

Development, validation, and evaluation of allergic rhinitis symptoms and impact assessment (ARSIA) questionnaire

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ABSTRACT

Introduction: Allergic rhinitis (AR) is an inflammatory disease of the nasal mucosa. It is among the most common diseases globally and usually persists throughout life. Allergic Rhinitis and Its Impact on Asthma (ARIA) is a well-established guideline applicable to AR and was updated regularly since 2001, aiming to improve the care for AR patients. We proposed a new questionnaire that addresses the severity of allergic rhinitis symptoms, specifically nasal symptoms, and its impact on quality of life in terms of specific vital activities such as sleeping, working, school performance, leisure, or sport, based on the ARIA guideline. The objective was to develop, validate and evaluate Allergic Rhinitis Symptoms and Impact Assessment (ARSIA) questionnaire among allergic rhinitis patients in Hospital Sultan Abdul Halim, Sungai Petani (HSAH), and Hospital Universiti Sains Malaysia (HUSM).

Materials and Methods: This is a prospective observational study to develop, validate and evaluate the ARSIA questionnaire based on ARIA guidelines. The sample will be obtained from the list of patients under follow-up in the ORL clinic HSAH and HUSM with ages of 18 to 60 years, patients clinically diagnosed with allergic rhinitis, and with positive skin prick test.

Results: A total of 150 patients with a positive skin prick test participated in this study. In the 'nasal symptom' and 'impact on daily activities' domains, calculated Cronbach's alpha shows a value of 0.878 and 0.811 respectively. The inter-item correlation was calculated to analyse internal consistency reliability. Items B3 and B4 were dropped from the questionnaire as both showed a low correlation with other items. New Cronbach's alpha for the daily activities domain was 0.830, which showed better internal consistency reliability.

All of the items were analysed for sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). Clinician diagnosis from the proforma was used as a comparison to the participant's responses. In the analysis, a cut-off points of 12 was used to classify the patient's nasal symptoms into intermittent or persistent, with a sensitivity of 75%, specificity of 86%, PPV of 95%, and NPV of 51%. Whereas, a cut-off point of 15 was used to

classify the rhinitis impact on daily activities into mild or moderate/severe, with a sensitivity of 58%, specificity of 100%, PPV of 100%, and NPV of 42%.

The only item in the 'control' domain has been dropped out following a consensus of experts and judgement as it has not been used in the clinician diagnosis and thus, is unable to test for sensitivity, specificity, PPV, and NPV.

Conclusion: This newly developed, validated, and evaluated questionnaire is a good tool for the evaluation of allergic rhinitis symptoms and their impact on daily activities. It is important to understand that AR symptoms could have a significant impact on daily activities. Although further study and testing are needed, it provides an initial means for evaluating the patient condition and control level, as well as patients' perception of their rhinitis control.

KEYWORDS:

Allergic rhinitis; questionnaire; hypersensitivity; immunoglobulin E

INTRODUCTION

Allergic rhinitis (AR) is an inflammatory disease of the nasal mucosa, highly prevalent with rates of up to 50% in some populations.^{1,2} It is among the most common diseases globally and usually persists throughout life.¹ The prevalence of self-reported AR has been estimated to be approximately 2 to 25% in children and 1% to greater than 40% in adults.^{1,3,4} AR is a systemic disease affecting not only nasal function but general well-being as well. As a chronic condition, AR puts a considerable economic burden on sufferers.

Exposure of allergic patients to the allergen will result in increased immunoglobulin E (IgE) and induce IgE-mediated response. It can be manifested clinically as nasal congestion, rhinorrhoea, postnasal drainage, nasal itching, and sneezing.^{4,5} Ocular symptoms are also frequent; allergic rhinoconjunctivitis is associated with itching and redness of the eyes and tearing. Other symptoms include itching of the palate, postnasal drip, and cough.

AR is frequently associated with asthma. There are about 15 to 38% of patients with asthma with AR, and rhinitis symptoms are present in 6 to 85% of patients with asthma.⁶⁻

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8 AR also is a risk factor for asthma, and thus uncontrolled AR affects asthma control.^{6,9}

AR might not appear to be serious as it does not associate with severe morbidity and mortality. Appropriate treatment will improve its symptoms, and thus the quality of life, and work and school performance.

