

Assessing Nasal Symptom Control

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Rhinitis is a common chronic disease that significantly impacts morbidity, health care costs, work and school productivity, and quality of life. Therefore, appropriate management is paramount to help to reduce the burden of disease. In current clinical practice, there are no validated instruments widely used to assess rhinitis control. In this review, we describe the tools available for assessing nasal symptom control in patients with rhinitis. The recently developed Allergic Rhinitis Control Assessment is a promising tool with demonstrated validity, reliability, and ease of use. Health care providers are encouraged to use the rhinitis-specific tools and incorporate other objective measures, such as rhinoscopy and rhinometric techniques, when evaluating patients with rhinitis. Further research is needed to evaluate the benefits and shortcomings of the available rhinitis- and rhinosinusitis-specific instruments to establish their role in clinical practice.

Introduction

Rhinitis is a common chronic disease that significantly impacts morbidity, health care costs, work and school productivity, and quality of life [1,2]. In 2002, the estimated direct and indirect costs attributed to allergic rhinitis alone in the United States were \$11.58 billion [3]. The estimated prevalence of allergic rhinitis is 10% to 30% in adults and up to 40% in children [1,4]. Up to 87% of patients with rhinitis may have a combination of allergic and nonallergic rhinitis [1]. Regardless of the etiology, the clinical manifestations of rhinitis are similar: nasal congestion, rhinorrhea, sneezing, and nasal itching. These nasal symptoms may be accompanied by ocular and ear symptoms. The significant burden associated with rhinitis underscores the importance of accurate diagnosis and appropriate management.

The current approach to disease assessment and management is based purely on clinical symptoms with-

out the use of validated instruments. Although objective measures of nasal function such as acoustic rhinometry, rhinomanometry, and nasal peak flow are available, they can be somewhat cumbersome and do not always correlate well with patients' nasal symptoms [5]. Hence, these objective measures should be used in combination with a health assessment instrument to accurately assess disease severity and ascertain response to therapy in the clinical and research settings. Many instruments assessing some element of sinonasal disease have been published, but only a few adequately reflect control of rhinitis, and none have been widely adopted in the clinical setting. In this review, we focus on the currently available instruments and those under development for assessing nasal symptom control.

Instruments for Assessing Nasal Symptom Control

Two types of health assessment instruments exist: general health status instruments and disease-specific instruments [6]. General health status instruments generally assess quality of life and allow for comparisons between diseases; however, they are less useful for assessing an intervention's effect on a specific disease. Disease-specific tools are the most appropriate for detecting changes in health status resulting from interventions. Using disease-specific tools also helps to avoid the impact of comorbid conditions that may result in confounding variables.

Health-related assessment instruments should meet certain criteria with regard to reliability, validity, responsiveness, and ease of use [7]. Reliability refers to the internal consistency within an instrument—that is, how the individual items relate to each other. It suggests homogeneity of test items and that the test is free from random error. Test-retest reliability reflects stability over time with repeated testing. Validity is the degree to which an instrument truly measures what it is supposed to measure. Construct-related validity is the extent to which the condition gets worse. Discriminant validity refers to the ability to distinguish between groups affected by the disease and those not affected by the disease. Criterion-related validity is the extent to which the instrument scores relate to the gold standard; this is rarely tested due to lack of a gold standard. Responsiveness is the sensitivity to change over time. It accounts for confounding variables beyond the scope of the disease. Ease of use is an important attribute for a health-related assessment tool. A tool that is cumbersome would prevent further use [7].

Among the published instruments for assessing nasal symptoms, some favor a disease-specific symptom assessment, whereas others emphasize an assessment of general health. Given the coexistence of rhinitis symptoms with sinusitis and allergic conjunctivitis, some instruments combine rhinoconjunctivitis or rhinosinusitis symptoms. Several disease-specific instruments attempt to combine symptom and general health assessment, whereas few symptom-specific instruments examine rhinitis alone. We discuss many of these instruments, with emphasis on reliability, validity, and responsiveness.

