0.6 to 4.0 across criterion measures, with 8 (57%) of 14 between-group comparisons yielding MID estimates of between 2 and 3 points (average and median, 2.4 points). For comparisons between populations, the data suggest that a mean difference in RCAT scores between groups of greater than 2.4 would be clinically significant. For changes in individual patients over time, in which score changes are in integers, the value of 2.4 would be rounded up to a recommended MID of 3 points.

DISCUSSION

In the current longitudinal study the 6-item patient-completed RCAT was found to be a reliable and valid tool for measuring

TABLE IV. Known-groups discriminant validity analysis of RCAT scores

TNSS							
Rhinitis type	Mild		Moderate		Severe		ANOVA F
	No.	Mean (SD)	No.	Mean (SD)	No.	Mean (SD)	
SAR	50	20.0 (3.7)	67	17.5 (3.6)	35	14.1 (4.1)	26.54†
PAR	50	19.8 (3.9)	69	17.7 (3.6)	30	14.2 (3.8)	21.28†
NAR	43	21.8 (3.6)	49	18.2 (3.4)	7	14.4 (2.9)	20.68†
Total	143	20.5 (3.8)	185	17.8 (3.5)	72	14.1 (3.8)	72.70†
Physician's rating of rhinitis symptom control							
Rhinitis type	Well/completely		Somewhat		Not/poorly		ANOVA F
	No.	Mean (SD)	No.	Mean (SD)	No.	Mean (SD)	
SAR	15	19 (4.2)	52	18.8 (4.2)	85	16.5 (4.1)	5.88*
PAR	21	21.6 (4.4)	58	17.8 (4.1)	70	16.4 (3.5)	14.25†
NAR	17	21.8 (4.4)	44	20.5 (3.5)	38	17.4 (3.6)	10.9†
Total	53	20.9 (4.4)	154	18.9 (4.1)	193	16.7 (3.8)	28.58†
Physician's rating of disease severity							
Rhinitis type	Mild		Moderate		Severe		ANOVA F
	No.	Mean (SD)	No.	Mean (SD)	No.	Mean (SD)	
SAR	40	19.9 (3.5)	87	17.2 (4.3)	25	14.9 (3.5)	12.65†
PAR	60	19.3 (4.6)	71	17.1 (3.6)	18	14.8 (3.5)	9.88†
NAR	42	21.3 (3.9)	48	18.5 (3.6)	9	16.3 (3.9)	9.84†
Total	142	20.0 (4.2)	206	17.5 (3.9)	52	15.1 (3.6)	34.11†

* $P < .01$.† $P < .001$.

rhinitis symptom severity and control. Minimum standards of reliability for making group-level comparisons of scores were satisfied.¹³ Both the internal consistency reliability and test-retest reliability estimates for the RCAT were greater than 0.7 and were also very similar to reliability estimates observed with patient-based control tools developed in asthma care.^{7,8,20} RCAT scores showed adequate convergent validity ($r > 0.5$) with the TNSS and the patient's global rating of severity. Because the RCAT addresses dimensions of control and the TNSS assesses symptom severity, one would expect a relationship but not a strong correlation. Another important difference is that the TNSS is primarily used as a daily diary in clinical trials and therefore is not as feasible for use in routine clinical practice. One potential limitation of our study is that we included the TNSS, which only measures nasal symptom severity, rather than the total nasal and nonnasal symptom score, which includes an ocular symptom measure. Because the RCAT also includes a question about ocular symptoms, the total nasal and nonnasal symptom score could have been included as a validation criterion measure.

Interestingly, correlations between the RCAT score and physicians' ratings of rhinitis severity and control were relatively lower ($r \leq 0.4$). One could attribute this to discordance between physicians and patients in judging the severity and effect of rhinitis that the patient truly experiences. Another explanation could be related to the measurement properties of physicians' severity and control ratings. Both physicians' ratings were categorical (5-point scale), which provided a rather coarse measurement of both constructs, thus restricting the amount of variance that could be shared between the RCAT and these 2 measures. Because physicians' and patients' assessments at times might not be well correlated, as in this case, when used together, both types of clinical assessments can take into account both patient and physician perceptions.