The number of patients affected by allergies is increasing worldwide. The resulting allergic diseases lead to significant health care and social systems costs. Integrated care is needed for comprehensive care that later will lead to a better quality of life. Allergic Rhinitis and Its Impact on Asthma (ARIA) is a well-established guideline applicable to AR and was updated regularly since 2001, aiming to improve the care for AR patients. ARIA classifies the severity of AR into 'mild' or 'moderate/severe' based on the symptoms asked.¹⁰ Despite the multiple treatment options mentioned by the guideline, AR is still treated sub-optimally. The most commonly used medications are oral antihistamines, which are not the most effective medication for moderate-severe AR symptoms.^{11,12} This will lead to undertreated AR sufferers despite the high dependence on medication.^{13,14}

Based on the ARIA guideline, we proposed a new questionnaire that specifically addresses the severity of allergic rhinitis symptoms and its impact on quality of life in terms of specific vital activities such as sleeping, working, school performance, leisure, or sport.

MATERIALS AND METHODS

There were two phases involved in this study. The first phase was the development of the questionnaire, followed by the second phase, which was the validation and reliability of the questionnaire. The data was measured for sensitivity, specificity, (PPV), and (NPV).

Phase 1: Development of Allergic Rhinitis Symptoms and Impact Assessment (ARSIA) questionnaire

This phase involved the development of a new questionnaire on allergic rhinitis symptoms and impact assessment based on ARIA guidelines. Few literatures were reviewed and analysed including ARIA.^{10,15-17} Consultation from experts (consisting of three otorhinolaryngologists, one family medicine specialist, and one community medicine specialist) was also taken to develop this ARSIA questionnaire draft. The concepts identified in the literature review were used in the selection of items and the formation of the relevant questionnaire sections.

This newly drafted questionnaire was divided into two parts – the first part is demographics which include age, gender, ethnicity, occupation, educational level, marital status, smoking, allergic status, and current medication. The second part had three domains which consist of 15 items. The domains include nasal symptoms (five items), impact on daily activities (nine items), and symptoms control (one item, refer to appendix).

In the nasal symptom domain, the 4-point Likert scale response was used for each item. It is further divided into two

columns to separate symptoms within 4 weeks and within 6 months duration. In the column of symptoms in the last 4 weeks, responses are assigned to a score of 0 for 'never', 1 for '1-4 times per week', 2 for '5-6 times per week', and 3 for '7 days per week', while in the column of symptoms in the last 6 months, it is assigned a score as 0 for '1-4 consecutive weeks', 1 for '5-8 consecutive weeks', 2 for '9-12 consecutive weeks', and 3 for 'more than 12 consecutive weeks'.

The impact on daily activities domain used the 5-point Likert scale response to each item, and the response was assigned to a score of 1 for 'Never', 2 for 'Rarely', 3 for 'Sometimes', 4 for 'Often', and 5 for 'Extremely often'.

While the control domain used the 5-point Likert scale response to this item, the response was assigned a score of 1 for 'Never', 2 for 'Rarely', 3 for 'Sometimes', 4 for 'Most of the time', and 5 for 'Always'.

Phase 2: Validity and reliability of the ARSIA questionnaire

In the second phase, the ARSIA questionnaire was validated based on content, face, and construct validity.

Content Validation

Content validity assessed the relevance and representability of each item to a specific domain of the panel of experts. Setting up content validity is important for evaluating a questionnaire and should be the priority in developing an instrument. Content validity provides information on the representativeness and clarity of items and provides preliminary evidence on the construct validity. It helps improve an instrument through recommendations from experts.¹⁸

There are a few methods that can be used to assess the content validity of a questionnaire. The content validity index (CVI) is the most widely used method. There are two kinds of CVI; item-level CVI (I-CVI) and scale-level CVI (S-CVI).¹⁸

In this study, we invited five experts who pretested the questionnaire to evaluate for potential problems when used by respondents. Each expert independently rated the relevance of each item for each domain of the questionnaire to the conceptual framework using a 4-point Likert scale (1 = not relevant, 2 = somewhat relevant, 3 = relevant, 4 = very relevant). A CVI of at least 0.80 is considered adequate for accepting an item as valid.¹⁸ Another parameter was the Scale-level CVI of averaging calculation method (S-CVI/Ave). S-CVI/Ave is calculated by taking the sum of the I-CVIs divided by the total number of items, and the value must be 0.90 and above to be considered acceptable content validity.¹⁹