Rhinitis-specific tools

Rhinoconjunctivitis Quality of Life Questionnaire

The Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ) was developed to measure health-related quality of life in rhinoconjunctivitis clinical trials [8]. It is composed of 28 questions that address the following domains of quality-of-life impairment: rhinitis symptoms, conjunctivitis symptoms, systemic symptoms, sleep disturbance, practical problems, activity limitations, and emotional problems. It uses a seven-point scale and requires individuals to recall symptoms and activities within the past week. Questionnaire items were generated through the experience of investigators, a review of general health-related quality-of-life measures, and interviews with rhinoconjunctivitis patients. Items were pretested to clarify issues of wording and item presentation. The RQLQ was tested for validity, reproducibility, and responsiveness in a randomized, double-blind trial of standard versus as-needed beclomethasone dipropionate nasal spray in ragweed pollen-induced rhinoconjunctivitis [8]. Validity was demonstrated by a moderate to strong relationship between changes in symptom diary scores and changes in RQLQ scores. Responsiveness was evaluated by administering the RQLQ at three different time points: during the first week of the ragweed season, at the height of the season, and during the last week of the season. Nasal symptoms and nonhayfever symptom domains of the instrument and the overall score were comparable in their responsiveness to the daily diary. Test-retest reliability was assessed by administering the instrument on two occasions—2 weeks apart—during a period of clinical stability; results showed a close relationship between scores on the two administrations, with no significant change over time. With its well-established validity, responsiveness, and test-retest reliability, the RQLQ is a commonly used tool in research settings that has been used in comparison to validate some of the newer instruments, such as the Rhinitis Symptom Utility Index (RSUI) [9]. However, its major disadvantage is the length of the questionnaire, which may negatively affect its ease of use and make it less practical in the clinical setting.

Rhinitis Symptom Utility Index

This is a symptom-specific instrument primarily applicable to rhinitis. The RSUI was designed as a global outcome measure to complement general and disease-specific,

health-related quality-of-life measures and as an outcome indicator for evaluating the cost-effectiveness of treatment alternatives in rhinitis patients [9]. It consists of 10 questions that assess the severity and frequency of nasal congestion; rhinorrhea; sneezing; itchy nose or throat; and itchy, watery eyes during the previous 2 weeks, weighted according to patient preferences. Symptoms were chosen based on rhinitis literature reviews, patient interviews, and interviews with physicians experienced in managing rhinitis. Unlike the RQLQ, the RSUI emphasizes the importance of incorporating patient preferences to ensure that the rhinitis symptoms included in the instrument represent the perceived burden on functioning and well-being [9]. Symptom frequency and severity are measured on a four-point Likert scale. The RSUI score, which takes into account the preference weights, was derived based on multiattribute utility assessment methods. The validity and reliability of the RSUI were evaluated in a cross-sectional survey of 100 adult patients with allergic rhinitis [9]. Validity was evaluated by examining the relationship between RSUI scores and indicators of disease severity, disability days, rhinitis-specific health-related quality of life (using the RQLQ [8]), and generic health utility (using the Health Utility Index Mark 2—a multiattribute health utility index [10]). Validity was demonstrated by the instrument's ability to discriminate between patient groups based on physician-rated severity. It also correlated significantly with the RQLQ, with the highest correlation observed between RSUI and RQLQ nasal symptoms. The RSUI only moderately correlated with the Health Utility Index Mark 2, suggesting that the RSUI assesses disease-specific dimensions of health that do not strongly overlap with that of a generic multiattribute utility measure [9]. The RSUI is relatively easy to use. However, it showed a weak test-retest reliability that has been attributed to fluctuation in rhinitis symptoms [7,9].

In 2003, the Joint Task Force on Practice Parameters for Allergy, Asthma and Immunology first published a new seven-point visual analogue scale for assessing the severity of allergic rhinitis symptoms [11]. In this practice parameter, Spector et al. [11] acknowledge the importance of concomitant assessment of nonnasal symptoms and quality of life; however, they suggest that each of these domains (nonnasal symptoms and quality of life) be assessed separately using a similar instrument. The nasal symptom domain assesses six items: sneezing, runny nose, congestion, itchy nose, postnasal drip, and total nasal symptoms. A major advantage of this tool is that it allows clinicians to focus solely on assessing nasal symptom severity when necessary. The updated practice parameter, published in 2008, recommends using this tool [1•]. Although it is easy to use, it has not been evaluated for validity, reliability, and responsiveness [1•,11].