The discriminant validity of the RCAT was also demonstrated because mean RCAT scores differed significantly across patient groups that differed in physicians' ratings of disease severity and symptom control, as well as TNSS staging. More importantly, the differences in mean RCAT scores observed across these patient groups were consistent with stated hypotheses in both total patients and in subgroups stratified by type of rhinitis (patients with PAR, SAR, and NAR).

Previous articles documented the development of the RCAT and provided preliminary evidence of the reliability and validity.^{11,12} The current study represents the first test of the reliability and validity of the RCAT in patients recruited from the offices of allergists, otolaryngologists, or both. The RCAT was administered in the current study in its final format of 6 items, as opposed to being embedded among 20 other candidate questions, as in the previous study. In addition, the current study was longitudinal, which provided the opportunity to investigate test-retest reliability and the responsiveness of the RCAT to changes in rhinitis severity and symptom control, as well as to define an MID. Lastly, a qualitative study used patient focus groups to investigate the content validity of the RCAT. This latter feature is of utmost importance for the RCAT to be considered a valid outcome measure in clinical trials, given the new US Food and Drug Administration guidelines for PRO instrument development.²¹

Aside from being a useful tool for identifying patients experiencing problems with rhinitis symptom control, the RCAT might be suitable for periodic monitoring of patients with rhinitis, as supported by the findings in this study that RCAT scores were responsive to physician-rated changes in rhinitis severity and symptom control. In addition, RCAT scores were shown to respond to changes in TNSS staging and to patient-reported changes in symptom intensity. When administered to the patient repeatedly over time, the RCAT might be useful in gauging

TABLE V. Responsiveness of RCAT scores* to changes in severity and control measures

Disease type	Change in TNSS						ANOVA F
	Improving		Same		Worse		
	No.	Mean (SD)	No.	Mean (SD)	No.	Mean (SD)	
SAR	42	3.79 (5.0)	73	0.88 (3.2)	35	−0.86 (3.4)	14.97‡
PAR	42	3.90 (4.4)	74	1.16 (3.3)	29	−1.21 (2.6)	18.68‡
NAR	28	4.03 (3.8)	52	1.04 (2.9)	18	−1.50 (2.7)	18.10‡
Total	112	3.89 (4.5)	199	1.03 (3.1)	82	−1.12 (3.0)	50.24‡

Disease type	Change in rhinitis symptom control						ANOVA F
	Improving		Same		Worse		
	No.	Mean (SD)	No.	Mean (SD)	No.	Mean (SD)	
SAR	68	2.59 (4.4)	53	0.08 (3.5)	29	0.45 (3.9)	6.65†
PAR	54	3.11 (4.7)	65	0.46 (3.1)	26	0.65 (3.1)	8.13‡
NAR	30	3.73 (4.1)	46	1.30 (2.7)	22	−1.45 (2.5)	17.42‡
Total	152	3.00 (4.4)	164	0.57 (3.1)	77	−0.03 (3.3)	23.66‡

Disease type	Change in rhinitis severity						ANOVA F
	Improving		Same		Worse		
	No.	Mean (SD)	No.	Mean (SD)	No.	Mean (SD)	
SAR	41	3.68 (4.7)	76	0.71 (3.7)	33	−0.36 (3.1)	11.59‡
PAR	34	5.12 (4.5)	78	0.37 (3.1)	33	0.36 (2.6)	25.41‡
NAR	31	2.90 (3.2)	49	1.16 (3.8)	18	−0.39 (3.0)	5.39†
Total	106	3.92 (4.3)	203	0.69 (3.5)	84	−0.08 (2.9)	36.46‡

Disease type	Patient's report of change in rhinitis symptoms						ANOVA F
	Improving		Same		Worse		
	No.	Mean (SD)	No.	Mean (SD)	No.	Mean (SD)	
SAR	55	3.81 (4.2)	47	1.12 (2.9)	46	−1.64 (3.0)	29.6‡
PAR	51	4.12 (4.5)	53	0.58 (2.4)	41	−0.62 (3.0)	23.7‡
NAR	33	3.30 (3.8)	47	1.13 (3.1)	18	−1.14 (3.2)	10.6‡
Total	139	3.82 (4.3)	149	0.89 (2.8)	105	−1.13 (3.0)	63.3‡

*Mean change in score from visit 1 to visit 2 (visit 2 score minus visit 1 score).

