

ESPRINT-15 Questionnaire (Spanish Version): Reference Values According to Disease Severity Using Both the Original and the Modified ARIA Classifications

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■ Abstract

Objective: ESPRINT-15 is a specific and validated instrument to measure health-related quality of life in adults with allergic rhinitis. The aim of this study was to obtain new reference values based on disease severity using both the original and the modified versions of the Allergic Rhinitis and its Impact on Asthma (ARIA) guidelines.

Methods: ESPRINT-15 was administered to a representative sample of adults with allergic rhinitis in Spain. As in a previous study by our group, means and percentiles were analyzed for 16 quotas based on gender, allergic rhinitis type (intermittent vs persistent), and 4 symptom intensity groups according to the total symptom score (TSS4). The novel aspect of the present study was our application the severity criteria proposed by both the original and the modified ARIA classifications.

Results: Of the 2756 patients in our previous dataset, 2580 were included in the present analysis. In terms of symptom severity, women had relatively more intense symptoms than men with both ARIA classifications. In fact, using only the modified ARIA classification, we were able to determine that severe rhinitis is moderately more frequent in women (27% vs 23%), although the difference is not statistically significant.

Conclusions: The new set of reference values enables the ESPRINT-15 questionnaire to be adapted to the current severity classification. Consequently, this quality of life tool (<http://www.seaic.org/inicio/esprint>) can be easily used and better interpreted in daily clinical practice.

Key words: Allergic rhinitis. Quality of life. ESPRINT questionnaire (Spanish version). Reference values.

■ Resumen

Objetivo: El cuestionario ESPRINT-15 es una herramienta de calidad específica y validada para evaluar la calidad de vida relacionada con la salud, en pacientes con rinitis alérgica. El objetivo del estudio fue obtener nuevos valores de referencia basados en la gravedad de la enfermedad utilizando tanto la clasificación ARIA original como la modificada.

Métodos: El cuestionario ESPRINT-15 había sido evaluado en una muestra representativa de pacientes adultos con rinitis alérgica en España. De igual forma que en el estudio previo, se calcularon las medias y los percentiles teniendo en cuenta 16 cuotas en base al sexo, al tipo de rinitis alérgica (intermitente vs persistente) y la puntuación de un total de 4 síntomas (TSS4). La novedad ha sido ahora aplicar los criterios de severidad de los síntomas propuestos en la clasificación ARIA original y en la modificada.

Resultados: Un total de 2.756 pacientes registrados en nuestra base de datos original, 2.580 casos han sido incluidos en el presente análisis. En relación a la gravedad de los síntomas, para ambas clasificaciones ARIA, las mujeres han presentado un relativo empeoramiento en la gravedad de los síntomas en comparación con los hombres. En realidad, solo con la clasificación ARIA modificada hemos podido detectar que la categoría grave es moderadamente más frecuente, aunque sin significación estadística en mujeres (27%) que en hombres (23%).

Conclusiones: Estos nuevos valores de referencia permiten una mayor adecuación del cuestionario ESPRINT-15 a la actual clasificación de gravedad. En consecuencia esta herramienta en calidad de vida puede utilizarse más fácilmente (SEAIC website) e interpretarse mejor en la práctica clínica.

Palabras clave: Rinitis alérgica. Calidad de vida. Cuestionario ESPRINT (versión Española). Valores de referencia.

Introduction

Allergic rhinitis (AR) is a common and increasingly prevalent disease with a significant impact on health-related quality of life (HRQOL) [1] that should be assessed using standardized validated questionnaires. We previously reported the use of a new specific HRQOL questionnaire, ESPRINT, in 2 versions, a 28-item version for research purposes [2] and a shorter 15-item version to be used in clinical practice [3]. Both versions have been validated in Spain.

