



The rhinitis control assessment test: implications for the present and future

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Purpose of review

To summarize the development of the Rhinitis Control Assessment Test (RCAT), its usefulness in clinical practice, and the benefit it provides for patients who are bothered by allergic and nonallergic rhinitis.

Recent findings

The RCAT, a simple, brief, self-administered questionnaire, was developed to assist physicians in the assessment of patient's rhinitis control in clinical practice. It was also to help patients appreciate what rhinitis control is. The RCAT generates a rhinitis score that can be easily understood and is appropriate for long-term monitoring of rhinitis control.

Summary

Rhinitis control remains an elusive goal for physicians and patients. Having a patient-rated screening instrument, like the RCAT, to assist in achieving this goal was felt to be important. If used appropriately, it reflects the multidimensional aspect of rhinitis control. It should also result in an improvement in the quality of care for patients with rhinitis.

Keywords

control, quality of life, questionnaire, rhinitis, rhinitis control assessment test

INTRODUCTION

The burden of both allergic rhinitis and nonallergic rhinitis (NAR) is considerable [1,2]. Allergic rhinitis affects 10–30% of adults and up to 42% of children in the USA [3–6]. Despite the recent epidemiologic evidence that the incidence of allergic rhinitis is increasing worldwide [4,6–9], less than 12% of allergy sufferers seek medical recommendations from a physician [10,11], resulting in allergic rhinitis being frequently under recognized, misdiagnosed, and ineffectively treated in the USA [5,12]. Allergic rhinitis is typically manifested by patients having nasal congestion, rhinorrhea, sneezing, and nasal itching as well as ocular redness, tearing, and itching. Nearly 50% of allergic rhinitis patients will experience symptoms for at least 4 months of the year [13]. Allergic rhinitis, as a non-life threatening disease, has not been regarded as a serious health problem, despite the evidence suggesting it has important short-term and long-term health consequences [14]. The SF-36, a generic health instrument, and the Rhinitis Quality of Life Questionnaire, a disease-specific health instrument, reveal that allergic rhinitis impairs the physical, cognitive, psychological, and social aspects of quality of life [15–18]. Allergic rhinitis is also frequently

associated with problems related to sleep. Lack of sleep and fatigue can ultimately cause reduced productivity at work (presenteeism), diminished school performance, and to a lesser degree absenteeism, contributing to a considerable economic burden [1,19,20]. The direct cost of allergic rhinitis in the USA was estimated at over \$11 billion in 2005 [21]. Indirect costs, such as missed work and decreased productivity, were assessed in a survey of over 8000 U.S. employees [22]. The authors found that allergic rhinitis affected over half of the employees surveyed and accounted for a lost productivity of \$678 per employee per year, which made it the most costly of the 15 conditions examined [22].

The economic burden is further enhanced by allergic rhinitis and asthma often being comorbid conditions [23,24]. Approximately 85% of asthmatic patients have allergic rhinitis [24], whereas

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Curr Opin Allergy Clin Immunol 2014, 14:13–19

DOI:10.1097/ACI.000000000000020

KEY POINTS

- Allergic and nonallergic rhinitis are prevalent conditions that compromise the physical, emotional, mental, and social well being of patients.
- Despite the availability of effective therapies, well controlled rhinitis is difficult to obtain in many patients.
- The assessment of rhinitis control is critical in determining whether rhinitis care is optimized or whether adjusting treatment strategies to achieve control is needed.
- The Rhinitis Control Assessment Test was developed to be a simple, brief, self-administered questionnaire to benefit both patients and physicians in knowing when rhinitis control is achieved.

up to 40% of allergic rhinitis patients have or will develop asthma [25]. Allergic rhinitis was traditionally subdivided into seasonal allergic rhinitis (SAR) and perennial allergic rhinitis (PAR) diseases. However, as perennial allergic symptoms may not be present year round, whereas some seasonal allergens trigger nasal and ocular symptoms most of the year, the Allergic Rhinitis and its Impact on Asthma (ARIA) guidelines classify allergic rhinitis as intermittent or persistent [24]. ARIA guidelines also classify severity as mild or moderate–severe based on sleep disturbances, impairment of daily activities/sport, impairment of work/school, and troublesome symptoms [23,24]. Furthermore, ARIA guidelines recommend that asthma patients be evaluated for allergic rhinitis and that allergic rhinitis patients be evaluated for asthma, with aggressive early treatment of allergic rhinitis decreasing the severity and morbidity associated with asthma [26–28].

