Validation study of the pediatric allergic rhinitis quality of life questionnaire

Antigoni Mavroudi,¹ Elisavet- Anna Chrysochoou,¹ Robert J. Boyle,² Antonis Papastergiopoulos,³ Nikolaos Karantaglis,¹ Agathi Karagiannidou,¹ Ioannis Xinias,¹ Evangelia Farmaki,³ Elpis Hatzigorous,¹ Fotios Kirvassilis,¹ Grigorios Kourentas,¹ John Tsanakas¹ and John O. Warner²

Summary

Background: The Paediatric Allergic Rhinitis Quality of Life Questionnaire (Ped-AR-QoL) is the first tool developed for the assessment of health-related quality of life (QoL) in Greek children with allergic rhinitis (AR).

Objective: The aim of the current study was to validate the child and parent forms of the Ped-AR-QoL in children aged 6-14 years-old who suffered from AR and were followed in a pediatric allergy clinic.

Methods: The Ped-AR-QoL, which was completed by 112 children and their parents, was correlated to the generic QoL questionnaire (Disabkids), which is already valid in Greece for children with chronic disorders, as well as with expert opinions on the severity of disease.

Results: The Ped-AR-QoL child and parent forms had very good internal consistency (α values of 0.797 and 0.872, respectively), while there was a moderate positive correlation of the disease-specific questionnaire with most of the subscales of the generic questionnaire. There has been a statistically significant association between the Ped-AR-QoL and the expert perception of disease severity.

Conclusions: The Ped-AR-QoL had very good reliability and convergent validity when compared with the generic Disabkids QoL. The significance of the association between the disease-specific questionnaire and the expert opinion is an important finding validating the questionnaire. The Ped-AR-QoL may become a helpful tool which can be used in everyday clinical practice by clinicians and it may also be used for assessing therapeutic interventions in clinical trials. (Asian Pac J Allergy Immunol 2016;34:159-65)

Keywords: allergic rhinitis, quality of life, children, questionnaire, validation study

Introduction

Allergic rhinitis (AR) is the most common chronic pediatric disorder. The international Study of Asthma and Allergies in childhood phase III found that the global average of current rhinoconjuctivitis symptoms in the 13-14 year age group was 14.6% on average and the average prevalence of rhinoconjuctivitis symptoms in the 6-7 year group was 8.5%.¹ Patients with allergies perceive their symptoms as causing significant disruption to their daily lives. Nasal blockage, itching, rhinorrhea and sneezing may cause severe distraction during class hours, while uncontrolled symptoms at night, leading to sleep loss, secondary daytime fatigue and sleepiness, may also contribute to learning impairment. Complications of AR like sinusitis, Eustachian tube dysfunction and associated conductive hearing loss may enhance learning dysfunction.² These children are often embarrassed at school and have diminished social interaction and consequent isolation.²,³ Multiple co-morbidities like sinusitis, asthma, conjunctivitis, eczema, Eustachian tube dysfunction, and otitis media associated with AR often remain undiagnosed and untreated, adding to the morbidity. Allergen avoidance along with pharmacotherapy is the mainstay of treatment. Medications have bothersome side effects which
cause children to resist therapy. Intranasal corticosteroids, although being the most effective form of therapy available to date, may cause adverse effects, such as dry nose, nasal stinging, mucosal crusting, throat irritation and nasal bleeding. AR in children has a significant impact on the quality of life, negatively affects the family and impairs the process of learning. The aim of the study was to develop and validate the Greek version of a Quality of Life (QoL) questionnaire, which is suitable for assessing the quality of life among 6-14-year-old children with allergic rhinitis. Currently, there is no validated specific tool for assessing allergic rhinitis QoL suitable for use in children between 6 and 14 years of age in Greece. Other published questionnaires are valid for different populations and in different age groups of children.

**Methods**

Ethical approval for this study was provided by the Ethics Committee of the Aristotle University of Thessaloniki.