† $P < .01$.‡ $P < .001$.**TABLE VI.** Summary of the performance of the RCAT compared with physicians' ratings in screening for rhinitis symptom control problems at various cut points along the score distribution (range, 6-30)

Cut point	OR	95% CI	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Correctly classified (%)	AUROC
≤14	2.97*	1.14-7.71	23.6	90.6	94.3	15.3	32.5	0.571
≤15	2.18*	1.03-4.62	30.8	83.0	92.2	15.5	37.8	0.569
≤16	2.81*	1.36-5.77	39.5	81.1	93.2	17.0	45.0	0.603
≤17	3.21*	1.63-6.31	48.4	77.4	93.3	18.6	52.3	0.629
≤18	2.55*	1.39-4.68	56.8	66.0	91.6	18.9	58.0	0.614
≤19	3.73*	2.02-6.85	65.7	66.0	92.7	22.7	65.8	0.659
≤20	4.77*	2.61-8.71	75.8	60.4	92.6	27.6	73.8	0.681
≤21	5.90*	3.21-10.84	83.0	54.7	92.3	33.0	79.3	0.689
≤22	5.85*	3.12-10.96	87.6	45.3	91.3	35.8	82.0	0.665
≤23	6.10*	3.05-12.16	92.2	34.0	90.1	40.0	84.5	0.631
≤24	6.05*	2.68-13.69	95.4	22.6	89.0	42.9	85.8	0.590
≤25	6.45*	2.23-18.61	97.7	13.2	88.1	46.7	86.5	0.555

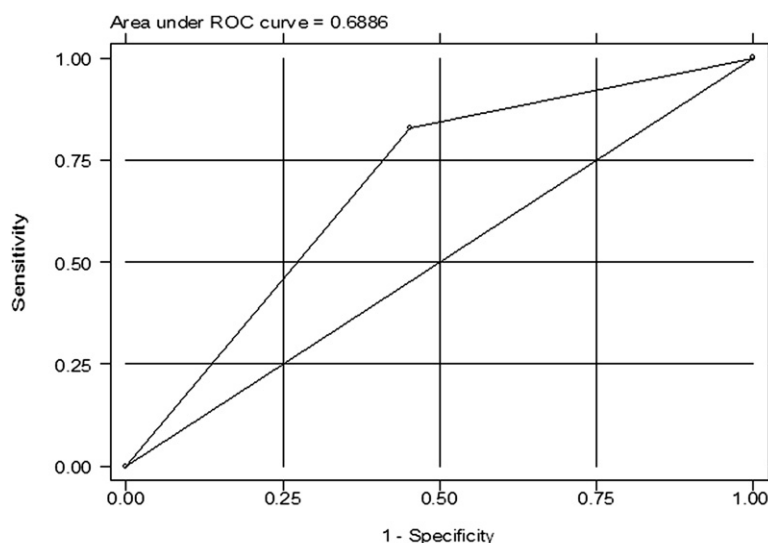
AUROC, Area under the receiver operating curve; NPV, negative predictive value; OR, odds ratio; PPV, positive predictive value.

* $P < .05$.

the success of therapeutic interventions and in identifying deterioration in rhinitis symptom control and therefore can be considered a useful tool both in clinical practice and for clinical research.

Tests were conducted in this study to evaluate the ability of the RCAT to identify patients with rhinitis symptom control

problems. Results suggest that a score of 21 or less (RCAT score range, 6-30) might be useful in identifying patients who are experiencing control problems. This cut-point score provided the largest area under the ROC curve (0.69), the best balance of sensitivity and specificity, and a 79.3% correct classification rate. Depending on the specific objectives of the user of the RCAT,



Note: One intersection between sensitivity and specificity was used for the ROC curve

FIG 2. Area under the ROC curve for cut point 21 on the RCAT scale.

