DEVELOPMENT, VALIDATION, AND EVALUATION OF THE ALLERGIC RHINITIS SYMPTOMS AND IMPACT ASSESSMENT (ARSIA) QUESTIONNAIRE

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ABSTRAK (BAHASA MELAYU)

Pengenalan: Alahan rhinitis (AR) adalah penyakit radang mukosa hidung. Ia adalah antara penyakit global di seluruh dunia dan kebiasaannya ia berterusan seumur hidup. Allergic Rhinitis and Its Impact on Asthma (ARIA) ialah garis panduan yang mantap yang boleh digunakan untuk penyakit AR dan dikemaskini secara kerap sejak 2001, bertujuan untuk meningkatkan penjagaan pesakit AR. Terdapat beberapa soal selidik yang diterbitkan yang direka untuk menilai gejala rinitis, kawalan, dan kesannya terhadap aktiviti harian. Kami mencadangkan soal selidik baharu untuk menilai simptom alahan rhinitis dan kesannya terhadap aktiviti harian pesakit, berdasarkan garis panduan ARIA.

Objektif: Membangun, mengesahkan dan menilai soal selidik Allergic Rhinitis Symptoms and Impact Assessment (ARSIA) dalam kalangan pesakit alahan rhinitis di Hospital Sultan Abdul Halim, Sungai Petani (HSAH), dan Hospital Universiti Sains Malaysia (HUSM).

Kaedah: Ini adalah kajian pemerhatian prospektif untuk membangunkan, mengesahkan dan menilai soal selidik ARSIA berdasarkan garis panduan ARIA. Sampel akan diperolehi daripada senarai pesakit di bawah rawatan susulan di klinik ORL HSAH dan HUSM yang berumur 18 hingga 60 tahun, pesakit yang secara klinikal didiagnos dengan alahan rhinitis, dan dengan ujian ‘skin prick test’ yang positif.

Keputusan: Seramai 150 orang pesakit dengan ujian ‘skin prick test’ positif mengambil bahagian dalam kajian ini. Dalam domain 'simptom hidung' dan 'kesan ke atas aktiviti harian', alpha Cronbach yang dikira menunjukkan nilai masing-masing 0.878 dan 0.811. Korelasi antara item dikira untuk menganalisis kebolehpercayaan ketekalan dalaman. Item B3 dan B4

telah digugurkan daripada soal selidik kerana kedua-duanya menunjukkan korelasi yang rendah dengan item lain. Alpha Cronbach baharu untuk domain aktiviti harian ialah 0.830, yang menunjukkan kebolehpercayaan konsistensi dalaman yang lebih baik.

Kesemua item telah dianalisis untuk kepekaan, kekhususan, nilai ramalan positif (PPV) dan nilai ramalan negatif (NPV). Diagnosis doktor dari proforma digunakan sebagai perbandingan dengan borang soal-selidik peserta. Dalam analisis, titik potong 12 digunakan untuk mengklasifikasikan gejala hidung pesakit kepada terputus-putus atau berterusan, dengan kepekaan 75%, kekhususan 86%, PPV sebanyak 95%, dan NPV sebanyak 51%. Manakala, titik potong 15 digunakan untuk mengklasifikasikan kesan alahan rhinitis pada aktiviti harian kepada ringan atau sederhana/teruk, dengan kepekaan 58%, kekhususan 100%, PPV 100%, dan NPV sebanyak 42%.

Satu-satunya item dalam domain 'kawalan gejala' telah digugurkan berikutan konsensus pakar dan pertimbangan kerana ia tidak digunakan dalam diagnosis doktor dan oleh itu, tidak dapat diuji kepekaan, kekhususan, PPV dan NPV.

Kesimpulan: Soal selidik yang baru dibangunkan, disahkan dan dinilai ini merupakan instrumen yang baik untuk menilai gejala alahan rhinitis dan kesannya terhadap aktiviti harian. Adalah penting untuk memahami bahawa simptom AR boleh memberi kesan yang ketara terhadap aktiviti harian. Walaupun kajian dan ujian lanjut masih diperlukan, instrumen ini mampu menyediakan cara awal untuk menilai keadaan pesakit dan tahap kawalan, serta persepsi pesakit terhadap kawalan alahan rhinitis mereka.

ABSTRACT (ENGLISH)

Background: 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. There are few published questionnaires designed to assess rhinitis symptoms and some to assess its control and impact on daily activities. We proposed a new questionnaire that specifically 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.

Objective: 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).

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 old, 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

analyze 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 analyzed 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 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%. Whereas, 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%.