**Patient and Parent sample**

One hundred and twelve children (75 boys and 37 girls) aged 6-14 years (Mean age: 10.37±2.24), with persistent allergic rhinitis, who suffered from AR symptoms more than 4 days per week, fulfilled the inclusion criteria and agreed to participate. Patients who were diagnosed with an allergy to grass pollen (Cynodon dactylon, Medow fescue, rue grass, timothy grass), tree pollen (olive, Pinus silvestris, Platanus, Cupressus), weed pollen (Cynodon dactylon, Medow fescue), mold (Alternaria alternata, Aspergillus fumigatus) and dust mite (Dermatophagoides pteronyssinus, Dermatophagoides farinae) by a pediatric allergy specialist at the clinic were invited to participate in the research study. Diagnosis was based on a detailed clinical history, a physical examination and positive skin prick tests to the relative aeroallergens. Children with asthma were not excluded from the study if they had achieved good asthma control for the previous 6 months.

With regard to the parent sample, the participants were the children's parents with AR. In 96% of cases, the questionnaires were completed by the child's mother.

**Materials**

The Pediatric Allergic Rhinitis Quality of Life Questionnaire (PedARhQoL) consists of 20 items selected to represent five health concepts (domains): symptoms, symptom duration, emotion, activities and sleep and different aspects of the experience of managing and living with allergic rhinitis. It is scored using a scale ranging from zero to three (never: 0, rarely: 1, sometimes: 2 and frequently: 3). Children indicate how much they have been bothered by allergic rhinitis symptoms, as well as the symptom duration (none: 0, less than an hour: 1, between 1-4 hours: 2, longer than 4 hours in total: 3) and frequency, i.e. how many times a symptom occurred per week (never: 0, rarely: 1, sometimes: 2 and frequently: 3). Scores ranged from 20 to 80 with a higher score indicating a poorer quality of life.

The Pediatric Allergic Rhinitis QoL Questionnaire - Parent Form (PedARhQoL PF) was completed by parents to indicate their perception of their child’s experience of allergic rhinitis. The scale is identical to the PedRhQoL Questionnaire and consists of 20 items with the focus of the questions altered from the first person to “your child”, for example “In the last two weeks how much has your child been bothered by the following symptoms”.

The Disabkids Pediatric QoL questionnaire is a 37 item self-report generic QoL scale for children. It measures the physical, emotional, social and school functioning and provides a total scale score, a the physical health summary score and a psychosocial health summary score. Children rate how often they experience things on a five point scale. Scores range from 0 to 100 with higher scores representing a poorer QoL. The scale has good reliability for total scale score, with a Cronbach’s alpha of (0.70-0.87) and has published normal data for healthy and patient populations.

The Disabkids Pediatric QoL questionnaire PF is a generic health measurement tool used to examine the physical and psychosocial functioning in children; it has been validated for parents of children aged 6-14 years. It consists of 37 items that measure functioning in a range of physical and psychosocial dimensions. It consists of 5 scales ranging from 0 (never troubled) to 5 (extremely troubled). Questions include issues concerning social activities, worries and anxieties over the previous two weeks. A higher score indicates greater burden. Internal validity has been reported to be strong (Cronbach’s α= 0.83-0.84).

Patients and their parents were asked to complete both the PAR-QL-PF and the Disabkids Pediatric QoL questionnaire (Child's and PF) after the children had been subjected to skin prick testing and were found to be allergic to various aeroallergens. The questionnaires were returned immediately at the
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end of each consultation. The questionnaires were not anonymized.

Patterns of responses were examined with respect to (a) nasal eosinophilia from mild to moderate (fewer than 5 eosinophils in the nasal smear per optic field) and severe (more than 5 eosinophils in the nasal smear per optic field), (b) Sniff Nasal Inspiratory Pressure determined by the Sniff Test (normal range: 104±26 cm H₂O in boys and 93± 23 cm H₂O in girls), (c) Mucociliary Clearance Time (normal range: 5.11±1.51 min), as assessed by a Research Associate of the Pediatric Allergy Clinic, and (d) the clinician’s perception of disease severity (mild, moderate or severe).

