Health-related quality of life (HRQOL) questionnaires are increasingly used in a variety of clinical and research settings including clinical trials, health surveys, clinical practice, and economic analyses of health care interventions (1, 2). Such measures are generally multidimensional (3) and include the measurement of symptoms, functional limitations, general health perceptions, and psychological well-being (4). The importance of HRQOL measurement in rhinitis is indicated by the fact that the World Health Organization’s Allergic Rhinitis and its Impact on Asthma (ARIA) guidelines base the classification of rhinitis severity on the impact of the disease on daily life (5).

Several instruments have been developed to measure HRQOL in rhinoconjunctivitis and allergic rhinitis (AR) (6–8). One of the most frequently used is the Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ). The original version of the questionnaire, which consists of 28 items in seven dimensions, has proved its usefulness and validity (9–12). A shorter version of the questionnaire
Comparing the ESPRINT-15 and mini-RQLQ questionnaires

[Mini-Rhinoconjunctivitis Quality of Life Questionnaire (MiniRQLQ)] was developed for use in clinical trials, patient monitoring, and epidemiological surveys (13).

None of the existing instruments to measure HRQOL in rhinitis was developed in Spain. As there is no guarantee that the HRQOL concerns of patients with rhinitis will be the same across several countries or cultures (14), a new measure – the Esprint-28 – was developed to explore and measure the impact of AR on HRQOL from the point of view of Spanish AR patients. This new instrument has been shown to have excellent psychometric characteristics (15). A short form of the instrument – the ESPRINT-15 – was also developed which includes 15 items in four dimensions. The ESPRINT-15 was developed to provide an instrument which would be suitable for use in a variety of contexts, including clinical practice, observational studies, and clinical trials. In order to test the performance of the ESPRINT-15, we compared its psychometric characteristics with those of the MiniRQLQ, as the latter is probably the gold standard short-form questionnaire for HRQOL measurement in clinical trials and other settings in rhinitis and rhinoconjunctivitis.

Head to head studies of this sort in which two instruments are administered to the same group of patients are recommended to provide comparative evidence for alternative instruments for a given study (16, 17). The objective of the present study was to compare the measurement properties of the ESPRINT-15 and the MiniRQLQ in terms of their reliability, validity, and sensitivity to change.

Patients and methods

Study design and participants

The two questionnaires were included in a prospective, observational study performed between March and August 2004 in the allergy and ENT departments of 27 Spanish hospitals. Each center consecutively included patients over 18-years old with a diagnosis of AR based on any clinically relevant allergen sensitization who met inclusion criteria and agreed to participate. Approximately 66% of patients were scheduled to complete the questionnaires on two occasions, at baseline and 2–4 weeks after baseline in order to evaluate test–retest reproducibility and sensitivity to change. All patients provided informed consent to participate in the study, which was approved by the Ethics Committee of the Hospital Clínic i Provincial in Barcelona.

Outcomes measurement

Health-related quality of life was assessed using the ESPRINT-15 and the MiniRQLQ (13). The ESPRINT-15 was developed out of a longer 28 item version which was designed to reflect and measure the HRQOL concerns of Spanish patients with persistent (PER) or intermittent allergic rhinitis (IAR) (15). The 28 item version was developed from literature reviews, discussions with clinical experts, and focus groups with patients and has been shown to meet psychometric requirements for this type of questionnaire (18, 19). The shorter version consists of 15 items in four dimensions (symptoms, daily activities, sleep, and psychological well-being) (see Table 1).

Item reduction was carried out based on the frequency and distribution of responses, analysis of clinical impact (i.e. frequency and importance scores of the individual items), item-scale correlations, Rasch analysis, and expert opinion. The 15 item version provides an overall score which ranges from 0 to 5.8 and dimension scores with a range from 0 to 6. Lower scores indicate better QOL. The measurement goal of the ESPRINT-15 is both discrimination and evaluation.

