# The impact of allergic rhinitis on symptoms, and quality of life using the new criterion of ARIA severity classification*

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**Rhinology 50:** 33-36, 2012
**DOI:** 10.4193/Rhino.11.071

***Received for publication:**
April 5, 2011
**accepted:** Ocotber 9, 2011

## Summary

**Introduction:** Allergic rhinitis (AR) is a common disease with major socieconomic burden and a significant impact on quality of life.

**Objective:** The objective of the study was to assess the impact of AR severity, using the modified ARIA (m-ARIA) severity criterion in order to discriminate among moderate and severe AR, in symptoms and quality of life assessed with the questionnaire ESPRINT-15.

**Methods:** The specific quality of life questionnaire (ESPRINT-15) was applied in over thousand untreated AR patients. Severity was evaluated by the m-ARIA classification, which categorizes AR as mild, moderate, and severe. Nasal symptoms were evaluated by using categorized (none, low, middle, and high) Total Four Symptom Score (T4SS).

**Results:** Using the m-ARIA severity classification, significant differences in quality of life, both global score and specific domains, and categorized T4SS were found among the AR severity groups.

**Conclusion:** Modified ARIA severity classification in mild, moderate, and severe allergic rhinitis clearly discriminates the impact of AR in all domains of quality of life and categorized symptom's score.

**Key words:** allergic rhinitis, severity ARIA, symptoms, quality of life, ESPRINT-15

## Introduction

Allergic rhinitis (AR) is a common and increasingly prevalent disease that generates an important socioeconomic burden and a significant impact on quality of life (QoL) [1]. A new-related quality of life questionnaire in AR (ESPRINT) has been validated in the Spanish population [2-4].

The Allergic Rhinitis and its Impact on Asthma (ARIA) document developed a new classification based on symptom duration: intermittent (IAR) and persistent (PER) rhinitis. The ARIA classification also introduced a system for assessing AR severity based on the impairment of four health-related quality of life (HRQL) items: sleep, daily activities, sport and leisure, work or school performance, and troublesome symptoms. In this classification, AR is mild when there is no impairment of any of these items, while moderate/severe when one or more of these items are impaired [1]. Moreover, the large prevalence of moderate/severe rhinitis (69 - 90%) suggests an important heterogeneity in this disease severity group [5-7].
Our group has recently proposed a modification of the ARIA (m-ARIA) severity classification, by maintaining the original severity items, which allows to discriminate between allergic rhinitis patients with different levels of severity: mild (not affected items), moderate (one to three affected items), and severe (four affected items) [8].

The objective of the study was to assess the impact of the severity of allergic rhinitis, classified under the new m-ARIA criterion [8], in symptoms and quality of life assessed with the questionnaire ESPRINT-15.

## Methods

### Study design and population

The study was performed using a pre-existing database from a cross-sectional, population-based study. The study consisted of a survey conducted from April to June 2005 to evaluate a large representative data on adult out-patient population suffering from AR in Spain. Patient's characteristics have been published elsewhere [14]. Participants were older than 18 years, with a confirmed diagnosis of AR and currently visiting their physician for AR. The study investigators (n = 539) were general practitioners (68%), ENT specialists (18%), or allergologists (9%) from primary care and hospital-based settings distributed throughout Spain. In 5% of the cases the speciality was not identified. Patients with untreated AR (n = 1,058) were recruited. This study was approved by the Ethics Committee of Hospital Clinic de Barcelona (Spain).

### Patient's clinical evaluation

In addition to sociodemographic characteristics of patients (age, gender, and educational level), data about the type of AR rhinitis (persistent or intermittent, according to ARIA definition) [1].

Different outcome measures were administered:

- AR severity classification. AR severity was assessed by the four ARIA items (sleep, daily activities/sport, work/school performance, and troublesome symptoms) to classify patients on different levels of disease severity [1]: mild (no affected items), moderate/severe (one or more affected items); as well as distinguishing between moderate (1 to 3 affected items) and severe (4 affected items), based on the modified criterion [8].
- ESPRINT-15 questionnaire. This is an AR specific quality of life questionnaire, validated in Spain, which contains 15 items covering five domains: symptoms (5 items), daily activities (3 items), sleep (3 items), psychological affectation (3 items), and wellness (1 item). Items were scored, both global and specific domains, using a six-point Likert scale ranging from 0 to 6 (the worst quality of life) [2,3].
- Total Four Symptom Scale (T4SS): assessed by the sum of four rhinitis nasal symptoms (nasal congestion, rhinorrhea, nasal itching, and sneezing, ranged from 0 to 3 (0 = no symptoms, 1 = mild, 2 = moderate and 3 = severe). The investigators categorized the overall symptoms score as none (0 - 2), low (3 - 6) middle (7 - 9) and high (10 - 12).

