

Validation of the Spanish Version of the Food Allergy Quality of Life Questionnaire—Adult Form (S-FAQLQ-AF)

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■ Abstract

Introduction: Specific food allergy quality of life questionnaires have been developed within the context of the EuroPrevall project. We aimed to adapt and validate the Food Allergy Quality of Life Questionnaire-Adult Form (FAQLQ-AF) in the Spanish language.

Methods: The original English questionnaire was translated and culturally adapted into Spanish following World Health Organization guidelines. The final Spanish version of the FAQLQ-AF (S-FAQLQ-AF) was approved by the original authors. Consecutive patients (≥ 18 years old) who fulfilled the following criteria were recruited: 1) diagnosis of food allergy defined as immediate allergic symptoms and a positive prick test or IgE against the culprit food(s) and 2) physician-assessed ability to complete the questionnaires. Patients completed the S-FAQLQ-AF and a Spanish version of the SF-12 questionnaire. Reliability was assessed 10 to 14 days after completion of the first questionnaire.

Results: Eighty-two consecutive outpatients were recruited and cross-sectional validity was assessed based on the correlation between the S-FAQLQ-AF and the Food Allergy Independent Measure (FAIM) in this population ($\rho=0.83$, $P<.0001$). The S-FAQLQ-AF showed excellent internal consistency (Cronbach α , 0.95). S-FAQLQ-AF domains also had excellent internal consistency: $\alpha=0.93$ for allergen avoidance-dietary restrictions; $\alpha=0.83$ for emotional impact; $\alpha=0.85$ for risk of accidental exposure, and $\alpha=0.66$ for food allergy related health. Limited correlation was found between the S-FAQLQ-AF and the SF-12.

Conclusion: The S-FAQLQ-AF is a valid, short, easy-to-use, and reliable instrument that discriminates between patients with different atopic phenotypes and is suitable for assessing the impact of IgE-mediated food allergy on patient quality of life.

Key words: Quality of life. Food allergy. Questionnaire. Specific questionnaire. Health-related quality of life. HRQL. Anaphylaxis.

■ Resumen

Introducción: Se evalúa el impacto de la alergia alimentaria sobre la calidad de vida, mediante cuestionarios específicos integrado en el proyecto EuroPrevall. Validar y adaptar a lengua castellana el cuestionario FAQLQ-AF.

Material y métodos: La traducción y adaptación cultural del cuestionario original se realizó siguiendo recomendaciones de la OMS. Los autores del cuestionario original aceptaron la versión en lengua castellana del FAQLQ-AF (S-FAQLQ-AF). Los pacientes fueron incluidos siguiendo los siguientes criterios: (1) Síntomas alérgicos tras ingesta de un alimento y prick test positivos o IgE frente al alimento implicado, (2) Un médico evaluó la capacidad de los pacientes para completar los cuestionarios (S-FAQLQ-AF y el genérico SF-12). Para explorar la

fiabilidad de las respuestas entre 10 y 14 días después de rellenar el primer cuestionario, los pacientes rellenaban de nuevo el S-FAQLQ-AF con preguntas en distinto orden.

Resultados: Ochenta y dos pacientes (≥ 18 años) fueron incluidos. La validez de constructo fue evaluada a partir de la correlación entre el S-FAQLQ-AF y el FAIM (Medida Independiente de la Alergia a Alimentos ($\rho = 0.83$, $p < .0001$). El cuestionario S-FAQLQ-AF (Cronbach- $\alpha = 0.95$) y sus diferentes dominios mostraron excelente consistencia interna: Evitación de alérgenos ($\alpha = 0.93$); impacto emocional ($\alpha = 0.83$), riesgo de exposición accidental ($\alpha = 0.85$) y salud relacionada con alergia alimentaria ($\alpha = 0.66$). No se halló correlación entre el S-FAQLQ-AF y el cuestionario SF-12.

Conclusión: La versión Española del cuestionario de adultos FAQLQ-AF es una herramienta válida, fiable, fácil de usar, rápida de completar y sensible al cambio, discriminando pacientes con diferentes fenotipos atópicos, para evaluar el impacto de la alergia alimentaria en la calidad de vida.