Patients with nasal and ocular symptoms may also have NAR [29–31]. Whereas allergic rhinitis results from allergen exposure in sensitized individuals to a relevant allergen, NAR is a common chronic non-IgE-dependent nasal condition [32,33]. Differentiating between allergic rhinitis and NAR is not always possible based on just signs and symptoms, but is frequently one of exclusion based on the history, physical exam, and, in some cases, being skin test negative to allergens [33]. It is estimated that the prevalence of NAR is approximately one-third that of allergic rhinitis [34]. Distinguishing between allergic rhinitis and NAR may be difficult because allergic rhinitis and NAR can coexist in patients [31,35]. According to the National Rhinitis Task Force Survey, approximately 43% of patients diagnosed with rhinitis have pure allergic

rhinitis, 23% have NAR, and 34% have mixed rhinitis [36].

The challenge facing rhinitis patients is getting them to recognize that their frequent and bothersome nasal and ocular symptoms, which result in activity limitations and impact their quality of life, are controllable if identified and appropriately treated. The effective management of both allergic and NAR requires ongoing monitoring of its control. This article reviews the development of the Rhinitis Control Assessment Test (RCAT), an instrument for assessing rhinitis symptom control and how it may benefit the patients and physicians.

METHODS

The development of the RCAT consisted of three phases: item generation and cognitive testing (qualitative) [14]; item reduction and examination of the preliminary psychometric properties of the shortened questionnaire [37]; and a longitudinal validation study [38] to test the reliability, validity, and responsiveness of the RCAT and to determine a cut-point to distinguish between controlled and uncontrolled rhinitis.

The approach to the item-generation phase of development of the RCAT described by Nathan *et al.* [14] followed the guidelines described in the Food and Drug Administration patient-reported outcomes guidance document [39]. In brief, concepts to be measured were identified through a thorough review of the literature, including patient-based, rhinitis-specific instruments. Four focus groups involving patients of at least 18 years with a self-reported diagnosis of rhinitis were conducted to supplement the literature review. Items were refined by cognitive testing to maximize clarity and understanding. Finally, an optimal recall period and meaningful response scale was selected based on patient input. A clinician advisory board was used to generate constructs and assist in identifying the final draft questionnaire items.

The second phase of the RCAT development as reported by Schatz *et al.* [37] was an item reduction study to develop a simple, concise, patient-completed screening tool useful for clinical practice and patients. The primary endpoint of the study was the identification of the appropriate RCAT questions that have the strongest correlation with the Physician Global Assessment of rhinitis control. This phase also explored the preliminary psychometric properties of the shortened questionnaire. During the clinic visit, patients completed the Total Nasal Symptom Score (TNSS) and the 26-item developmental RCAT, in that order. For the TNSS, patients rated the severity of the

individual symptoms of nasal congestion, itchy nose, runny nose, postnasal drip, and sneezing on a scale ranging from 0 (symptom not present) to 3 (symptom difficult to tolerate, interferes with activities of daily living, or sleeping) for the previous 24 h. Scores for the five individual symptoms were summed to arrive at a TNSS (range 0–15).

Also during the clinic visit, physicians, blinded to the patient's responses to the TNSS and the RCAT draft questionnaire, completed the Physician Global Assessment, three questions assessing rhinitis control, severity, and need for change in therapy. Physicians based their assessment of control on a five-point scale (completely controlled, well controlled, somewhat controlled, poorly controlled, and not controlled at all). Physicians were also asked whether they would change the patients' therapy with options being to increase therapy, make no change in therapy, or reduce therapy.