Allergic Rhinitis Control Assessment

The Allergic Rhinitis Control Assessment (ARCA) is a new instrument developed specifically for patients and

providers to assess rhinitis control [12••]. The development and validation of the ARCA was presented at the American College of Allergy, Asthma and Immunology national meeting in 2007 and the American Academy of Allergy, Asthma and Immunology annual meeting in 2008. The development of ARCA began with 33 initial items identified based on literature review, patient focus groups, and clinician input. With additional patient input, these were reduced to 26 items scored on a five-point scale. An item reduction study then determined the items most predictive of rhinitis control in order to determine a preliminary threshold for controlled versus not well-controlled disease and to evaluate the ARCA's screening accuracy. This study, which was conducted among 410 patients with allergic rhinitis, was also used to evaluate the instrument's validity. A backward stepwise logistic regression analysis was used to identify the six items most predictive of the physician-rated rhinitis control: frequency of sneezing, nasal congestion, watery eyes, avoidance of activities, self-rated control, and sleep interference. These six items now comprise the ARCA, which requires patients to recall symptoms and activities within the past week. The ARCA showed good ability to discriminate between disease severity groups when compared with total nasal symptom severity, physician disease severity, change in therapy, and physician control rating. The items in the ARCA also correlated highly with all RQLQ domains and demonstrated internal consistency. One major advantage of using the ARCA is that a cutoff score has been established, with scores greater than 19 suggesting adequate control of rhinitis symptoms and scores 19 or lower suggesting symptoms not adequately controlled. This cutoff score differentiates the ARCA from other instruments and makes it an attractive tool for assessing nasal symptom control. Another practical advantage is that the instrument is brief and easy to use. Nonetheless, further evaluation of the ARCA is necessary to establish responsiveness and test-retest reliability.

Rhinosinusitis-specific tools

Rhinosinusitis Outcome Measure

The Rhinosinusitis Outcome Measure (RSOM-31), a validated measure of health status and quality of life in rhinosinusitis patients, is grouped into seven domains: nasal symptoms, eye symptoms, sleep symptoms, ear symptoms, general symptoms, practical problems, and emotional consequences [13]. It includes 31 items and has two categorical rating scales to indicate "magnitude" and "importance" of each item, both of which determine the RSOM score. Validity was measured in a study of 142 patients; RSOM scores were compared with subscales of the Medical Outcomes Study Short Form 36 (SF-36) [14], the most widely tested and used tool for measuring general health [7]. RSOM scores correlated significantly with an overall global quality-of-life question and with some subscales of the Medical Outcomes Study SF-36 [13]. The average RSOM score indicated improvement over time

and was significantly correlated with patients' assessment of their response to treatment. Although the RSOM-31 showed good validity, it is not easy to use [7]. Subsequent modification of this instrument led to the development of the Sinonasal Outcome Test (SNOT)-20 [15], SNOT-16 [16], and SNOT-22 [17].

Sinonasal Outcome Test-20

The SNOT-20 is a disease-specific, health-related quality-of-life measure used for rhinosinusitis [15]. It differs from the RSOM-31 in that 11 items thought to be redundant were eliminated. Furthermore, unlike the RSOM scoring system, which incorporates magnitude and importance of each item, the SNOT-20 scoring system includes only the magnitude score. The instrument consists of 20 questions about nasal, sinus, and general issues. With this measure, patients indicate the severity of symptoms in each domain and specify the five items that are most important to them and that they expect to improve with treatment. Reliability and validity were analyzed in a group of patients with signs and symptoms of rhinosinusitis compared with a group of patients with no rhinosinusitis-related problems [15]. The instrument showed good internal consistency and high degree of correlation between test scores at two separate time points 2 weeks apart. When SNOT-20 scores were compared between the disease-affected and the disease-unaffected groups, a significant difference was observed, with the affected group having worse scores. Patients who indicated improvement in rhinosinusitis at 6 months had greater change from baseline SNOT-20 scores than those who indicated no improvement or worsening of disease. The mean SNOT-20 score for items identified as "important" was significantly higher than the overall SNOT-20 score, indicating that items that are marked "important" are more severe. Responsiveness was measured over a 1-year period, and the SNOT-20 demonstrated moderate sensitivity to clinical change [15]. These results established the reliability, validity, and responsiveness of the SNOT-20. However, one major shortcoming is that it omits two important items—nasal blockage and loss of smell and taste—which limits its usefulness in assessing nasal symptom control. Modifications of SNOT-20 to include these omitted items led to the development of other instruments, such as SNOT-22 [17] and Sinonasal Assessment Questionnaire (SNAQ-11) [18].