The MiniRQLQ consists of 14 items in five dimensions (activities, practical problems, nose symptoms, eye symptoms, and other symptoms) and is derived from the longer version of the instrument (13). In this study, the 28 item version of the RQLQ was administered, but for the purposes of comparison we derived scores for the MiniRQLQ as it is more directly comparable with the ESPRINT-15. The RQLQ has been recently adapted and validated for use in Spain (20). Scores for the MiniRQLQ were obtained using the algorithm provided by the original authors (13). The MiniRQLQ provides both an overall score and a score by dimension, with lower scores also indicating better HRQOL.

Generic HRQOL was assessed using the Medical Outcomes Study 12-Item Short-Form Health Survey (SF-12) (21), a shortened version of the 36-item health survey, which has been adapted and validated for use in Spain (22). The SF–12 provides two measures of physical [physical component summary (PCS)] and mental health [mental component summary (MCS)], with lower scores indicating worse health status and higher scores indicating better health status.

### Table 1. Main characteristics of the ESPRINT-15 questionnaire and the MiniRQLQ questionnaire

<table>
<thead>
<tr>
<th></th>
<th>Number of items</th>
<th>Number of dimensions</th>
<th>Dimensions</th>
<th>Overall and dimension scores</th>
<th>Score ranges</th>
</tr>
</thead>
<tbody>
<tr>
<td>MiniRQLQ</td>
<td>14</td>
<td>5</td>
<td>Activity limitations</td>
<td>Yes</td>
<td>Overall and dimension scores from 0 (no impairment) to 6 (greatest impairment)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Practical problems</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Nose symptoms</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Eye symptoms</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Other symptoms</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Symptoms</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Daily activities</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Sleep</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Psychological impact</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ESPRINT-15</td>
<td>15</td>
<td>4</td>
<td></td>
<td>Yes</td>
<td>Overall score from 0 (minimum impact in HRQOL) to 5.8 (maximum impact in HRQOL)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Dimension scores from 0 (minimum impact in HRQOL) to 6 (maximum impact in HRQOL)</td>
</tr>
</tbody>
</table>

HRQOL, Health-related quality of life; miniRQLQ, Mini-Rhinoconjunctivitis Quality of Life Questionnaire.
All SF-12 scores were calculated using standard scoring algorithms for the Spanish population, which yield a mean score of 50 and a SD of 10 in the general population (21). All three HRQOL questionnaires were self-administered. The ESPRINT-15 was administered first, followed by the MiniRQLQ and the SF-12.

**Other variables**

Data were also collected on socio-demographic (sex, age, and educational level) and clinical characteristics (time since diagnosis, type and severity of AR according to the ARIA Initiative guidelines (5), presence and type of comorbidities, treatments for AR, and symptom intensity). Allergic rhinitis symptom intensity was measured using the Total Symptom Score (TSS-4), which is defined as the sum of nasal symptoms of obstruction, rhinorrhea, itch, and sneeze scores. Each of these is scored on a scale from 0 to 3 resulting in a TSS-4 score ranging from 0 (no symptoms) to 12 (maximum symptom intensity) (23). To be included, patients had to score at least three points on the TSS-4.

A health status transition item was administered at the second visit to assess changes in patients’ self-perceived health and to be able to classify patients as stable, improved or deteriorated (24). Patients answered on a Likert-type ordinal scale with 13 response options (greatly improved = +6, no change = 0, and greatly worsened = −6).

**Statistical analysis**

**Floor-ceiling effects and reliability.** The floor and ceiling effects (the proportion of patients with the worst and best possible scores, respectively) were calculated for both questionnaires by overall score and dimension. Questionnaire reliability was studied by determining internal consistency (Cronbach’s alpha) and test–retest reliability (intraclass correlation coefficient; ICC). Test–retest reliability was assessed in patients scoring −1.0, 0, or +1 on the health transition item. Cronbach’s alpha and ICC values of 0.70 or over were predefined as satisfactory (19).