Face Validation

Then, the face validity of the ARSIA questionnaire was conducted on ten respondents in the ORL clinic at Sultan Abdul Halim Hospital in printed form. Face validity is used to assess the comprehensibility and clarity of each item. Ten respondents were involved in the assessment. Instrument review by a sample of subjects that represents the target population is another important component of instrument development. The face validity index (FVI) is quantified as

Table I: Content validation for the ARSIA questionnaire

	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	I-CVI
Nasal symptom domain						
Q1	1	1	1	1	1	1
Q2	1	1	1	1	1	1
Q3	1	1	1	1	1	1
Q4	1	1	1	1	1	1
Q5	1	1	1	1	1	1
Impact on daily activities domain						
Q1	1	1	1	1	1	1
Q2	1	1	1	0	1	0.8
Q3	1	1	1	1	1	1
Q4	1	1	1	1	1	1
Q5	1	1	1	1	1	1
Q6	1	1	1	1	1	1
Q7	1	1	1	1	1	1
Q8	1	1	1	1	1	1
Q9	1	0	1	1	1	0.8
Control domain						
Q10	1	1	1	1	1	1
					S-CVI/Ave	0.97

Table II: Face validation for the ARSIA questionnaire

	R1	R2	R3	R4	R5	R6	R7	R8	R9	R10	I-FVI
Nasal symptom domain											
Q1	1	1	1	1	1	1	1	1	1	1	1
Q2	1	1	1	1	1	1	1	1	1	1	1
Q3	1	1	1	1	1	1	1	1	0	1	0.9
Q4	1	1	1	1	1	1	1	1	1	1	1
Q5	1	1	1	1	1	1	1	1	0	1	0.9
Impact on daily activities domain											
Q1	1	1	1	1	1	1	1	1	0	1	0.9
Q2	1	1	1	1	1	1	1	1	0	1	0.9
Q3	1	1	1	1	1	1	1	1	0	1	0.9
Q4	1	1	1	1	1	1	1	1	0	0	0.8
Q5	1	1	1	1	1	1	1	1	1	1	0.9
Q6	1	1	1	1	1	1	1	1	0	1	0.9
Q7	1	1	1	1	1	1	1	1	1	1	1
Q8	1	1	1	1	1	1	1	1	1	1	1
Q9	1	1	1	1	1	1	1	0	0	1	0.8
Control domain											
Q10	1	1	1	1	1	1	1	1	1	1	1
									S-FVI/Ave	0.93	

the thought processes of target users of an instrument.^{20,21} In this study, we used the method to calculate the FVI based on the recommendation by Yusoff M 2019.²⁰ The items were rated based on a Likert scale ranging from 1 (not clear or not comprehensible) to 4 (very clear or very comprehensible). The item-face validity index (I-FVI) and scale-face validity index (S-FVI/Ave) were calculated. I-FVI is calculated as the number of respondents giving a rating of 3 to 4 for each item divided by the total number of respondents, and S-FVI/Ave is calculated based on the sum of the I-FVIs divided by the total number of respondents. The recommended FVI for ten respondents is at least 0.83.²⁰

Psychometric Validation Study

For construct validity, a total of hundred and fifty patients who fulfilled the inclusion and exclusion criteria participated in this study. Cronbach's alpha was used to measure this questionnaire's construct validity and internal consistency. Each domain in the questionnaire is unidimensional.

Criterion validity was also conducted simultaneously with the construct validity. ORL specialist or attendant doctor did an assessment based on ARIA classification using clinical proforma.

After the validity was completed, the questionnaires were analysed to assess their sensitivity, specificity, PPV, and NPV. The internal consistency reliability, a Cronbach's alpha coefficient >0.70 is considered acceptable.²²

The study was a cross-sectional study. It was conducted amongst patients who fulfilled inclusion and exclusion criteria, attending the Otorhinolaryngology Clinic Hospital Sultan Abdul Halim (HSAH) and Hospital Universiti Sains Malaysia (HUSM), from January 1, 2021, until December 31, 2021. The sample size was determined using a 2-Parameter Logic Item Response Theory (2-PL IRT) analysis. The required sample size for 2-PL IRT was by taking a ratio of 10:1 to each item, and it showed 150 participants were required.