Sinonasal Outcome Test-22

The SNOT-22 is a modification of SNOT-20 that includes two previously omitted items: nasal blockage and sense of taste and smell [17]. In a study assessing patient outcomes after surgery for nasal polyposis and chronic rhinosinusitis (CRS), Hopkins et al. [17] used SNOT-22 scores as the main outcome measure. The instrument showed high internal consistency, thereby providing assurance that the two additional items measure aspects of the same underlying construct measured by the original SNOT-20. The SNOT-22 also demonstrated good discriminant valid-

ity, as it showed greater score improvement in patients undergoing nasal polypectomy compared with the score improvement in patients undergoing surgery from CRS alone. Another advantage is its ease of use.

Sinonasal Assessment Questionnaire

The SNAQ-11 was designed as a modification of the SNOT-20 [18]. In the SNAQ-11, two important items omitted in the SNOT-20 (nasal obstruction and anosmia) were added, making it similar to the SNOT-22. The main difference between the SNAQ-11 and the SNOT-22 is that the SNAQ-11 also eliminated other SNOT-20 items that were not directly focused on rhinosinusitis symptoms, such as reduced productivity, reduced concentration, and frustration/irritability. This resulted in a shorter, 11-question tool that is more rhinosinusitis focused. Symptoms assessed in the SNAQ-11 include nasal obstruction, congestion, facial pain, anterior nasal discharge, sneezing, hyposmia, sleep disturbance, postnasal drip, headache, cough, and earache. The SNAQ-11 was evaluated in a prospective study of patients undergoing endoscopic sinus surgery; SNAQ-11 and SNOT-20 scores were compared preoperatively and postoperatively [18]. The results indicated that both instruments demonstrated change in scores postoperatively, reflecting symptomatic improvement. However, a larger change occurred in the postoperative SNAQ-11 score compared with the change in the postoperative SNOT-20 score, which suggests that the SNAQ-11 may be more reliable [18]. Nonetheless, the SNAQ-11 was not evaluated for internal consistency and responsiveness. The shorter length of the SNAQ-11 relative to the SNOT-20 and the SNOT-22 makes it easier to use.

Sinonasal Outcome Test-16

The SNOT-16, a student research project, was extracted from the SNOT-20 shortly after the development of the SNOT-20 as a means of independently evaluating the SNOT test [16]. In this project, the SNOT-16 was evaluated in a study population of rhinosinusitis patients as compared with patients without history of rhinosinusitis. It demonstrated a high degree of homogeneity of test items. To measure validity, SNOT-16 was compared with SF-36, and SNOT-16 scores were significantly correlated with most SF-36 subscales [16]. Discriminant validity was demonstrated by higher scores in the rhinosinusitis patients than in the disease-unaffected group [16]. Although its validity and reliability are well established, the SNOT-16 is not widely used [7]. Compared with the SNOT-20, the SNOT-16 is somewhat redundant and does not appear to address the shortcomings of the SNOT-20.