**Validity.** Validity was tested in two ways. Convergent validity was tested by estimating Spearman correlations between symptom scores (measured using the TSS-4), scores on the SF-12 PCS and MCS and scores on the individual dimensions and global scores of the ESPRINT-15 and MiniRQLQ. Correlations of <0.40, 0.40–0.60, and >0.60 were defined as weak, moderate, and strong, respectively (25). The pattern of correlations between the ESPRINT-15 and MiniRQLQ and the TSS-4, PCS, and MCS were expected to reflect the similarities and differences in content between the different measures. Symptoms dimensions on the two disease-specific instruments were expected to show higher correlations with the TSS-4 score than with the SF-12 PCS or MCS; dimensions measuring the psychological impact of AR in the disease-specific measures were expected to have higher correlations with the MCS than the PCS, and dimensions measuring the physical impact of the disease, such as the Activities of Daily Living dimension, were expected to correlate more strongly with the PCS than with the MCS.

Known groups validity was tested by determining whether the two instruments were able to discriminate between patients with IAR and persistent AR. On the basis of previous studies, patients with PER were expected to report worse HRQOL than patients with IAR, due to their having more severe symptoms (26). Comparisons between groups were performed using the Mann–Whitney U-test.

**Sensitivity to change.** Sensitivity to change was assessed by using an unpaired t-test to determine whether the instruments could detect a difference between patients who reported a change over the study period (i.e. patients scoring +2 or −2 or greater on the health status transition item at the second visit) and patients who did not report any change. Effect sizes and standardized response means (SRM) were also calculated for the overall score and dimension scores of both instrument. Effect sizes were calculated as the difference between group means divided by the pooled standard deviation and can range from 0 to positive infinity. Values of ~0.2 are considered to represent a small change, ~0.5 moderate change, and ~0.8 or higher a large change in the attribute of interest (27). The SRM was calculated by dividing the mean change in score by the standard deviation of the change scores between the two study visits (28).

**Minimal clinically important difference.** The minimal clinically important difference (MCID) for the two instruments was evaluated using data from patients who reported a change of ±2 or 3 on the health status transition item.

**Results**

Evaluable responses were obtained from 400 patients (Table 2) at the first and 259 patients at the second visit (64.8%). Patient sample characteristics at the first visit are shown in Table 2. The study population was relatively young (mean age = 32.3 years, SD = 9.7 years), 62% were women, and 59% had PER.

As shown in Table 3, no relevant floor or ceiling effects for the overall scores were observed for either questionnaire. The highest floor effect was for the practical problems dimension on the MiniRQLQ (14.5% of respondents with the lowest possible score) and the highest ceiling effect was for the ‘sleep’ dimension on the ESPRINT-15 (9.8% of respondents with the highest possible score). Both questionnaires showed good internal consistency, with Cronbach’s alpha values of 0.90 and 0.92 for the MiniRQLQ and ESPRINT-15 overall scores, respectively, and from 0.69 to 0.90 for individual dimensions. Test–retest reliability was also satisfactory for both instruments, with ICCs of 0.77 and 0.80 for the MiniRQLQ and ESPRINT-15 overall scores, respectively.

The results of testing convergent validity between the different outcomes measures used in the study are shown in (Table 4). Correlations between the disease-specific HRQOL measures, the TSS-4, and the PCS were moderate to strong. Correlations between the SF-12 MCS and the ESPRINT-15 and MiniRQLQ were weaker, both for the overall and dimension scores. As expected, the symptom scales of the two disease-specific measures correlated more strongly with the TSS-4 scale than with either the PCS or the MCS, whilst the activities dimensions on both questionnaires correlated more strongly with the TSS-4 or the PCS than with the MCS. The Psychological Impact dimension of the ESPRINT-15 had the highest correlation with the MCS of any of the ESPRINT-15 dimensions (0.27), though unexpectedly it showed a higher correlation with the PCS (0.37).