The final phase of the RCAT developmental process was the longitudinal study described in detail by Meltzer *et al.* [38[•]]. This was a nontreatment study that consisted of two clinician visits occurring 15–29 days apart. Patients completed the item-reduced RCAT questionnaire and the TNSS. Physicians completed the Physician's Global Assessment. Internal consistency, test–retest reliability,

convergent validity, known-groups validity, and responsiveness were evaluated. Content validity of the RCAT was also assessed by performing individual interviews with a separate group of 58 adult patients. This study also determined a cut-point score for uncontrolled rhinitis.

RESULTS

In the initial phase, a draft questionnaire consisting of 33 items was developed [14]. The face validity and clinical relevance of the draft items were confirmed by the clinician advisory board with no items removed. However, based on three rounds of cognitive debriefing with patients, seven items were removed yielding a 26-item questionnaire that assessed five constructs: symptom frequency and bothersomeness (runny nose, congestion, sneezing, postnasal drip, itchy eyes, watery eyes, sinus pain or pressure, headache, fatigue, and any other nasal or allergy symptom); symptom impact (interference with sleep or concentration, mood, daily activities, and social or leisure activities); activity avoidance (avoidance of or inability to perform activities); rhinitis control (nasal or allergy symptom control); and rhinitis medication use (need for or how often taken) (Fig. 1) [14,37]. A five-point Likert response

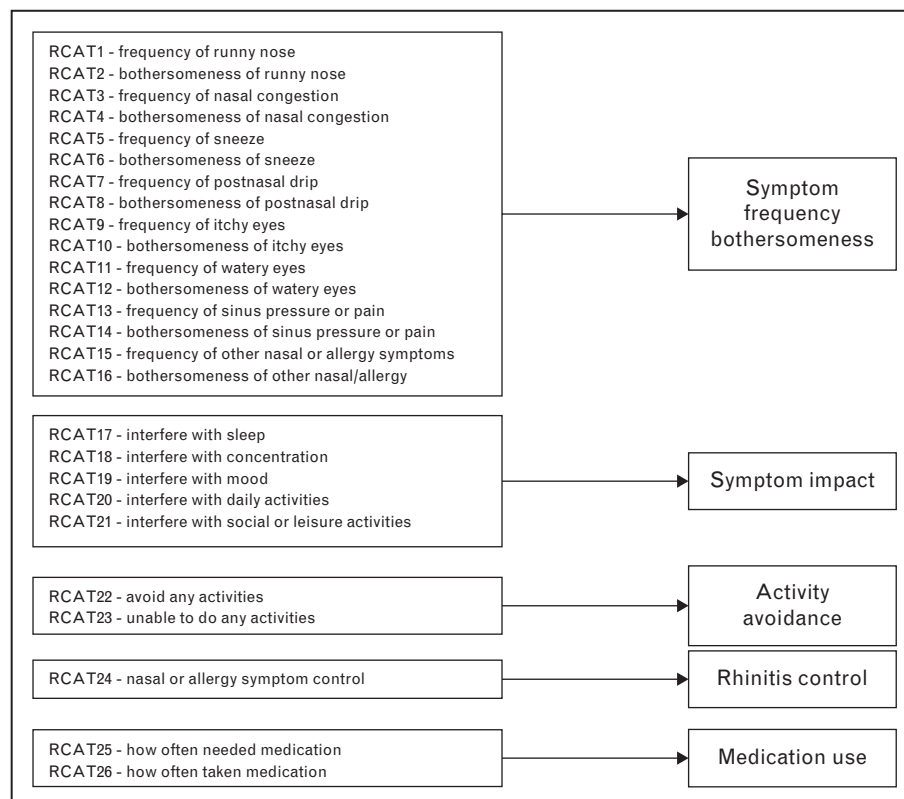


FIGURE 1. Rhinitis control assessment test items and constructs: developmental questionnaire. Data from Schatz *et al.* [37].