Table III: Socio-demographics data of the participants

Variables	Mean (SD)	N (%)
Age	35.23 (12.34)	
<21	Range = 18-60	23(15.3)
21-30		35(23.3)
31-40		43(28.7)
41-50		27(18.0)
51-60		22(14.7)
Gender		
Male		50(33.3)
Female		100(66.7)
Ethnic		
Malay		127(84.7)
Chinese		3(2.0)
Indian		16(10.7)
Others		1(0.7)
Missing		3(2.0)
Occupation		
Non-professional		81(54.0)
Professional		69(46.0)
Education level		
Primary		5(3.3)
Secondary		72(48.0)
Tertiary		73(48.7)
Marital status		
Unmarried		51(34.0)
Married		99(66.0)
Smoking		
Yes		15(10.0)
Passive		6(4.0)
No		129(86.0)

Table IV: Sensitivity, specificity, PPV, and NPV for the 'nasal symptoms' domain

Cut-off point used	Sensitivity	Specificity	PPV	NPV
9 and less	61	94	97	42
10 and less	68	91	96	47
11 and less	74	89	96	49
12 and less	75	86	95	51

Table V: Sensitivity, specificity, PPV, and NPV for the 'impact on daily activities' domain

Cut-off point	Sensitivity	Specificity	PPV	NPV
10	16	100	100	26
11	23	100	100	28
12	28	100	100	30
13	34	100	100	32
14	40	100	100	33
15	58	100	100	42

The purposive sampling method was used for recruitment. Participants ranged from 18 years of age to 60 years of age, clinically diagnosed with allergic rhinitis, with a positive skin prick test. Exclusion criteria included a patient who has nasal polyposis or confirmed mucociliary disease, a patient with a nasal anatomical abnormality, and a patient with mental retardation, neuromuscular diseases, cardiovascular diseases, or psychological problems.

The questionnaire was hand-delivered to the patients who were willing to participate and hand-collected once they had completed the questionnaire. ORL specialists or doctors who attended the participant were required to fill up the proforma

based on clinical assessment, and they will be blinded to the questionnaire scoring by the patient prior to the assessment.

Data Analysis (sensitivity, specificity, (PPV), and (NPV))

Data entry and statistical analysis were performed using Statistical Package for Social Sciences (SPSS) version 26.0. The data entered were then checked for outliers and missing values. Descriptive statistics were employed to summarise the socio-demographic characteristics of subjects. The findings were presented based on the types and distribution of the data. Categorical data were presented as frequencies and percentages, while numerical data were presented as means and standard deviations (if normally distributed), or as

medians and interquartile ranges (if not normally distributed).

Specificity, sensitivity, PPV, and NPV of the questionnaire were calculated and tabulated. The sensitivity of a test helps rule out a disease when the test is negative, whereas a specificity of a test will rule out a disease when the test is positive. PPV and NPV are directly related to prevalence. PPV is the probability that a positive test will truly have that specific disease. While NPV is the probability of a negative test which will truly not have that specific disease.²³ The ARSIA questionnaire reliability was measured through internal consistency, inter-item correlation, and Cronbach's alpha coefficient. The questionnaire items were considered a good internal consistency if the total Cronbach's alpha value was more than 0.7.²⁴

Ethical Considerations

Ethical approval was obtained from the Medical Research & Ethics Committee (MREC) of the Ministry of Health, Malaysia via the National Medical Research Register (NMRR), and the Human Research Ethics Committee of USM (JEPeM). Verbal consent was obtained from each participant prior to conducting this study.

RESULTS

Content Validity

The I-CVI relevancy for the nasal symptom domain ranges from 0.9 to 1, while for the impact on daily activities domain ranges from 0.8 to 1, and the control domain is 1 (Table I). The S-CVI/Ave is 0.97. In all of the domains (nasal symptoms, impact on daily activities, and control), the I-CVI is ≥ 0.8 . Thus, 5 items in the nasal symptom domain, 9 items in the impact on daily activities domain, and 1 item in the control domain were kept. Modifications were made to a few items based on the suggestions of the experts. The final ARSIA questionnaire consists of 15 items.