Figure 1 shows the results of testing for differences between patients with IAR and PER. There were statis-
tically significant differences ($P < 0.05$) in scores for the two groups on almost all of the ESPRINT-15 and MiniRQLQ dimensions as well as on the overall scores on the two instruments. PER patients had statistically significant worse scores on all dimensions of both HRQOL instruments, except the eye symptoms dimension of the MiniRQLQ, and had poorer overall scores than IAR patients.

Table 5 shows the results of testing for differences between patients reporting a change of ±2 or greater on the health status transition item ($n = 197$) and patients who did not report any change ($n = 48$). Differences between the two groups were statistically significant at $P < 0.001$ for all dimensions and the overall score. SRMs ranged between 0.7 (MiniRQLQ eye symptoms dimension) and 1.3 (MiniRQLQ nose symptoms dimensions) on the two instruments. The SRM for the overall score was 1.1 on both instruments.

### Discussion

The short form ESPRINT-15, and its parent version, the ESPRINT-28 (15) are the first instruments to measure HRQOL in AR which have been developed directly in a Spanish population and with Spanish-speaking populations in mind. This is an important target population, given that there are as many as 400 million native Spanish
speakers worldwide. However, it is also crucial to assess the measurement properties of any new instrument. In the present study, we found that the measurement properties of the new instrument were similar to those of what might be considered a gold standard instrument in the field of HRQOL measurement in AR, the MiniRQLQ. Therefore, the ESPRINT-15 can be recommended as an alternative to the MiniRQLQ, particularly in Spanish-speaking populations.

In terms of content, the major differences between the two instruments are that the MiniRQLQ has a dimension covering practical problems and places more emphasis on symptoms, while the ESPRINT-15 has two dimensions (Sleep and Psychological impact) which are not included in the MiniRQLQ. Items measuring practical problems associated with AR, such as the need to blow one’s nose repeatedly, were found not to be of great importance to Spanish patients during focus groups and item development (15). The inclusion of a sleep dimension may be a strong point of the ESPRINT-15 questionnaire, as sleep problems have been identified as being of importance to AR patients (29), and are identified as being of particular relevance in the ARIA guidelines (5). These differences in content are likely to be relevant when selecting one of the instruments for a given study. For example, if secondary effects on sleep or efficacy in terms of the psychological impact of a new treatment are expected, the ESPRINT-15 would be more appropriate. On the other hand, the MiniRQLQ would be more appropriate in studies focusing on symptoms.

Both the ESPRINT-15 and the MiniRQLQ performed well in psychometric terms, and met accepted criteria for use in clinical studies (18, 19, 28). The instruments had few floor or ceiling effects and had Cronbach’s alpha values which were close to or above the recommended level of 0.7 for use at the group level (19, 28). Two dimensions on the ESPRINT-15 and one dimension on the MiniRQLQ as well as the overall scores on both instruments had Cronbach’s alpha values of 0.9 or above, which would allow them to be used at individual patient level (30). Results for test–retest reliability were also satisfactory, though two dimensions on the MiniRQLQ and one on the ESPRINT-15 did not reach the recommended ICC values of 0.7 (30). Two of these dimensions measured symptoms, and such dimensions may fare poorly on test–retest reliability because of symptom volatility. Intervals between questionnaire administrations need to take this into account if reliability is not to be underestimated.

Correlations between the MiniRQLQ and the ESPRINT-15, the TSS-4, and the SF-12 PCS and MCS