Palabras clave: Calidad de vida. Alergia a alimentos. Cuestionarios. Cuestionarios específicos. Calidad de vida relacionada con la salud. CVRS. Anafilaxia.

Introduction

Food allergy has increased in developed countries and can have a dramatic effect on quality of life and even cause fatal reactions [1-5]. Strict avoidance of the culprit food(s) and use of emergency medications are currently the main management tools for food allergy [4,6]. New approaches such as specific oral tolerance induction and the use of monoclonal antibodies seem promising [3].

Food-allergic patients need to be constantly alert as to what they are eating, handling, or, in certain situations, even breathing [7,8], and this constant threat of exposure and need for vigilance can have a tremendous impact on their quality of life [7-10]. Several studies have analyzed the impact of food allergy on health-related quality of life (HRQOL) in adults and children in different countries, but no specific questionnaires have yet been developed and validated in the Spanish language [7-10]. Spain, with a population of 47 million people, has certain cultural, socioeconomic, linguistic, and culinary aspects that set it aside from other European countries [6]. Therefore, both the cultural and linguistic adaptation and validation of the original Food Allergy Quality of Life Questionnaire-Adult Form (FAQLQ-AF) in Spanish seems desirable in order to assess the impact of food allergy on the quality of life of Spanish patients. It could also be useful for millions of Spanish-speaking individuals worldwide.

The FAQLQ-AF is available for adults and was developed and validated in the context of the EuroPrevall Project, a multicenter European food allergy research project whose objectives include analyzing the impact of food allergies on quality of life. It is currently available in Dutch and English [7-11].

In this article, we report the adaptation and cross-sectional validation of the first disease-specific HRQOL questionnaire for adults with food allergy in Spanish, namely the Spanish Food Allergy Quality of Life Questionnaire-Adult Form (S-FAQLQ-AF).

Methods

Participants and Procedure

Patients aged 18 years or older with a physician-diagnosed food allergy were recruited at our outpatient allergy clinic

at Hospital Universitario Ramón y Cajal in Madrid, Spain. All patients fulfilled the following criteria: 1) diagnosis of food allergy, defined as immediate allergic symptoms and positive prick test or IgE to the culprit food(s) and 2) ability to complete the questionnaires as assessed by a physician. The validation of the S-FAQLQ-AF was performed in Spanish. The original FAQLQ-AF and Food Allergy Independent Measure (FAIM) were translated into Spanish following World Health Organization guidelines [12]. The final Spanish version of the FAQLQ-AF (S-FAQLQ-AF) was approved by the original authors. The Spanish version of the FAQLQ-AF can be found at <http://www.seaic.org/wp-content/plugins/download-monitor/download.php?id=FAQLQ-AF1-29.pdf>.

Prior to cross-sectional validation, the questionnaire was piloted in several patients recruited from the Spanish Food and Latex Allergy Association, AEPNAA. Following this pilot stage, which revealed no major problems, the S-FAQLQ-AF, the FAIM, and the SF-12, a generic quality of life questionnaire that constitutes the short form of the SF-36 [8-11,12-15], were distributed to 82 food-allergic patients at our outpatient clinic at Hospital Universitario Ramón y Cajal. The following descriptive characteristics were recorded: age, sex, type and number of food allergies, type of symptoms, and diagnosis. The study was approved by the hospital's medical ethics committee, and all patients completed the questionnaires after giving written informed consent.

Cross-Sectional Validation

Construct Validity

The construct validity of HRQOL questionnaires is generally evaluated through comparison with an objective measurement or tool that characterizes the extent or severity of the particular disease being assessed [7]. Prior to the development of the FAIM, no appropriate independent measure was available for this purpose. The FAIM comprises 6 questions (4 expectation of outcome questions and 2 independent measure items) and has been shown to be valid, relevant, and reliable in adults, adolescents, and children. Thus, in order to investigate the construct validity of the S-FAQLQ-AF, we calculated the correlation coefficients between the S-FAQLQ-AF and the FAIM [11,13,15].

Convergent and Discriminant Validity

Construct validity was further investigated by convergent validity (using the Spanish version of the SF-12 v2.0) and discriminant validity.