Face Validity

The I-FVI for the nasal symptom domain ranges from 0.9 to 1, while for the impact on daily activities domain ranges from 0.8 to 1.0, and the control domain is 1 (Table II). All items were valid with I-FVI ranging from 0.80 to 1.00, S-FVI/Ave of 0.93 indicates the questionnaire was found to be very clear and easy to answer, and indicated the appearance and layout would be acceptable to the intended target group.

Psychometric Analysis

A total of 150 patients participated in this study consisting of 50 men and 100 women, with ages ranging from 18 to 60 years. The mean age was 35.2. The majority of them were Malays 127 (84.7%) (Table III). Three participants were missing ethnic data.

The participants' allergic status was asked, including food, dust, animal or insect, climate changes, smoke, and drugs. Among the participants, a majority of them had food and dust allergies and were on antihistamines with intranasal steroids. Every participant had a skin prick test evaluation at least once in their life.

Validity and Reliability of the Questionnaire

1- 'Nasal symptoms' domain

In the nasal symptom domain, there were five items (items A1-A5, refer to appendix), further divided into two columns to separate symptoms within 4 weeks and 6 months duration. The internal consistency reliability, a Cronbach's alpha coefficient >0.70 is considered acceptable.²² Cronbach's alpha was calculated from these ten items (five items with two columns each), showing a value of 0.878. All of the items were kept and further analysed for sensitivity, specificity, PPV, and NPV. Clinician diagnosis from the proforma was used as a comparison to the participants' responses.

In the analysis, a cut point of 12 was used to classify the patient's nasal symptoms into intermittent or persistent, with a sensitivity of 75%, specificity of 86%, PPV of 95%, and NPV of 51%. A score of 12 or less will turn into the intermittent group, whereas more than 12 is the persistent group (Table IV).

2- 'Impact on daily activities' domain

The impact on daily activities domain has nine items (items B1-B9) (refer to appendix). The internal consistency reliability, a Cronbach's alpha coefficient >0.70 is considered acceptable.²² Cronbach's alpha of 0.811 was achieved, showing that all the items were good. The inter-item correlation was calculated to analyse internal consistency reliability. Item B3 (Due to your allergic rhinitis impact on you in the last 4 weeks, do you need to increase the use (dose or frequency) of your medicines?) and B4 (Due to your allergic rhinitis impact on you in the last 4 weeks, do you avoid any activities (for example, gardening, visiting a house with a dog or cat)?) showed a low correlation with other items. The ideal range of average inter-item correlation is 0.15 to 0.50.²⁵ Thus, items B3 and B4 were dropped from the questionnaire. New Cronbach's alpha was 0.830, which showed better internal consistency reliability after the items were dropped.

All of the remaining items were further analysed for sensitivity, specificity, positive PPV, and NPV. Clinician diagnosis from the proforma was used as a comparison to the participants' responses.

In the analysis, a cut point of 15 was used to classify the rhinitis impact on daily activities into mild or moderate/severe, with a sensitivity of 58%, specificity of 100%, PPV of 100%, and NPV of 42%. A score of 15 or less is considered mild, whereas more than 15 is considered moderate/severe (Table V).

3- 'Control' domain

The only item in this domain, C1 (due to your allergic rhinitis impact on you in the last 4 weeks, do you feel your allergy is controlled?) has been dropped out following a consensus of experts and judgment as it has not been used in the clinician diagnosis and thus, unable to test for sensitivity, specificity, PPV, and NPV.

Assessment of the Validated Items

For the impact on the daily activity domain, seven of nine items showed good inter-item correlation. However, two items

(B3 and B4) showed poor correlation with other items (less than 0.15) and thus have been dropped out.

In the control domain, the only item, that was C1, has been dropped out as it was not included in the physician's diagnosis in the proforma.

DISCUSSION

AR and nonallergic rhinitis (NAR) are considered one of the major global health concerns with increasing prevalence worldwide. AR is when the nasal symptoms are triggered by an allergen, whereas NAR is when nasal symptoms occur in relation to nonallergic, non-infectious triggers such as changes in weather, exposure to smoke or odours, hormonal related, or some drugs.²⁶

The main factors highlighted in the Allergic Rhinitis and its Impact on Asthma (ARIA) guideline include nasal symptoms and their impact on daily activities. It is used in classifying a patient's condition into 'intermittent' or 'persistent', and 'mild' or 'moderate/severe'. In the ARIA guidelines, intermittent symptoms are described as symptoms in less than 4 days per week or less than 4 consecutive weeks, whereas persistent symptoms are defined as nasal symptoms more than 4 days per week and more than 4 consecutive weeks. A patient with symptoms not affecting their daily activities is considered mild, whereas symptoms affecting their daily activities are considered moderate to severe AR.