1. <u>During the past week</u> , how often did you have nasal congestion?				
Never	Rarely	Sometimes	Often	Extremely often
☐ ⁵	☐ ⁴	☐ ³	☐ ²	☐ ¹
2. <u>During the past week</u> , how often did you sneeze?				
Never	Rarely	Sometimes	Often	Extremely often
☐ ⁵	☐ ⁴	☐ ³	☐ ²	☐ ¹
3. <u>During the past week</u> , how often did you have watery eyes?				
Never	Rarely	Sometimes	Often	Extremely often
☐ ⁵	☐ ⁴	☐ ³	☐ ²	☐ ¹
4. <u>During the past week</u> , to what extent did your nasal or other allergy symptoms interfere with your sleep?				
Never	Rarely	Sometimes	Often	Extremely often
☐ ⁵	☐ ⁴	☐ ³	☐ ²	☐ ¹
5. <u>During the past week</u> , how often did you <u>avoid</u> 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. <u>During the past week</u> , how well were your nasal or other allergy symptoms controlled?				
Completely	Very	Somewhat	A little	Not at all
☐ ⁵	☐ ⁴	☐ ³	☐ ²	☐ ¹

FIGURE 2. Rhinitis control assessment test. Data from Meltzer *et al.* [38[•]].

scale and a 1-week recall period for each item were adopted.

In the second phase, the developmental 26-item RCAT questionnaire was administered to 410 patients with allergic rhinitis (210 with PAR and 200 with SAR) at 26 sites of allergists and otolaryngologists across the USA, after obtaining the investigational review board's (IRB) approval and written informed consent from all the participants [37]. A stepwise regression analyses, generated six RCAT items. Items identified included frequency of nasal congestion, sneezing and watery eyes; sleep interference; avoidance of activities; and patient rating of control; using the five-point Likert response scale. RCAT scores range from 6 to 30, with higher scores indicating better control (Fig. 2) [38[•]]. The six-item RCAT showed good convergent validity with the TNSS. The discriminate validity was demonstrated as mean RCAT scores differed significantly across the group of patients differing in physician-rated disease severity, TNSS severity, and physician-recommended change in therapy [37].

In the third phase [38[•]], a longitudinal study in 402 patients (150 with PAR, 152 with SAR, and

100 with NAR) was performed at 29 sites of allergists and otolaryngologists after IRB approval and written informed consent. The six-item RCAT longitudinal study showed internal consistency and test-retest reliability. Convergent validity was demonstrated between RCAT and TNSS and Physician Global Assessment scores. The RCAT demonstrated adequate reliability, validity, and responsiveness, and was deemed acceptable and appropriate by patients who suffered from both allergic and NAR. The six selected RCAT items checked for content validity through 58 one-on-one interviews confirmed the items to be relevant, clear in intent, easy to answer, and provided an accurate picture of the severity of their rhinitis [38[•]]. The results suggested a cut-point score of 21 or less based on its sensitivity and specificity to identify patients experiencing rhinitis symptom control issues [38[•]].

DISCUSSION

Allergic and NAR are prevalent conditions that compromise the physical, emotional, mental, and

social well being of affected patients. The effective management of rhinitis first requires an accurate diagnosis. Despite the availability of effective therapies, well controlled rhinitis is difficult to obtain for many patients. The assessment of rhinitis control is critical for determining whether optimal rhinitis care is achieved or whether adjusting treatment strategies is needed. The RCAT was developed to assist in the assessment of problems with control of nasal and ocular symptoms that might warrant additional testing or referral to a specialist for further evaluation and treatment [38[•]]. The final RCAT was intended to be a simple, brief, easy to self-administer, patient-friendly questionnaire to benefit both patients and physicians in this process. RCAT question responses are measured on a five-point scale with total score ranging from 6 to 30, with higher scores indicating better control. Although the RCAT was initially developed with the thought of measuring symptom control in patients with only allergic rhinitis, patients with NAR were included in the developmental process and the longitudinal study [14,38[•]].