### Table 5. Responsiveness: mean change in score in patients scoring ±2 or more on the health status transition item

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Patients who were stable between visits: mean (SD), (n = 48)</th>
<th>Patients who changed between visits: mean (SD), (n = 197)</th>
<th>Difference (P-value)</th>
<th>SRM</th>
</tr>
</thead>
<tbody>
<tr>
<td>MiniRQLQ</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Activity limitations</td>
<td>0.2 (1.3)</td>
<td>1.6 (1.7)</td>
<td>&lt;0.001</td>
<td>1.0</td>
</tr>
<tr>
<td>Practical problems</td>
<td>0.4 (1.3)</td>
<td>2.1 (1.8)</td>
<td>&lt;0.001</td>
<td>1.2</td>
</tr>
<tr>
<td>Nose symptoms</td>
<td>0.3 (1.3)</td>
<td>2.1 (1.6)</td>
<td>&lt;0.001</td>
<td>1.3</td>
</tr>
<tr>
<td>Eye symptoms</td>
<td>0.4 (1.1)</td>
<td>1.3 (1.8)</td>
<td>&lt;0.001</td>
<td>0.7</td>
</tr>
<tr>
<td>Other symptoms</td>
<td>0.3 (0.9)</td>
<td>1.0 (1.2)</td>
<td>&lt;0.001</td>
<td>0.9</td>
</tr>
<tr>
<td>Global score</td>
<td>0.2 (0.7)</td>
<td>1.4 (1.2)</td>
<td>&lt;0.001</td>
<td>1.1</td>
</tr>
<tr>
<td>ESPRINT-15</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptoms</td>
<td>0.3 (1.2)</td>
<td>1.8 (1.5)</td>
<td>&lt;0.001</td>
<td>1.2</td>
</tr>
<tr>
<td>Daily activities</td>
<td>0.2 (1.4)</td>
<td>1.7 (1.7)</td>
<td>&lt;0.001</td>
<td>1.0</td>
</tr>
<tr>
<td>Sleep</td>
<td>0.1 (1.2)</td>
<td>1.5 (1.7)</td>
<td>&lt;0.001</td>
<td>0.9</td>
</tr>
<tr>
<td>Psychological impact</td>
<td>0.2 (1.0)</td>
<td>1.7 (1.7)</td>
<td>&lt;0.001</td>
<td>1.1</td>
</tr>
<tr>
<td>Global score</td>
<td>0.2 (0.9)</td>
<td>1.6 (1.4)</td>
<td>&lt;0.001</td>
<td>1.1</td>
</tr>
</tbody>
</table>

SRM, standardized response mean; MiniRQLQ, Mini-Rhinoconjunctivitis Quality of Life Questionnaire.

### Table 6. Minimal clinically important difference

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Global rating of change</th>
<th>0–1 (n = 48)</th>
<th>2–3 (n = 66)</th>
<th>4–5 (n = 99)</th>
<th>6 (n = 32)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MiniRQLQ</td>
<td>Global score</td>
<td>0.2 (0.7)</td>
<td>0.8 (0.9)</td>
<td>1.6 (1.2)</td>
<td>2.2 (1.4)</td>
</tr>
<tr>
<td>ESPRINT-15</td>
<td>Global score</td>
<td>0.2 (0.9)</td>
<td>0.9 (1.0)</td>
<td>1.7 (1.3)</td>
<td>2.6 (1.5)</td>
</tr>
</tbody>
</table>

MiniRQLQ, Mini-Rhinoconjunctivitis Quality of Life Questionnaire. Mean change in global scores vs global rating of change.

Figure 1. Comparison of scores in patients with IAR and PER. ESPRINT-15 vs MiniRQLQ (n = 400). *P < 0.05.
were generally as expected, and indicate satisfactory convergent validity for the two instruments. The only unexpected result was that the ESPRINT-15 psychological impact dimension correlated more highly with the SF-12s PCS than the MCS. As well as indicating a significant association between the physical and emotional aspects of the disease, this finding likely also reflects the different focus of items in the SF-12 MCS compared with the ESPRINT-15. In the first, items focus on performing tasks because of emotional problems, feeling calm and peaceful, or feeling sad and downhearted. In the second, items are very disease specific and refer to aspects such as feeling irritable or fed up because of the disease, or always having the disease on one’s mind.