The ARIA classification acknowledged the impact of a disease that was often qualified as trivial. The ARIA 'mild' and 'moderate/severe' classification has strengths and weaknesses. It is very simple to administer since it is based on yes or no answers. The ARIA duration and severity classifications have been implemented in several countries and patient populations. Cohort studies of adults and paediatric AR patients in Spain found that symptoms, Rhinitis Quality of Life Questionnaire, and visual analogue scale scores were significantly higher in 'moderate/severe' than in 'mild' AR.^{27,28} The level of awareness and application of the ARIA severity classification is less. A study by Demoli et. al found that only about 54% of physicians were aware of the ARIA classification.²⁹

The knowledge of ARIA classification by primary care practitioners did not influence the use of H1-antihistamine and/or intranasal steroid as a function of the patient's disease severity.²⁹ Researchers also found that ARIA severity did not significantly influence medication prescription.³⁰

Patient education, allergen avoidance, and pharmacotherapy are required for the optimal treatment of AR patients.³¹ Allergen immunotherapy is another option for treatment for certain patients. Skin prick test is the gold standard for allergy testing. Patients with uncertain allergy histories might benefit from this test for their allergen avoidance. The main goal for AR is to achieve good control and to reduce its impact on daily activities, work or school performance, sport or leisure, and sleep. A reliable AR control assessment tool is important and needed to evaluate this AR symptom. For pharmacotherapy in AR control, the patient

should be prescribed an antihistamine and/or intranasal steroid spray. Patients with uncontrolled AR symptoms should be considered for increased medication dosage or additional other AR treatment. While for controlled AR, stepping-down treatment is recommended to identify the minimum medication needed to maintain control.³² Most AR patients could get their symptoms controlled after a standard treatment as proposed by ARIA.

The ARIA guidelines state that treatment should be tailored to the severity of the disease, comorbidities, treatment availability, affordability, and patient preference. Thus, methods for measuring the disease severity and its control must be uniform, reproducible, quick, and easy to perform in routine practice.³³ Focus should be on the disease's impact on daily activities.

Few AR control tools have been validated including RCAT, CARAT, and ARCT, to assess the AR control levels. Recent ARCT has been validated in step-up and step-down medication strategies. They found that the AR control rate was similar in the ARCT group and the control group, whereas less medication use, and medical cost were found in the ARCT group.³¹

This study is aimed to develop, validate, and evaluate a tool to simultaneously assess AR symptoms and their impact on daily activities, based on ARIA guidelines.

Participants are required to answer demographic, allergy status and current medication in part 1 of the ARSIA questionnaire. In part 2(a) of the ARSIA questionnaire, participants are required to answer both in the 4 weeks and 6 months column, and the score will be summed up. Based on reliability statistics Cronbach alpha, sensitivity, specificity, PPV, and NPV compared to the physician diagnoses, showed all these items were good. In part 2(b), the impact on daily activities such as irritability, sleep disturbance, leisure, sport, school or work performance, troublesome symptoms, and relationship with a spouse were assessed.

We found that the ARSIA questionnaire has good internal consistency and internal validity.

We also observed a good correlation in terms of sensitivity, specificity, PPV, and NPV, compared to physician diagnoses that were made clinically based on ARIA guidelines.

These two parts of the questionnaire will give a score each and a comparison during each follow-up visit could be made. Reducing the total score indicates improvement in the nasal symptoms and their impact on daily activities, whereas increasing the score indicates worsening symptoms.

Further studies with larger datasets and involving multicentre are needed to establish the cut values for the ARSIA questionnaire. However, the existing data seems to suggest a score of '12 or less' for the symptoms indicates intermittent, 'more than 12' indicates persistent, '15 or less' for the impact on daily activities indicated mild, and 'more than 15' indicates moderate/severe.

In summary, this study showed that the ARSIA questionnaire has good internal consistency and internal validity, with good sensitivity, specificity, (PPV), and (NPV). Therefore, the ARSIA questionnaire can be used to rapidly screen for patients having rhinitis symptom control problems. It also can help patients in communicating with doctors about problems with their nasal disease. This patient assessed ARSIA questionnaire can complement the physician's assessment, and in addition, it should also perform well as a standalone measure of the patient's perception of their symptom control.