Procedure
The study was conducted from September 2009 to July 2014 at the Pediatric Allergy Clinic, 3rd Department of Pediatrics, Aristotle University of Thessaloniki. Participants had not received any treatment for their rhinitis and were asked to complete the same questionnaires before and after receiving a two month treatment with intranasal fluticasone propionate to investigate test-retest reliability. The washout period was four days. All patients underwent the following clinical assessment before and after treatment: 1) Nasal smear eosinophilia, 2) Determination of Sniff Nasal Inspiratory Pressure (PNIFR), 3) Determination of Mucociliary Clearance Time (MCT), and 4) The clinician’s perception regarding the severity of the disease, who was blinded to QoL scores before and after treatment.

Data analysis
Data analysis was conducted using SPSS version 21.0 (IBM Inc. Armonk, NY). All tests were 2-tailed with a significance level set at alpha=0.05. Reliability analysis was applied to the PedARhQoL and the Disabkids Pediatric QoL questionnaire. Internal consistency was assessed through the Cronbach’s alpha coefficient and the Guttman split-half coefficient. Pearson’s bivariate correlations were calculated between scores measured on a continuous scale to assess convergent validity. Intraclass correlations were calculated to assess the temporal stability of the scale. We expected a Cronbach’s alpha of >0.7 and <0.9. Following Cohen’s conventions to interpret effect sizes for correlations, we expected moderate convergent validity correlations of >0.3 with subscales measuring similar aspects of the scale, including the effects in regards to patient’s time, emotions, activities and general health. Between subjects, t-tests were performed to assess the discriminative validity of PedARhQoL and the PedARhQoL PF, by comparing AR demographic characteristics.

Results
Patient sample
Reliability and consistency over time of the PedARhQoL
The PedARhQoL had very good internal consistency with a Cronbach’s alpha of 0.797 and Guttman split-half coefficient of 0.735 at time point one and very good internal consistency with a Cronbach’s alpha of 0.837 and Guttman split-half coefficient of 0.722 at time point two. There was a moderate intraclass correlation between the responses to both questionnaires in the two time points (ICC = 0.43). There was a statistically significant difference between the means at time point one (mean = 37.5, SD = 7.4) and at time point two (mean = 30.9, SD = 7.6), (t (111) = 7.071, p < 0.001). There was a statistically significant difference between the mean scores of the two questionnaires at time point one (mean = 37.0 ± SD = 8.4) and time point two (mean = 30.9 ± SD = 7.6), (t (111) = 7.071, p < 0.001).

Convergent validity
The PedARhQoL correlated moderately well with the Disabkids Pediatric QoL total QoL score in the two time points with Pearson’s coefficient: r = 0.480 (p < 0.001) at time point one and r = 0.336 (p < 0.001) at time point two. The PedARhQoL at time point one was moderately correlated before and after treatment with the following QoL subclasses, i.e. on a typical day, the emotional and social QoL. There has been a low positive correlation with QoL related to drug use. The PedARhQoL had low negative correlation with QoL in general and low negative correlation with QoL related to friendship (Table 1).

Discriminative validity
There was no correlation of the PedARhQoL scores with the child’s age at time point one (p = 0.480 (p < 0.001) at time point one and r = 0.336 (p < 0.001) at time point two. The PedARhQoL at time point one was moderately correlated before and after treatment with the following QoL subclasses, i.e. on a typical day, the emotional and social QoL. There has been a low positive correlation with QoL related to drug use. The PedARhQoL had low negative correlation with QoL in general and low negative correlation with QoL related to friendship (Table 1).