The only item in the 'control' domain has been dropped out following a consensus of experts and judgement as it does 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

Chapter 1

INTRODUCTION

CHAPTER 1: 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 results in increased immunoglobulin E (IgE) and induce IgE-mediated response. It can be manifested clinically as nasal congestion, rhinorrhea, 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.[6-8] 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. However, AR reduces the quality of life of many patients and impairs sleep quality and thus cognitive function. It also decreased school and work performances, especially during the peak pollen season.[10] 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. Among recommendations from this guideline includes allergen avoidance, pharmacotherapy, and allergen immunotherapy. ARIA also suggests stepwise pharmacotherapy according to the initial treatment response. It has a significant impact by raising awareness of AR and improving the diagnosis and treatment of rhinitis sufferers. 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 especially in self-selecting medication by the patient. The most used medications are oral antihistamines, which are not the most effective medication for moderate-severe AR symptoms.[11,12] This will lead to undertreated among AR sufferers despite the high dependence on medication.[13,14]

Currently, there are few published questionnaires designed to assess rhinitis symptoms and some to assess its control and impact on daily activities such as the Control of Allergic Rhinitis and Asthma Test (CARAT), Rhinitis Control Assessment Test (RCAT), Allergy Rhinitis Control Test (ARCT), and Sinonasal Outcome Test-22 (SNOT-22).

Based on the ARIA guideline, we proposed a new questionnaire to assess rhinitis symptoms and their impact on patients' daily activities. In the ARIA classification, allergic rhinitis can be classified as "mild" and "moderate/severe" depending on the severity of the symptoms and their impact on social life, school, and work. ARIA also classifies allergy rhinitis symptoms into "intermittent", in which the symptoms are presently less than 4 days a week or less than

4 consecutive weeks, and “persistent”, in which the symptoms occurred more than 4 days a week and more than 4 consecutive weeks.

Chapter 2

OBJECTIVES OF STUDY

CHAPTER 2: OBJECTIVES OF THE STUDY

2.1 GENERAL OBJECTIVES

To develop, validate and evaluate Allergic Rhinitis Symptoms and Impact Assessment (ARSIA) questionnaire among allergic rhinitis patients in Hospital Sultan Abdul Halim, Sungai Petani, and Hospital Universiti Sains Malaysia.

2.2 SPECIFIC OBJECTIVES

The specific objectives for this study were as the following:

1)To develop and validate the ARSIA questionnaire as a tool to classify allergic rhinitis severity based on ARIA guidelines.

2)To develop and validate the ARSIA questionnaire as a tool to evaluate the impact of allergic rhinitis on their daily activities.

Chapter 3

MANUSCRIPT

TITLE PAGE

DEVELOPMENT, VALIDATION, AND EVALUATION OF ALLERGIC RHINITIS SYMPTOMS AND IMPACT ASSESSMENT (ARSIA) QUESTIONNAIRE

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The authors have no conflict of interest to declare pertaining to this article.

ABSTRACT

Background: 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. There is no questionnaire specifically addressing 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. Based on the ARIA guideline, we proposed a new questionnaire to assess rhinitis symptoms and their impact on patient's daily activities.

Objective: 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).

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 old, 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 analyze

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 impact on daily activities domain was 0.830, which showed better internal consistency reliability.

All the items were analyzed 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 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%. Whereas, 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%.

The only item in the 'control' domain has been dropped out following a consensus of experts and judgment as it does 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's condition and control level, as well as patients' perception of their rhinitis control.

Keywords: Allergic rhinitis, Questionnaire, Hypersensitivity, Immunoglobulin E

Introduction

Background of study

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 results in increased immunoglobulin E (IgE) and induce IgE-mediated response. It can be manifested clinically as nasal congestion, rhinorrhea, 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.[6-8] 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. However, AR reduces the quality of life of many patients and impairs sleep quality and thus cognitive function. It also decreased school and work performances, especially during the peak pollen season.[10] 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. Among recommendations from this guideline includes allergen avoidance, pharmacotherapy, and allergen immunotherapy. ARIA also suggests stepwise pharmacotherapy according to the initial treatment response. It has a significant impact by raising awareness of AR and improving the diagnosis and treatment of rhinitis sufferers. 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 especially in self-selecting medication by the patient. 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 among AR sufferers despite the high dependence on medication.[13,14]

Currently, there are few published questionnaires designed to assess rhinitis symptoms and some to assess its control and impact on daily activities such as the Control of Allergic Rhinitis and Asthma Test (CARAT), Rhinitis Control Assessment Test (RCAT), Allergy Rhinitis Control Test (ARCT), and Sinonasal Outcome Test-22 (SNOT-22).

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. In the ARIA classification, allergic rhinitis can be classified as "mild" and "moderate/severe" depending on the severity of the symptoms and their impact on social life, school, and work. ARIA also classifies allergy rhinitis symptoms into "intermittent", in which the symptoms are presently less than 4 days a week or less than 4 consecutive weeks, and "persistent", in which the symptoms occurred more than 4 days a week and more than 4 consecutive weeks.