CONCLUSION

This newly developed, validated, and evaluated questionnaire is a good tool for the evaluation of allergic rhinitis symptoms and their impact on daily activities. It is important to understand that AR symptoms could have a significant impact on daily activities. Although further study and testing are needed, it provides an initial means for evaluating the patient's condition and control level, as well as patients' perception of their rhinitis control.

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REFERENCES

- Kateralis CH, Lee BW, Potter PC, Maspero JF, Cingi C, Lopatin A, et al. Prevalence and diversity of allergic rhinitis in regions of the world beyond Europe and North America. *Clin Exp Allergy* 2012; 42: 186-207.
- Bauchau V, Durham SR. Epidemiological characterisation of the intermittent and persistent types of allergic rhinitis. *Allergy* 2005; 60: 350-53.
- Asher MI, Montefort S, Bjorksten B, Lai CK, Strachan DP, Weiland SK, et al. Worldwide time trends in prevalence of symptoms of asthma, allergic rhino-conjunctivitis, and eczema in childhood: ISAAC phases one and three repeat multicountry cross-sectional surveys. *Lancet* 2006; 368: 733-43.
- Bousquet J, Van Cauwenberge P, Khaltaev N. Aria workshop group, world health organisation. *J Allergy Clin Immunol* 2001; 108(5): 5147-334.
- Keith PK, Desrosiers M, Laister T, Schellenberg RR, Wasserman S. The burden of allergic rhinitis (AR) in Canada: perspectives of physicians and patients. *Allergy Asthma Clin Immunol* 2012; 8(1): 7.
- Leynaert B, Bousquet J, Neukirch C, Liard R, Neukirch F. Perennial rhinitis: an independent risk factors for asthma in nonatopic subjects: results from European community respiratory health survey. *J Allergy Clin Immunol* 1999; 104: 301-4.
- Gergen PJ, Turkeltaub PC. The association of individual allergen reactivity with respiratory disease in a national sample; data from the second national health and nutrition examination survey, 1976-80 (NHANES II). *J Allergy Clin Immunol* 1992; 90: 579-88.
- Sibbald B, Rink E. Epidemiology of seasonal and perennial rhinitis: clinical presentation and medical history. *Thorax* 1991; 46: 895-901.
- Corren J, Adinoff AD, Buchmeier AD, Irvin CG. Nasal beclomethasone prevents the seasonal increase in bronchial responsiveness in patients with allergic rhinitis and asthma. *J Allergy Clin Immunol* 1992; 90: 250-56.
- Bousquet J, Khaltaev N, Cruz AA, Denburg J, Fokkens WJ, Togias A, et al. Allergic rhinitis and its impact on asthma (ARIA) 2008 update (in collaboration with the world health organisation, GA (2)LEN and AllerGen). *Allergy* 2008; 63(suppl 86): 8-160.
- Tan R, Cvetkovski B, Kritikos V, Price D, Yan K, Smith P, et al. Identifying the hidden burden of allergic rhinitis (AR) in community pharmacy: a global phenomenon. *Asthma Res Pract* 2017; 3: 8.
- Williams A, Scadding G. Is reliance on self-medication and pharmacy care adequate for rhinitis patients? *Int J Clin Pract* 2009; 63(1): 98-104.
- Bosnic-Anticevich S, Kritikos V, Carter V, Yan KY, Armour C, Ryan D, et al. Lack of asthma and rhinitis control in general practitioner-managed patients prescribed fixed-dose combination therapy in Australia. *J Asthma* 2018; 55(6): 684-94.
- Tan R, Cvetkovski B, Kritikos V, Price D, Yan K, Smith P, et al. The burden of rhinitis and the impact of medication management within the community pharmacy setting. *J Allergy Clin Immunol Pract* 2018; 6(5): 1717-25.
- Azevedo P, Correia de Sousa J, Bousquet J, Bugalho-Almeida A, Del Giacco SR, Demoly P, et al. WHO collaborative centre for asthma and rhinitis, montpellier. Control of allergic rhinitis and asthma test (CARAT): dissemination and applications in primary care. *Prim Care Respir J* 2013; 22(1): 112-6.
- Nathan RA, Dalal AA, Stanford RH, Meltzer EO, Schatz M, Derebery J, et al. Qualitative development of the rhinitis control assessment test (RCAT), an instrument for evaluating rhinitis symptom control. *Patient* 2010; 3(2): 91-9.
- Kennedy JL, Hubbard MA, Huyett P, Patrie JT, Borish L, Payne SC. Sino-nasal outcome test (SNOT-22): a predictor of postsurgical improvement in patients with chronic sinusitis. *Ann Allergy Asthma Immunol* 2013; 111(4): 246-51.e2.
- Armstrong TS, Mendoza T, Gring I, Coco C, Cohen MZ, Eriksen L, et al. Validation of the M.D. Anderson symptom inventory brain tumor module (MDASI-BT). *J Neurooncol* 2006; 80(1): 27-35.
- Shi J, Mo X, Sun Z. Zhong Nan Da Xue Xue Bao Yi Xue Ban. [Content validity index in scale development]. *Journal of Central South University. Medical sciences.* 2012; 37(2): 152-5.
- Yusoff M. Abc of response process validation and face validity index calculation. *Educ Med J* 2019; 11(3): 55-61.
- Cook DA, Beckman TJ. Current concepts in validity and reliability for psychometric instruments: theory and application. *Am J Med* 2006; 119(2): 166.e167-166.e116.
- Stephanie Glen. Cronbach's Alpha: Simple Definition, Use and Interpretation. From StatisticsHowTo.com: Elementary Statistics for the rest of us! [cited December 2022]. Available from: <https://www.statisticshowto.com/probability-and-statistics/statistics-definitions/cronbachs-alpha-spss/>.
- Trevethan R. Sensitivity, specificity, and predictive values: foundations, pliabilities, and pitfalls in research and practice. *Front Public Health* 2017; 5: 307.
- Hair J, Anderson R, Babin B, Black W. *Multivariate Data Analysis: A Global Perspective.* (Vol. 7), New York, USA: Pearson; 2010.
- Stephanie Glen. Average Inter-Item Correlation: Definition, Example. From StatisticsHowTo.com: Elementary Statistics for the rest of us! [cited December 2022]. Available from: <https://www.statisticshowto.com/average-inter-item-correlation/>.
- Tran NP, Vickery J, Blaiss MS. Management of rhinitis: allergic and non-allergic. *Allergy Asthma Immunol Res* 2011; 3(3): 148-56.
- Del Cuvillo A, Montoro J, Bartra J, Valero A, Ferrer M, Jauregui I, et al. Validation of ARIA duration and severity classifications in Spanish allergic rhinitis patients - the ADRIAL cohort study. *Rhinology* 2010; 48: 201-5.