Parent sample
Reliability of the PedARhQoL PF
The PedARhQoL PF had very good internal consistency with a Cronbach’s alpha of 0.872 and a
Guttman split-half coefficient of 0.774 at time point one and very good internal consistency with a Cronbach’s alpha of 0.895 and Guttman split-half coefficient of 0.723 at time point two. The interclass correlation between responses to both questionnaires in the two time points was (ICC = 0.246). There was a statistically significant difference between the means at time point one (mean = 40.6 ± SD = 9.8) and time point two (mean = 32.9 ± SD = 9.1), (t (111) = 6.734, p < 0.001).

Convergent validity of the PedARhQoL PF
The PedARhQoL PF correlated moderately well with the Disabkids Pediatric QoL Parent Form (PF) total QoL score at the two time points with Pearson’s coefficient r = 0.533 (p < 0.001) at time point one and r = 0.361 (p < 0.001) at time point two. The PedARhQoL PF was moderately correlated before and after treatment with the following QoL subscales, i.e. on a typical day, the emotional QoL and social QoL. The PedARhQoL PF had a moderate negative correlation with the generic QoL, while there has been a low positive correlation with the QoL related to drug usage and a low negative correlation with the QoL related to friendship.

Discriminative validity of the PedARhQoL PF
There was no correlation of the PedARhQoL PF scores with the child’s age at time point one (p = 0.134) and time point two (p = 0.954). There was also no correlation of the PedARhQoL PF scores with the child’s sex at time point one (p = 0.476) and time point two (p = 0.851).

Patient Sample–Correlation with objective measurements (Nasal smear eosinophilia correlation-Mucociliary Clearance Time-Sniff Test) and expert’s opinion
The Pearson’s correlation coefficient between the PedARhQoL questionnaire and the variables PNIFR, MCT, Nasal eosinophilia at the two time points was not statistically significant.

Paired T-tests were performed to assess differences between mean values regarding the variables PNIFR, MCT and nasal eosinophilia before and after treatment. There was no statistically significant difference between the means at time point one and time point two with regard to PNIFR. There was a statistically significant difference between the means regarding the MCT at the time point one (mean =15.71 ± 11.892) and at time point two (mean = 11.71 ±9.316), (t (111) = 3.803, p < 0.001). There was a statistically significant difference regarding nasal eosinophilia between the means at the time point one (mean = 6.12 ± SD = 11.138) and time point two (mean=1.89±3.908), (t (111) = 4.033, p < 0.001).

However, there was a statistically significant difference in the means of PedARhQoL questionnaire scores according to the doctor’s opinion on disease severity before and after treatment (Table 3).

Parent Sample–Correlation with objective measurements (Nasal smear eosinophilia correlation-Mucociliary Clearance Time-Sniff Test) and expert’s opinion
The Pearson correlation coefficient did not show any significant relationship between the PedARhQoL PF and the variables PNIFR, MCT, and nasal eosinophilia at the two time points.

There was a statistically significant difference in the means of the PedARhQoL PF scores according to the doctor’s opinion on disease severity before and after treatment (Table 4).

### Table 1. Association of the PedARhQoL (child’s form) with the subscales of the generic QoL (Disabkids) for children with chronic diseases before and after treatment.

<table>
<thead>
<tr>
<th>Subscales of the Disabkids questionnaire</th>
<th>Pearson’s coefficient before treatment</th>
<th>Significance</th>
<th>Pearson’s coefficient after treatment</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>QoL on a typical day</td>
<td>r = 0.536</td>
<td>p &lt; 0.001</td>
<td>r = 0.446</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>Emotional QoL</td>
<td>r = 0.467</td>
<td>p &lt; 0.001</td>
<td>r = 0.409</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>QoL in relation to friendship</td>
<td>r = 0.373</td>
<td>p &lt; 0.001</td>
<td>r = 0.507</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>QoL regarding drug usage</td>
<td>r = 0.255</td>
<td>p = 0.005</td>
<td>r = 0.252</td>
<td>p &lt; 0.007</td>
</tr>
</tbody>
</table>
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Discussion

The PedARhQoL Child’s Form and PF are disease-specific QoL scales specifically designed for children with allergic rhinitis. The present study has demonstrated that they have very good reliability in children recruited from a specific allergy clinic and good convergent validity when correlated with most of the Disabkids subscales. However, these correlations were not very strong, reflecting the generic nature of the Disabkids QoL. These generic questionnaires are sensitive to factors that are likely to be more strongly influenced by non-AR events and comorbidities.