Problem statement and justification of the study

There are few published questionnaires designed to assess rhinitis symptoms and some to assess its control and impact on daily activities. No questionnaire addresses both 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. Without a complete questionnaire, it is very difficult to assess a patient's symptoms, the impact of the symptoms on daily life, and the treatment response.

We are conducting a study to develop, validate and evaluate the questionnaire on allergic rhinitis symptoms and its impact assessment based on ARIA guidelines and adapted to Malaysian populations.

Research question

Is the ARSIA questionnaire a psychometrically valid tool for assessing the nasal symptoms of allergic rhinitis patients and its impact on daily activities?

Objectives

-General objective

To develop, validate and evaluate Allergic Rhinitis Symptoms and Impact Assessment (ARSIA) questionnaire among allergic rhinitis patients in Hospital Sultan Abdul Halim, Sungai Petani, and Hospital Universiti Sains Malaysia.

-Specific objective

1)To develop and validate the ARSIA questionnaire as a tool to classify allergic rhinitis severity based on ARIA guidelines.

2)To develop and validate the ARSIA questionnaire as a tool to evaluate the impact of allergic rhinitis on their daily activities.

Hypothesis

The ARSIA questionnaire is a psychometrically valid tool for assessing the severity of nasal symptoms and their impact on allergic rhinitis patients.

Methodology

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, positive predictive value (PPV), and negative predictive value (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 analyzed including ARIA.[10,15-17] Consultation from experts (consisting of three otorhinolaryngologists, one family medicine specialist, and 1 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 consists of

15 items. The domains include nasal symptoms (5 items), impact on daily activities (9 items), and symptoms control (1 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 four weeks and within six months duration. In the column of symptoms in the last four 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 six 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 as 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 validation of the ARSIA questionnaire was done based on content validity, face validity, 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] For example, in this study, if 3 of 5 content experts rate the item as relevant (3 or 4) the CVI would be 3/5=0.6, which does not meet the 0.8 level required, and implies that the item needs revision or should be dropped. 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 an acceptable content validity.[19] All our items were valid with CVI ranging from 0.8 to 1.00, S-CVI/Ave of 0.97, and they were retained as per the initial questionnaire.

The content validity of the questionnaire was conducted by a panel of 5 experts. The panel rated the items for relevancy using a 4-point Likert scale ranging from not relevant to very relevant. The panel also made some recommendations for the items. Modifications were made to the draft of the ARSIA questionnaire after the content validation.

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 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 3-4 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 10 respondents is at least 0.83.[20]

The final draft of the questionnaire at this stage contained two parts. Part one is the demography data (includes age, gender, ethnicity, occupation, educational level, marital status, smoking, allergic status, and current medication) and part two contains the questionnaire with three domains (nasal symptoms, impact on daily activities, and control) consisting of a total of 15 items.

Psychometric Validation Study

For construct validity, a total of 150 patients who fulfilled the inclusion and exclusion criteria participated in this study. Cronbach's alpha was used to measure the construct validity and internal consistency of this questionnaire. Each domain in the questionnaire is unidimensional.

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

After the validity was completed, the questionnaires were analyzed 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.

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, positive predictive value (PPV), and negative predictive value (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 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 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 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 very clear and found 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 old. The mean age was 35.2. The majority of them were Malays 127 (84.7%), followed by Indians 16 (10.7%), Chinese 3 (2.0%), and Others 1 (0.7%) (Table III). 3 participants were missing ethnic data. The majority of the participants were non-professional workers 81 (54%), and 69 (46%) were professional. 73 (48.7%) participants have a tertiary educational level, whereas 72 (48%) secondary level, and only 5 (3.3%) primary level of education. Most of the participants were non-smokers 129 (86%).

The allergic status was asked of the participants including food, dust, animal or insect, climate changes, smoke, and drugs. Among the participants, the 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. A majority had an allergy to house dust mite 104 (69.3%), followed by storage mite 96 (64%), prawn 37 (24.7%), cockroach 36 (24%), and cat 30 (20%).

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), and are further divided into two columns to separate symptoms within four weeks and six 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 analyzed 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 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 analyze internal consistency reliability. Item B3 (Due to your allergic rhinitis impact on you in the last four 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 four 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 analyzed for sensitivity, specificity, positive PPV, and NPV. Clinician diagnosis from the proforma was used as a comparison to the participant's 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 four weeks, do you feel your allergy is controlled?) has been dropped out following a consensus of experts and judgment as it does 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 was C1 has been dropped out as it was not included in the physician's diagnosis in the proforma.

The final questionnaire after the psychometric validation is shown on the next page.

	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 I: Content 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

Table II: Face validation for the ARSIA questionnaire