We extended our dataset in order to facilitate the interpretability of the questionnaire. A recent cross-sectional, descriptive study by Valero et al [4] obtained reference values for a wide and representative sample of 2756 Spanish patients with AR recruited by general practitioners (GPs), primary health or hospital allergologists, and ear, nose, and throat (ENT) specialists. Means and percentiles were calculated for 16 quotas based on sociodemographic data (age, gender, education), type of AR (persistent/ intermittent), and 4 groups of symptoms (nasal obstruction, rhinorrhea, itching, and sneezing) whose intensity was graded according to the total symptom score (TSS4) and expressed using a Likert scale ranging from absent (0) to severe (3). The score obtained showed symptoms to be very mild (<3 points), mild (3-6 points), moderate (7-9 points), or severe (10-12 points). We observed statistically significant differences according to gender (women's scores were significantly higher [worse] than men's), type of rhinitis (scores were higher in patients with persistent rhinitis), and degrees of symptom intensity (scores increased progressively from very mild to severe). Furthermore, multiple linear regression showed that gender, type of AR, and symptom severity were all independently associated with HRQOL. It is important to highlight that the magnitude of the differences in symptom severity between each consecutive quota reinforced the usefulness of providing these references values stratified by severity. However, a limitation of this analysis was that a nonconventional classification of symptom intensity was used instead of the current Allergic Rhinitis and its Impact on Asthma (ARIA) severity classification [1].

Therefore, in order to obtain reference values consistent with accepted degrees of severity of AR, we reassessed the questionnaire.

Material and Methods

Study Design

As described in our previous paper [4], we performed a cross-sectional, descriptive study using quota sampling to ensure that a wide range of patients with AR would respond to ESPRINT-15. GPs, ENT specialists, and primary health and hospital allergologists in Spain were invited to recruit patients for the study, as described below.

To ensure a sufficiently representative sample, 16 quotas were defined based on the following variables: gender (men vs women), AR symptom duration (intermittent vs persistent) [1], and 4 symptom intensity groups according to the TSS4.

Outcomes

The number of impaired items (sleep, daily activities/sport/leisure, work/school performance, and troublesome symptoms) makes it possible to grade the severity of AR according to the original ARIA classification (o-ARIA) as mild (no affected items) or moderate/severe (1 or more affected items). A modified ARIA severity classification (m-ARIA) proposed by Valero et al [5,6] was also used. m-ARIA discriminates between moderate and severe symptoms and defines the severity of AR as mild (no affected items), moderate (1 to 3 affected items), and severe (all 4 items are affected).

Statistical Analysis

In order to report sufficiently accurate mean score values for each decile, 170 patients were considered necessary for each quota (ie, 17 patients per decile). The final overall theoretical sample size was estimated at 2720 patients. The quotas were randomly assigned and reported to the investigators using a specially designed form.

A multivariate analysis was performed to confirm the association between the overall score of the questionnaire (dependent variable) and the variables by which the overall score was stratified, including gender, age, AR type, and

symptom intensity (independent variables). The mean, standard deviation, interquartile range, and deciles of the overall scores were obtained for the 16 quotas. All the analyses were performed using SPSS 11.0.

Table 1. Characteristics of the Study Population

	Total (N=2580)		Men (n=1221)		Women (n=1359)	
Age, y, mean (SD)	47.3	(16.9)	46.9	(16.8)	47.6	(16.8)
Education received, No. (%)						
Little education	394	(15.4)	143	(11.7)	251	(18.6)
Primary education completed	795	(30.9)	362	(29.7)	433	(32.0)
Secondary education completed	833	(32.4)	421	(34.6)	412	(30.5)
University education completed	547	(21.3)	292	(24.0)	255	(18.9)
Subtotal	2569		1218		1351	
Allergic rhinitis, No. (%)						
Persistent	1255	(48.6)	586	(48.0)	669	(49.2)
Intermittent	1325	(51.4)	635	(52.0)	690	(50.8)
Subtotal	2580		1221		1359	
Severity: original ARIA, No. (%)						
Mild	317	(12.3)	167	(13.7)	150	(11.0)
Moderate or Severe	2263	(87.7)	1054	(86.3)	1209	(89.0)
Subtotal	2580		1221		1359	
Severity: modified ARIA, No. (%)						
Mild	317	(12.3)	167	(13.7)	150	(11.0)
Moderate	1611	(62.4)	768	(62.9)	843	(62.0)
Severe	652	(25.3)	286	(23.4)	366	(27.0)
Subtotal	2580		1221		1359	

Abbreviations: ARIA, Allergic Rhinitis and its Impact on Asthma.