With regard to known groups validity, both instruments also detected statistically significant differences between patients with IAR and PER, with PER patients having consistently worse scores on almost all dimensions of both instruments. This confirms the findings of previous studies, which have also indicated poorer HRQOL in PER patients (26).

Finally, both instruments were sensitive to change in patients reporting changes in their health status between visits. This is of particular importance if instruments are to be used in longitudinal studies to measure the impact of interventions for AR. In the present study, both instruments discriminated well between patients reporting a change in health status and those who did not. The SRMs showed that changes over time in patients reporting any type of change (improvement or deterioration) were large on most dimensions (26), though particularly on the symptoms dimensions. Changes between visits could be due to treatment (patients followed their usual course of treatment for AR between the two visits) or due to the natural evolution of the disease in untreated patients. The MCID was also very similar in both instruments and was similar to the MCID for the original MiniRQLQ (13).

One of the strengths of the present study was that the two measures were administered to the same patient population. Thus, differences in study samples are not likely to be the source of any differences in results of psychometric performance.

Study limitations include the fact that the order of administration of the two questionnaires was always the same, with the ESPRINT-15 being administered first. Administering one questionnaire after another may lead to a disadvantage for the second questionnaire, as the respondent’s fatigue may lead to poorer quality responses. This is unlikely in the present case, however, as the sample was relatively young and well-educated and both questionnaires are short and easy to complete. Furthermore, the items used in the Activity dimension were nonstandardized, which meant that patients had to choose which activities they wished to score in the Activity limitations dimension, whereas the MiniRQLQ normally employs three standardized questions to measure activity limitations. Nevertheless, both versions of the instrument have very similar psychometric properties (31), so the use of the nonstandardized version in the present study is unlikely to have significantly affected results. Finally, although the ideal approach would have been to compare the MiniRQLQ directly against the ESPRINT-15, the MiniRQLQ had not been validated for use in Spain at the time so the full RQLQ was administered, and the two short forms compared by extracting the data for the items forming the MiniRQLQ. This approach may have affected the performance of the MiniRQLQ, although its psychometric properties were similar to those observed in the original validation study (13). Nevertheless, it would be useful to compare the two short forms directly in the future.

When selecting an HRQOL instrument, various factors should be taken into account, including face validity, content validity, length, and cultural appropriateness, as well as psychometric performance. The broader scope of the ESPRINT-15, in comparison with the MiniRQLQ’s emphasis on symptoms, its specific inclusion of aspects considered important in the ARIA guidelines such as sleep, and the possibility of obtaining separate dimension scores for those aspects, as well as its likely relevance to Spanish speakers worldwide make the new instrument a noteworthy alternative to the MiniRQLQ.

In conclusion, both of the measures studied here performed well on established psychometric criteria. On the basis of these results, researchers can be confident in choosing either measure for future studies of HRQOL in AR, though they need to take into account the differences on domains covered and the target of the study in question when deciding which instrument to use. Given that the ESPRINT-15 was developed to specifically take into account the concerns of Spanish-speaking patients with AR it may be more appropriate for use in those populations than the MiniRQLQ.

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The ESPRINT Group of Investigators

Baltasar M, Hospital de Tortosa Verge de la Cinta, Tortosa, Spain; Bartra J, Serrano C, Hospital Clinic de Barcelona, Spain; Cardona V, Hospital Vall d’Hebrón, Barcelona, Spain; Castillo JA, CAP Jaume I, Vilanova i la Geltrú Barcelona, Spain; Cerda MT, Hospital Dr Josep Trueta, Valencia, Spain; Cistero A, Institut Universitari Dexeus, Barcelona, Spain; Conejero A, Hospital de la Cruz Roja, Sevilla, Spain; Davila I, Hospital Universitario, Salamanca, Spain; Escudero C, Hernandez E, Vereda A, Fundación Jimenez Díaz, Madrid, Spain; Fernandez B, Mencia J, Hospital de El Bierzo de Ponferrada, Leon, Spain; Fernández J, Hospital...
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