### Statistical analysis

Group comparisons were performed using unpaired Student's t-test, nonparametric Mann-Whitney U-test, and Chi-square or Fisher's exact statistics, when appropriate. Chi-square statistics were also used to examine differences in the T4SS (none, low, middle and high) among different AR severity levels. Comparisons of ESPRINT-15 and their AR severity were carried out by

Table 1. Characteristics of the allergic rhinitis (AR) study population.

| | Patients (n = 1.058) |
|---|---|
| Age, years (mean ± SD) | 47.2 ± 17.5 |
| Gender, women, n (%) | 528 (50) |
| Type of AR duration (%) | |
| Persistent | 38.5 |
| Intermittent | 61.5 |
| AR severity (ARIA original) (%) | |
| Mild | 17.8 |
| Moderate/severe | 82.2 |
| AR severity (New Criterion) (%) | |
| Mild | 17.8 |
| Moderate | 63.1 |
| Severe | 19.1 |
| ESPRINT questionnaire (mean ± SD) | |
| Global score | 2.01 ± 1.37 |
| Symptoms domain | 2.19 ± 1.38 |
| Daily activities domain | 1.86 ± 1.46 |
| Sleep domain | 1.96 ± 1.60 |
| Psychological impact domain | 1.89 ± 1.54 |
| Item 15 - Wellness | 2.93 ± 0.91 |

Table 2. ESPRINT-15 domain scores and AR severity according to the classification on mild, moderate and severe disease.

| Allergic Rhinitis Patients | | | | | |
|---|---|---|---|---|---|
| ESPRINT-15 scale | AR Severity (x ± SD) | | | p[1] | Significant comparisons [2] (p < 0.05) |
| Domains: | Mild (n = 184) | Moderate (n = 648) | Severe (n = 198) | | |
| Symptoms | 0.82 (0.78) | 2.17 (1.15) | 3.50 (1.23) | <0.001 | 1 vs 2; 2 vs 3; 1 vs 3 |
| Daily activities / Sport | 0.50 (0.62) | 1.73 (1.21) | 3.45 (1.32) | <0.001 | 1 vs 2; 2 vs 3; 1 vs 3 |
| Sleeping | 0.57 (0.77) | 1.85 (1.41) | 3.60 (1.37) | <0.001 | 1 vs 2; 2 vs 3; 1 vs 3 |
| Psychological affectation | 0.44 (0.69) | 1.80 (1.30) | 3.49 (1.39) | <0.001 | 1 vs 2; 2 vs 3; 1 vs 3 |
| Global score | 0.61 (0.63) | 1.93 (1,09) | 3.5 (1.18) | <0.001 | 1 vs 2; 2 vs 3; 1 vs 3 |

(1): p-value of ANOVA test for lineal trend, significance p < 0.05

(2): Post-hoc test for pair wise comparisons, significance p < 0.05

Table 3. Assessment of AR symptoms intensity (T4SS) by AR severity.

| Allergic Rhinitis Patients | | | | |
|---|---|---|---|---|
| Nasal Symptoms Intensity (0-12) | AR Severity, n (%) | | | |
| | Mild | Moderate | Severe | p |
| None (0-2) | 132 (71.7%) | 137 (21.1%) | 13 (6.6%) | 0.001 |
| Low (3-6) | 42 (22.8 %) | 241 (37.2%) | 32 (16.2%) | |
| Middle (7-9) | 9 (4.9%) | 200 (30.9%) | 56 (28.3%) | |
| High (10-12) | 1 (0.5 %) | 70 (10.8%) | 97 (49.0%) | |
| TOTAL | 184 | 648 | 198 | |

p-value test for Chi-square test, p < 0.05

ANOVA test for lineal trend. All hypothesis tests were two tailed, and statistical significance was assessed at the 0.05 levels. All statistical procedures were performed using an SPSS package version 13 for Windows (SPSS Inc, Chicago, IL, USA).

## Results

The study included untreated AR patients (n = 1,058). Clinical AR outcomes according to T4SS, disease severity, and HRQL are displayed in Table 1. Significant differences (p < 0.0001) were found between quality of life (global score and domains: symptoms, daily activities/sport, sleeping and psycological affectation) and T4SS scores among the different nasal symptoms intensity (none, low, middle, and high) with AR severity groups (mild, moderate, and severe) using the modified ARIA classification (Tables 2 and 3). According to AR severity the intensity of symptoms was as follows: mild (was not present or low in 94.5%), moderate (low or middle in 68%), and severe (middle or high in 77.3%).

## Discussion

The main finding of this study is the validation of AR severity classification according to the new ARIA criterion in mild, moderate, and severe [8], in a large population of patients that were clearly discriminated by quality of life, both in the global score and specific domains, and nasal symptom's score.

The severity classification of AR in mild, moderate, and severe significantly correlates with the impact on quality of life both in the overall score and in the different domains (global score and domains: symptoms, daily activities / sport, sleeping and psychological affectation) of quality of life questionnaire ESPRINT-15 [2-4]. The correlation was also significant with the intensity of nasal symptoms, categorized in none, low, middle and high.

In a previous report [9], we have demostrated that the modified ARIA severity classification can validly discriminate between moderate and severe allergic rhinitis in a large population of both

treated or untreated AR patients whose symptoms and quality of life were clearly different.

Having well-validated criteria to discriminate allergic rhinitis severity in mild, moderate and severe may also help to develop new epidemiological, clinical, and pharmaeconomic studies under the umbrella of the new concept of SCUAD (Severe Chronic Upper Airway Disease) [10]. Furthermore, a different attempt to validate a modified ARIA severity classification [11] has been recently found not to be useful and reliable enough [12] to be used in daily clinical practice.

In conclusion, we have shown that our modified ARIA severity classification in mild, moderate, and severe allergic rhinitis clearly discriminates in all domains of quality of life and categorized symptom's score and is valid to be used in daily clinical practice.

## Acknowledgments

This study was sponsored by an unrestricted educational grant from Grupo Uriach SA, Barcelona, Spain. We are extremely grateful to the 539 investigators who made this study possible.

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