Table 2. Reference Values for the ESPRINT-15 Summary Score According to Gender, Symptom Duration, and Original ARIA Severity Classification (N=2580)^a

Gender	Men (n=1221)				Women (n=1359)			
	Persistent AR (n=586)		Intermittent AR (n=635)		Persistent AR (n=669)		Intermittent AR (n=690)	
	Mild (n=65)	Mod-Sev (n=521)	Mild (n=102)	Mod-Sev (n=533)	Mild (n=65)	Mod-Sev (n=604)	Mild (n=85)	Mod-Sev (n=605)
Mean (SD)	0.5 (0.6)	2.6 (1.2)	0.6 (0.6)	2.3 (1.3)	0.8 (0.8)	2.7 (1.3)	0.7 (0.7)	2.4 (1.3)
Interquartile range	0.2-0.7	1.7-3.5	0.2-0.9	1.2-3.2	0.3-1.0	1.8-3.7	0.2-1.0	1.43-3.4
Deciles								
10	0.07	0.86	0.07	0.64	0.14	0.89	0.11	0.79
20	0.14	1.46	0.14	1.00	0.29	1.57	0.21	1.29
30	0.21	1.86	0.29	1.36	0.36	2.04	0.29	1.57
40	0.29	2.27	0.36	1.79	0.43	2.43	0.36	2.00
50	0.36	2.64	0.43	2.29	0.57	2.71	0.50	2.43
60	0.50	3.00	0.57	2.50	0.71	3.07	0.71	2.71
70	0.66	3.36	0.79	2.93	0.93	3.50	0.93	3.14
80	0.84	3.71	1.00	3.44	1.07	4.00	1.14	3.64
90	1.10	4.14	1.36	4.07	1.94	4.50	1.67	4.14
100	3.14	5.57	3.93	5.93	4.07	5.86	3.43	6.00

Abbreviations: AR, allergic rhinitis; Mod-Sev, moderate-to-severe.

^aAverage on the basis of 14 specific items. The summary score ranges between 0 (no impact on quality of life) and 6 (maximum impact on quality of life).

Table 3. Reference Values for the ESPRINT-15 Summary Score According to Gender, Symptom Duration, and Modified ARIA Severity Classification (N=2580)^a

Gender	Men (N=1221)						Women (N=1359)					
	Persistent AR (N=586)		Intermittent AR (N=635)		Intermittent AR (N=635)		Persistent AR (N=669)		Persistent AR (N=669)		Intermittent AR (N=690)	
Duration	Mild (n=65)	Moderate (n=361)	Severe (n=160)	Mild (n=102)	Moderate (n=407)	Severe (n=126)	Mild (n=65)	Moderate (n=394)	Severe (n=210)	Mild (n=85)	Moderate (n=449)	Severe (n=156)
Severity	0.5 (0.7)	2.2 (1.1)	3.4 (1.0)	0.6 (0.6)	1.9 (1.1)	3.5 (1.2)	0.8 (0.8)	2.2 (1.2)	3.7 (1.0)	0.7 (0.7)	2.1 (1.1)	3.5 (1.1)
Mean (SD)	0.2-0.7	1.4-3.0	3.0-4.1	0.2-0.9	1.0-2.6	2.8-4.4	0.3-1.0	1.3-3.0	3.0-4.5	0.2-1.0	1.2-2.8	2.8-4.3
Interquartile range	0.07	0.14	0.21	0.29	0.36	0.43	0.14	0.29	0.36	0.43	0.50	0.57
Deciles	0.07	0.71	2.01	0.07	0.56	1.89	0.14	0.68	2.43	0.11	0.64	1.91
10	0.14	1.14	2.79	0.14	0.90	2.57	0.29	1.07	2.86	0.21	1.00	2.64
20	0.21	1.50	3.09	0.29	1.21	3.15	0.36	1.57	3.14	0.29	1.36	3.00
30	0.29	1.86	3.36	0.36	1.50	3.49	0.43	1.86	3.53	0.36	1.64	3.36
40	0.36	2.14	3.50	0.43	1.79	3.71	0.57	2.25	3.71	0.50	2.00	3.64
50	0.50	2.57	3.79	0.57	2.21	3.94	0.71	2.50	4.00	0.71	2.36	3.86
60	0.66	2.86	3.93	0.79	2.43	4.14	0.93	2.86	4.34	0.93	2.64	4.14
70	0.84	3.14	4.21	1.00	2.79	4.54	1.07	3.21	4.57	1.14	3.07	4.50
80	1.10	3.71	4.71	1.36	3.36	4.86	1.94	3.76	4.93	1.67	3.57	5.02
90	3.14	4.79	5.57	3.93	5.57	5.93	4.07	5.43	5.86	3.43	5.14	6.00
100												

Abbreviation: AR, allergic rhinitis.
^aAverage on the basis of 14 specific items. The summary score ranges between 0 (no impact on quality of life) and 6 (maximum impact on quality of life).