Rhinosinusitis Task Force scoring system

In 1997, the Rhinosinusitis Task Force (RSTF) sponsored by the American Academy of Otolaryngology: Head and Neck Surgery developed a working definition for rhinosinusitis based on several clinical criteria [19]. The major criteria are facial pain/pressure, facial congestion, nasal obstruction,

altered sense of smell, nasal cavity purulence on examination, and acute fever; the minor criteria are headache, nonacute fever, halitosis, fatigue, dental pain, cough, and ear pain/pressure/fullness. Although these symptoms have not been validated, a recent attempt has been made to evaluate the RSTF criteria by comparing RSTF symptom scores with SNOT-20 scores [20]. RSTF symptoms were scored based on a visual analogue scale ranging from 0 (symptom absent) to 10 (maximum severity) in patients with CRS and in a control group of patients without CRS. When RSTF symptom scores were compared with those of the validated SNOT-20, a statistically significant correlation was observed between the two instruments. This suggests that RSTF scores based on a visual analogue scale may be useful in assessing outcomes in treatment of patients with CRS [20]. With only 14 items in the RSTF scoring system, it is shorter than the SNOT-20 and has the added benefit of including the two important nasal symptoms that were omitted in the SNOT-20: altered sense of smell and nasal blockage. However, one disadvantage of the RSTF scoring system is that a 10-point scale may be too cumbersome.

SN-5 (and SN-6) survey

The SN-6 survey was the original instrument designed to evaluate health-related quality of life in children with persistent sinonasal symptoms [21]. This survey is completed by the child's parent using a seven-point response scale with six domains: sinus infection, nasal obstruction, allergy symptoms, medication use, emotional distress, and activity limitations. The elimination of one item from the survey regarding medication use to improve psychometric validation led to the SN-5 survey, which includes the remaining five domains. Within each domain is a cluster of symptoms. The SN-5 was evaluated in children with sinonasal symptoms and demonstrated good test-retest reliability for the overall test score and the individual items. Good responsiveness to change was also observed in the study. Validity was demonstrated by correlations of all SN-5 items with external constructs such as the RQLQ [21]. However, because it is designed as a pediatric survey, it is not used in adults [7].

Rhinosinusitis Symptom Inventory

The Rhinosinusitis Symptom Inventory (RSI) was used in a nonrandomized, prospective clinical trial to determine the effectiveness of endoscopic sinus surgery in patients with CRS [22]. Items in this instrument address individual symptoms, medication use, physician visits, and missed workdays. Symptoms are scored based on a Likert scale ranging from 0 (symptom absent) to 5 (maximum severity). After surgery, significant decreases were found in sinonasal symptom scores; the largest effect sizes were noted for decreases in symptoms in the nasal, facial, and total symptom domains of the RSI [22]. Responsiveness of the RSI has been described previously [23]. However, the tool's reliability is unclear, as no published data exist for internal consistency.

Rhinosinusitis Disability Index

The Rhinosinusitis Disability Index (RSDI) is a reliable and valid tool that was created to evaluate the self-perceived impact of rhinosinusitis [24]. The tool was evaluated in a group of patients with rhinosinusitis or rhinitis compared with a group of patients without sinonasal disease. In this study, the RSDI showed good internal consistency and high test–retest correlation. Discriminant validity was demonstrated by the instrument’s ability to distinguish between patients with rhinosinusitis or rhinitis and those without these diseases. Although the RSDI is a disease-specific tool, it differs from other rhinosinusitis-specific tools in that it primarily evaluates the impact of rhinosinusitis on physical, emotional, and social functioning, thus focusing on disability.

Other rhinosinusitis assessment tools have been described elsewhere [6,7,18]. These include the Fairley Nasal Questionnaire (FNQ) [25], the General Nasal Patient Inventory (GNPI) [26], the Chronic Sinusitis Survey (CSS) [27], and the Cologne Questionnaire [28]. These tools are similar to the rhinosinusitis-specific tools described previously in that they assess one or more of the following: sinonasal symptoms, quality-of-life impairment, or disability related to rhinosinusitis. The FNQ and CSS are among the earliest tools developed for assessing rhinosinusitis control and have good psychometric validity and reliability [25,27]. The FNQ is a physician-derived questionnaire, whereas the GNPI was later created as a patient-oriented questionnaire [26]. GNPI scores correlated highly with FNQ scores, supporting its validity [26]. The CSS is somewhat different from other tools, as it measures the duration of symptoms or medication use as opposed to most other instruments, which measure disease severity. The Cologne Questionnaire, which was created for research purposes at the University of Cologne in Germany, has no record of psychometric reliability, validity, or responsiveness [28].