The Asthma Control Test (ACT), a patient-rated screening tool developed to measure the level of asthma control, has been successfully validated and utilized [40,41]. The ACT also has the endorsement of asthma treatment guidelines [25,42]. Similarly to that noted in asthma with the ACT, measuring rhinitis control with the RCAT is multidimensional. The six items selected (frequency of nasal congestion, sneezing, and watery eyes; sleep disruption; activity limitation caused by symptoms; and self-rating of symptom control) support this. Both the RCAT and ACT classify patient control into categories that range from well controlled to poorly controlled. Unlike in asthma, in which the ACT can be compared to a pulmonary function, there is no readily reproducible objective test to easily measure rhinitis control. Nasal peak flow measures nasal congestion, only one aspect of rhinitis control [43]. Similarly, the Congestion Quantifier seven-item test (CQ7) does not assess the other symptoms of rhinitis, such as sneezing and watery eyes which turn out in the RCAT to be important in the assessment of rhinitis control [44]. The TNSS, frequently used in clinical rhinitis trials to measure symptom severity, does not address the measures of control. A 1-week recall of symptoms is utilized for the RCAT, whereas a 4-week recall is utilized in ACT.

The overestimation of rhinitis control can result in failure to use needed interventions or to make necessary adjustments to medication regimens. A

large allergic rhinitis survey [19] supports the inclusion of sleep disruption and activity avoidance in the RCAT as being important in the assessment of rhinitis control. Poor sleep quality contributes to decrease workplace productivity and underperformance in school. Because many allergic rhinitis patients have learned to live with these disabilities, these outcomes have significant economic and societal impacts that can be reduced with better rhinitis control. Filling out the RCAT will assist in assessing these outcomes.

The patient-rated control item is another important inclusion in the RCAT. As noted with ACT, responses to the self-rating of control item helps to identify patients who would benefit from being educated on what rhinitis control is. This would be the case for patients who rate their disease as well controlled or completely controlled, but their responses to other items suggested otherwise [37].

As an accurate assessment of a patient's rhinitis control can improve and simplify management, a simple method for quantifying rhinitis control for both patients and physicians was needed. The RCAT seems to meet these goals. Patients can use the RCAT to assess their level of rhinitis control at home. It generates a rhinitis score that can be easily understood. Patients, knowing their score, have an objective measure of their level of rhinitis control. This should empower them to seek better if not total control of their rhinitis. For physicians, the RCAT gives a rapid and accurate assessment of rhinitis control, suitable for use in a busy clinical practice. It is an excellent tool for screening uncontrolled rhinitis and suitable for long-term monitoring of rhinitis control. It gives physicians an objective score that can be compared to the previous values. This score will be useful in guiding therapeutic decisions to facilitate optimal rhinitis control. It should encourage a better physician-patient dialog on how to achieve better control. In clinical practice, it is not only how we can help patients achieve and maintain rhinitis control, but also how to assess rhinitis control to know when it has been achieved.

An assessment tool to measure rhinitis control is important for patients who self-medicate. The RCAT becomes more important in an era in medicine in which therapeutic prescription options are decreasing, whereas over-the-counter options are likely to increase for rhinitis. As already seen with several of the second-generation antihistamines, there is a strong likelihood that a number of intra-nasal steroids will eventually become available without a prescription. Being able to monitor one's rhinitis control at home with the RCAT will allow

patients to know when it is time to step up their treatment to achieve better control or to step down treatment to see whether control can be maintained.

CONCLUSION

The RCAT is a reliable, valid, and responsive instrument to assess rhinitis control. The RCAT is simple to self-administer and should be useful to clinicians who are interested in assessing the level of rhinitis control in patients in their practice who have nasal and ocular symptoms and for patients who may not want to initially seek physician input on how to achieve better rhinitis control.

Acknowledgements

The author thanks Kathy Traxler for assistance in the preparation of this article.

Conflicts of interest

R.A.N. received research grants from Alcon, Amgen, AstraZeneca, Boehringer Ingelheim, Cephalon, Dyax, Forest, Genentech, GlaxoSmithKline, MAP, Med-Immune, Merck, Novartis, Pearl, Sanofi Aventis, Shire, Sunovian, Teva, Vectura and Viropharma; speaking honorarium from AstraZeneca, GlaxoSmithKline, Merck and Sunovian; consulting honorarium from Boehringer Ingelheim, GlaxoSmithKline, Bausch and Lomb, CSL Behring, and Sunovian.

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