The discriminative validity of the PedARhQoL and PedARhQoL PF did not correlate with children’s age or sex, indicating that the patients and their parents did not report a better QoL based on age or sex. There was no association between the PedARhQoL and PedARhQoL PF and the variables PNIFR, MCT and nasal eosinophilia, as these tests are not sensitive or specific for AR. The previous results indicate a poor association between subjective and objective measures of allergic rhinitis, as found by other investigators. Therefore, poor results in those measurements do not correlate with severe AR symptoms and consequently with a burden on QoL.

Unexpectedly, the PedARhQoL and PedARhQoL PF did not correlate with the subscale of generic QoL, which may be because stable patients with allergic rhinitis are usually treated as outpatients, unlike other children with chronic diseases, who may require hospitalized management. Several studies have documented that allergic rhinitis-related symptoms have caused most discomfort to patients and have deteriorated QoL in general. In this study, our group of patients did not perceive the particular AR-related symptoms as a significant problem deteriorating QoL in general. In keeping with previous studies, this suggests that disease-specific QoL measures are more sensitive to changes in disease severity than generic QoL measures.

Meltzer reported that nasal symptoms in children and practical matters may bother school colleagues and cause embarrassment and labeling. The patient group taking part in our study did not report social isolation or an impact on relationships with friends due to AR. Patient scores were also low regarding the use of medications, indicating that there was no significant burden on their quality of life due to the drugs used for treating AR symptoms.

Table 2. Association of the PedARhQoL (PF) with the subscales of the generic QoL (Disabkids) for children with chronic diseases before and after treatment

<table>
<thead>
<tr>
<th>Subscales of the Disabkids questionnaire</th>
<th>Pearson’s coefficient before treatment</th>
<th>Significance</th>
<th>Pearson’s coefficient after treatment</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>QoL on a typical day</td>
<td>r = 0.394</td>
<td>p &lt; 0.001</td>
<td>r = 0.354</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>Emotional QoL</td>
<td>r = 0.521</td>
<td>p &lt; 0.001</td>
<td>r = 0.370</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>QoL in relation to friendship</td>
<td>r = 0.487</td>
<td>p &lt; 0.001</td>
<td>r = 0.386</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>QoL regarding drug usage</td>
<td>r = 0.416</td>
<td>p &lt; 0.001</td>
<td>r = 0.294</td>
<td>p = 0.002</td>
</tr>
</tbody>
</table>

Table 3. Association of the PedARhQoL scores (child’s form) with the expert’s perception of disease severity before and after treatment. (One-way ANOVA used with Bonferroni correction for post-hoc)