TABLE VII. MID estimates for the RCAT scale

	Distribution-based approaches	
	SEM	½ SD
RCAT	2.1	2.2
Anchor-based approach		
Criterion measures		
TNSS	Mild vs moderate	Moderate vs severe
RCAT scale	2.7†	3.7†
Physician control rating	Not/poorly vs somewhat	Somewhat vs well/completely
RCAT scale	2.2†	2.0*
Physician's severity rating	Mild vs moderate	Moderate vs severe
RCAT scale	2.5†	2.4†
Change in TNSS	Improving vs same	Same vs worse
RCAT scale	2.9†	2.2†
Change in physician control rating	Improving vs same	Same vs worse
RCAT scale	2.4†	0.60
Change in physician's severity rating	Improving vs same	Same vs worse
RCAT scale	3.2†	0.8
Patient's self-reported change	Improving vs same	Same vs worse
RCAT scale	1.8†	4.0†
Mean estimate (anchor based)	2.4	
Median (anchor based)	2.4	

Note: The significance level for all pairwise comparisons is based on Bonferroni-corrected α values.

* $P < .01$.

† $P < .001$.

other cut-point scores could be considered. For example, if it is important to maximize specificity (fewer false-positive results), such as in the enrollment of patients into clinical trials, then cut-point scores of less than 21 might be more appropriate. In addition, the AUC is averaged across all severity levels, and therefore changes in positive predictive values might be dependent on symptom severity.

An exploratory analysis was conducted to determine a second cut-point score that could further delineate patients with rhinitis control problems into somewhat controlled and poorly controlled categories. The analysis suggests that a cut-point score of 17 or less might indicate patients with rhinitis whose symptoms are poorly controlled (data not shown); however, the variance in percentage correctly classified or AUC results across the cut points of 15 to 21 is small. Further study is needed to determine whether a second cut-point score is appropriate.

The recommended MID, which is the minimum change in RCAT score that might be clinically meaningful, is greater than 2.4 points based on the current analysis. This suggests that differences in mean RCAT scores between groups of greater than 2.4 points are likely to be clinically significant. Because scores in individual patients will be in whole numbers, a 3-point change from a previous assessment would indicate a meaningful change in an individual patient's rhinitis control.

Given the new PRO development guidelines established by the US Food and Drug Administration,²¹ it is imperative that all PRO instruments considered for use as efficacy end points in clinical trials have demonstrated content validity. The content of the initial 26 items considered for the RCAT was developed through patient and clinician input.¹¹ The subsequent qualitative study described herein documents the content validity of the 6 selected RCAT items through 58 one-on-one interviews. These patients indicated that all items were relevant, clear in intent, and easy to answer and provided an accurate picture of the severity of rhinitis. The symptoms assessed in the RCAT were considered the most important and prevalent symptoms by patients, although several patients suggested that additional symptoms be assessed, such as headaches, itchy eyes or throat, and runny nose. Each of these suggested symptoms were included in the initial bank of 26 items tested; however, as demonstrated in the results of the developmental study, these symptoms were not as reliable or valid as the 6 items selected for the RCAT.¹¹ Lastly, the 1-week recall period and the response options were found to be acceptable by all patients. Further validation of the RCAT across different populations with different socioeconomic backgrounds is warranted.

In conclusion, the results of the current study suggest that the RCAT can be used to rapidly screen for patients determined to have rhinitis symptom control problems and can help patients in communication with their doctors about the problems they are experiencing with their nasal disease. Use of the patient-assessed RCAT can complement the physician's assessment of rhinitis control, and in addition, the RCAT should perform well as a standalone measure of the patient's perception of rhinitis control. Finally, the results of this longitudinal validation study show that the RCAT is a reliable, valid, and responsive instrument for measuring changes in rhinitis symptom control over time among patients with allergic rhinitis and NAR.

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Clinical implications: This article describes the validation of a brief self-administered survey that patients and physicians can use to assess the burden and control of allergic rhinitis and NAR.

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