Results

Of the 2756 patients in our previous dataset [4], 2580 cases were included in the present analysis, namely, those who had completed data on symptom severity. The general characteristics of the sample are summarized in Table 1. The distribution of the variables concerning gender and AR type was balanced. As for symptom severity in both ARIA classifications, women had relatively more intense symptoms than men. In fact, using only the modified ARIA classification, we were able to determine that the severe category was moderately more frequent in women (27% vs 23%), although the difference was not statistically significant. In terms of educational level, 31% of patients had finished primary school, 32% had finished secondary school, and 21% had attended university.

Our previous multivariate analysis [4] used the overall score in the ESPRINT-15 questionnaire as a dependent variable and gender, age, AR type, and symptom intensity as independent variables. The results clearly showed that all the variables included in the model, except age, are independently associated with the overall score. The results confirmed that age was irrelevant for the preparation of the reference values, although it validated other variables (gender, AR type, and symptom intensity).

By applying these findings, new reference values for the summary score of the ESPRINT-15 questionnaire were established according to gender, AR type, and intensity of symptoms. These values are shown for both o-ARIA (Table 2) and m-ARIA (Table 3). The summary score ranges from 0 (no impact on HRQOL) to 6 (maximum impact on HRQOL).

Discussion

The novelty of the present analysis derives from the application of the severity criteria of the current classification of AR. The new set of reference values obtained enables an individual's score to be put into the context of both ARIA classifications (o-ARIA [1] and m-ARIA [5]) in terms of severity categories and by comparing it with that of the corresponding reference group.

Reference values have been applied in previous generic HRQOL questionnaires to make them more practical [7]. Although reference values facilitate interpretation of complex and multidimensional concepts such as health and intelligence, few studies analyze specific HRQOL instruments [8]. Reference values have been applied frequently in generic HRQOL instruments [9-13] and facilitate the application of ESPRINT [14]. The scores found should not be interpreted in isolation, but

compared with the most suitable reference group, since the reference value approach has proven useful in adult HRQOL instruments [7].

Our approach makes it possible to compare the score obtained with that obtained from the reference group. For example, if we compare 2 female patients with intermittent AR and the same HRQOL summary score (score=3.4) and suppose that Patient 1 presents severe symptoms while Patient 2 presents mild symptoms, we can ask whether the impact on HRQOL would be the same in both patients. The score of Patient 1 is found at percentile 30, meaning that only 30% of this reference group has obtained lower scores (lower impact on HRQOL). The score of Patient 2 is found at percentile 100, meaning that all patients with the same type of AR obtained a higher score (lower impact on HRQOL). Consequently, the percentiles show that the impact of AR symptoms on the HRQOL is much higher in Patient 2 than in Patient 1.

Despite the advantages of population reference values for conditions such as AR, which affects 21.5% of the Spanish population [15] and whose symptoms have repercussions on HRQOL, the approach is subject to limitations. For example, socioeconomic status was not taken into account during the construction of the reference values. Furthermore, reference values are useless if the patient does not answer at least 1 item in the questionnaire, thus making it impossible to calculate the summary score. Therefore, in this situation, the normal values should be applied and interpreted with caution.

These new reference values are presented on the SEAIC website (<http://www.seaic.org/inicio/esprint>) in an interactive and user-friendly interface for the diffusion and application of this tool in clinical practice, mainly by specialists [16].

In conclusion, the new reference values make the ESPRINT-15 questionnaire more useful according to the current classification of severity. Consequently, this tool can be easily used in daily clinical practice and even in online epidemiological studies.

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Conflicts of Interest

Dr Iñaki Izquierdo works for J Uriach y Compañía.

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