28. Jáuregui I, Dávila I, Sastre J, Bartra J, del Cuvillo A, Ferrer M, et al. Validation of ARIA (allergic rhinitis and its impact on asthma) classification in a pediatric population: the PEDRIAL study. *Pediatr Allergy Immunol* 2011; 22: 388-92.
29. Rouve S, Didier A, Demoly P, Jankowsky R, Klossek JM, Annesi-Maesano I. Numeric score and visual analog scale in assessing seasonal allergic rhinitis severity. *Rhinology* 2010; 48: 285-91.
30. Ramirez LF, Urbinelli R, Allaert FA, Demoly P. Combining H1-antihistamines and nasal corticosteroids to treat allergic rhinitis in general practice. *Allergy* 2011; 66: 1501-502.
31. Zhu R, Wang J, Wu Y, Yang Y, Huang N, Yang Y, et al. The allergic rhinitis control test questionnaire is valuable in guiding step-down pharmacotherapy treatment of allergic rhinitis. *J Allergy Clin Immunol Pract* 2019; 7(1): 272-78.
32. Demoly P, Broue-Chabbert A, Wessel F, Chartier A. Severity and disease control before house dust mite immunotherapy initiation: ANTARES a French observational survey. *Allergy Asthma Clin Immunol* 2016; 12: 13.
33. Bousquet J, Schunemann HJ, Samolinski B, Baena-Cagnani CE, Bachert C, Bonini S, et al. Allergic rhinitis and its impact on asthma (ARIA): achievements in 10 years and future needs. *J Allergy Clin Immunol* 2012; 130: 1049-62.