<table>
<thead>
<tr>
<th>Severity of AR based on the expert’s opinion</th>
<th>Mean score of the PedARhQoL before treatment (mean±sd)</th>
<th>Significance</th>
<th>Mean score of the PedARhQoL after treatment (mean±sd)</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
<td>30.7± 5.4</td>
<td>P &lt; 0.001</td>
<td>28.4 ± 5.2</td>
<td>P = 0.108</td>
</tr>
<tr>
<td>Moderate</td>
<td>38.3± 7.4</td>
<td>P &lt; 0.001</td>
<td>31.66 ± 7.96</td>
<td>P = 0.043</td>
</tr>
<tr>
<td>Severe</td>
<td>45.1± 8.8</td>
<td>P &lt; 0.003</td>
<td>35.6 ± 10.7</td>
<td>P &lt; 0.043</td>
</tr>
</tbody>
</table>
Nasal congestion is known to be prevalent and bothersome in an AR population. In a survey, including 500 children diagnosed with AR, nasal congestion was identified as the most frequently experienced nasal allergy symptom and was said to occur either every day (25%) or on most days (27%) each week during their worst month for allergy symptoms.6 Parents of children with AR also most frequently (27%) identified congestion as the most bothersome symptom.16 A survey of 2355 individuals included 460 who were primary caregivers of children suffering from AR; of these, 63% identified congestion as the symptom their children most wanted to prevent and the symptom that was most likely to trigger a visit to a physician (69%).17 In this study, 42% of children diagnosed with AR reported that nasal congestion affected a lot their everyday life, while 30% reported that their everyday life was moderately affected. In addition, 27.4% of caregivers reported moderate and 65.5% severe burden regarding their child’s everyday life, due to nasal congestion. In terms of objective measurements, low PNIFR scores indicating higher degree of obstruction did not correlate with impaired QoL.

Eosinophils are the principal effector cells involved in the pathogenesis of allergic inflammation. A study detecting eosinophilia of the nasal smear examination in patients with AR reported that the sensitivity, specificity, positive predictive value, and negative predictive value of this test were 74, 90, 88, and 77%, respectively.18 In this study, eosinophilia of the nasal smear did not correlate with high scores of the PedARhQoL and PedARhQoL PF, indicating impaired QoL.

Disturbances in nasal mucociliary clearance function are clearly a more common cause of long-term respiratory disease, nasal infection, sinusitis, rhinitis, and otitis media than are presently recognized.19 In this study, mucociliary clearance was assessed by the saccharin test. The saccharin test for nasal mucociliary clearance can be performed in the office, but has limited utility as a screening test for ciliary dyskinesis. It cannot be relied upon for a definite diagnosis of nasal ciliary dyskinesis but may be useful in diagnosing and following the resolution of secondary nasal ciliary dysfunction.20 In our study, prolonged MCT did not correlate with high scores for the PedARhQoL and PedARhQoL PF, indicating impaired QoL.

The expert’s classification of allergic rhinitis, when evaluating each patient, was based on the ARIA classification of AR. In the ARIA classification, allergic rhinitis can be classified as “mild” or “moderate/severe” depending on the severity of the symptoms and their impact on social life, school and work. According to ARIA, moderate or severe AR means that one or more of the following items are present: 1) sleep disturbance, 2) impairment of daily activities, leisure and/or sport, 3) impairment of school or work, and 4) troublesome symptoms. According to ARIA, mild AR means that none of the previous items are present.4 There was a statistically significant association between the PedARhQoL and PedARhQoL PF and the doctor’s perception of disease severity. The previous association shows that the scores for the questionnaires for both patients and their parents were low, moderate or high for mild, moderate and severe rhinitis, respectively, based on the doctor’s opinion.

Some studies demonstrate that the severity of rhinitis is a risk factor for asthma, irrespective of the presence of allergy.21 Many of the children recruited in this study who were diagnosed with rhinitis also had asthma (38.39%). However, children with asthma were included in the study if they had achieved good asthma control for the previous 6 months. Therefore, our patient group did not have a significant burden, deteriorating health in general.
In conclusion, the PedARhQoL and the PedARhQoL PF had very good reliability and convergent validity when compared with the generic Disabkids QoL. The discriminative validity of the PedARhQoL and PedARhQoL PF did not correlate with children’s age or sex. There was no association between the PedARhQoL and PedARhQoL PF and the variables PNIFR, MCT and nasal eosinophilia, in keeping with previous findings that subjective and objective measures of AR severity are not closely correlated. There was a statistically significant association between the PedARhQoL and PedARhQoL PF and the doctor’s perception of disease severity, indicating that the questionnaire is a helpful tool which may be used in everyday clinical practice in order to evaluate the severity of AR.

Conflicts of interest
The authors report no financial or other conflict of interest relevant to the subject of this article.

References