General health assessment tools

Medical Outcomes Study SF-36

Although it is not rhinitis specific, the SF-36 [14] is worth mentioning as the most widely tested and used tool for measuring general health [7,24]. It is a 36-item short form constructed to evaluate health status in the Medical Outcomes Study—a study designed to investigate factors that may explain variations in patient outcomes and to develop more practical tools for the routine monitoring of patient outcomes in medical practice [14,29]. The instrument assesses eight health concepts: limitations in physical activities due to health problems, limitations in social activities due to physical or emotional problems, limitations in usual role activities (eg, work or usual daily activities) due to physical health problems, bodily pain, general mental health (psychological distress and well-being), limitations in usual role activities due to emotional problems, vitality (energy and fatigue), and general health perceptions [14]. Its validity is well established [30]. SF-36

has been used to validate some rhinosinusitis instruments, such as the RSOM-31 [13] and the SNOT-16 [16]. As a general health assessment tool, SF-36 can allow for comparisons between diseases; however, a major limitation is that it lacks the depth needed to measure the effect of an intervention on a specific disease, such as rhinitis.

Discussion

In this review, we have described several tools that may be useful in assessing nasal symptom control. Although many instruments assess some element of sinonasal disease, only a few measure control of rhinitis, and none of the tools have been widely adopted in the clinical setting. The instrument developed by the Joint Task Force on Practice Parameters for Allergy, Asthma and Immunology [1•,11] is the only rhinitis-specific tool that focuses solely on assessing nasal symptom severity. Although this tool appears to be easy to use, that it has not yet been tested for validity and reliability is a major limitation for its use. Other rhinitis-specific tools, such as the RQLQ [8] and RSUI [9], have disadvantages that limit their usefulness in clinical practice. These disadvantages include the relatively long length of the RQLQ and the weak test–retest reliability of the RSUI. The shortcomings of these validated instruments led to the development of the ARCA.

An ideal tool for assessing nasal symptom control should center on assessing nasal symptoms and have excellent validity, reliability, responsiveness, and ease of use. The ARCA is an attractive tool with good reliability and validity [12••]. Its simplicity and relative brevity compared with the RSUI and RQLQ make it easier to use in clinical practice. However, the ARCA is not yet widely available because it was only recently developed and has not been published. The ARCA still needs to be evaluated for responsiveness and test–retest reliability.

We also have described several instruments that include assessment of disease control and quality of life in sinusitis patients. Due to frequent coexistence of rhinitis and sinusitis, a role exists for tools that assess both conditions in clinical practice. Among these tools, the SNOT-22 [17] probably has the most advantages, as it is easy to use and remains relatively comprehensive. Reliability, validity, and responsiveness of the SNOT-22 also have been documented. The SNAQ-11 [18], which may be compared with the SNOT-22, was less rigorously evaluated for validity and has not been tested for reliability and responsiveness. For assessing disability due to rhinosinusitis, the RSDI [24] is the most appropriate tool, as it is the only instrument with a primary focus on disability.

Regardless of the instrument used to assess rhinitis, health care providers are encouraged to incorporate objective measures, such as physical examination findings, rhinoscopy, and various rhinometric techniques, into rhinitis evaluation if they would be considered helpful [11].

Conclusions

Appropriate management of rhinitis is necessary to help to reduce the significant burden of the disease. We have described the few rhinitis-specific instruments available for assessing nasal symptom control in rhinitis patients. Although no gold standard instrument exists for assessing nasal symptoms, health care providers are encouraged to use these tools and incorporate other objective measures, such as physical examination findings and rhinometric studies, when evaluating patients with rhinitis. The recently developed ARCA is a promising tool, as it has demonstrated validity, reliability, and ease of use.

Disclosures

Dr. Katial serves on the speakers' bureau and as a consultant for GlaxoSmithKline. No other potential conflicts of interest relevant to this article were reported.

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