Discriminative Ability

To investigate the discriminative ability of the S-FAQLQ-AF, we compared the total S-FAQLQ-AF score between patients who reported anaphylaxis (≥ 2 of the following systemic symptoms: dizziness, palpitations, loss of vision, inability to stand, light headedness, collapse, loss of consciousness) and those who did not, between men and women, and between patients who reported many food allergies and those who reported few. We investigated which cutoff in terms of number of reported food allergies revealed a significant difference in the total S-FAQLQ-AF score [11,15-19].

Reliability

The test-retest reliability of the S-FAQLQ-AF was assessed by administering 2 versions of the questionnaire containing the same questions but in a different order 10 to 14 days apart [7,9-11,17].

Statistical Analyses

The raw S-FAQLQ-AF and FAIM scores 0 to 6 were recoded as 1 to 7 to facilitate statistical analyses. The total S-FAQLQ-AF score is the mean score of all items with a range of 1 (no impairment) to 7 (maximal impairment).

Cross-sectional validity was assessed by calculating Spearman correlation coefficients between the S-FAQLQ-AF and the FAIM (individual S-FAQLQ-AF items with individual FAIM items, individual S-FAQLQ-AF items with mean FAIM, total S-FAQLQ-AF score with mean FAIM, and total S-FAQLQ-AF score with individual FAIM items) [7,13,15,17,20,21].

Internal consistency was measured by calculating Cronbach α , with a value of 0.70 or higher considered acceptable [7,11,13,16-24]. Convergent and discriminant validity was assessed by calculating Spearman correlation coefficients between the S-FAQLQ-AF and the SF-12 scales.

Discriminative ability was measured using the Mann-Whitney U test. Test-retest reliability was assessed by calculating the intraclass correlation coefficient.

Results

Cross-Sectional Validation

Eighty-two patients were recruited from our clinic. They all had a food allergy confirmed by a compatible clinical history and IgE and/or a positive skin prick test to the culprit food between January 2007 and January 2008. A wide range of food allergies were represented, including all the most common allergies, as was the full spectrum of severity of reactions (from mild to severe).

The S-FAQLQ-AF, the FAIM, and the SF-12 were returned by all 82 adults (response rate, 100%). Thus, 82 questionnaires were assessable for the cross-sectional validation.

There were no significant differences between men ($n=26$) and women ($n=56$) in the descriptive analysis. The mean (SD) age of the sample was 31.4 (13.7) years. The most frequent culprit foods were fruits, nuts, fish, shellfish, and vegetables. Thirty-eight patients had 1 food allergy and 44 had 2 or more. The most common symptoms were respiratory (82% of patients) and cutaneous (67% of patients). Cardiovascular and gastrointestinal symptoms were less common.

Construct Validity

All items on the S-FAQLQ-AF correlated significantly with at least 1 of the FAIM questions and they all correlated significantly with the mean of the FAIM questions. The total S-FAQLQ-AF score correlated significantly with the mean FAIM ($\rho=0.95$, $P<.001$) and with the individual FAIM questions (Table).

Domain Structure and Internal Consistency

The items were grouped into 4 domains: allergen avoidance and dietary restrictions, emotional impact, risk of accidental exposure, and food allergy related health (FAH). The S-FAQLQ-AF and the domains had good or excellent internal consistency (Cronbach $\alpha > 0.70$) (Table).

Table. Domain Structure and Internal Consistency

| Variables | Minimum | Maximum | Mean (SD) | Cronbach α | Intraclass Correlation |
|------------------|---------|---------|-------------|-------------------|------------------------|
| Mean FAIM_AF | 1.50 | 6.33 | 3.59 (1.18) | 0.77 | 0.353 ($P<.0001$) |
| Mean S- FAQLQ-AF | 1.76 | 6.39 | 4.52 (1.25) | 0.95 | 0.83 ($P<.0001$) |
| FAQLQ_AADR | 1.00 | 6.64 | 4.10 (1.49) | 0.93 | 0.53 ($P<.0001$) |
| FAQLQ_EI | 1.86 | 6.86 | 4.89 (1.23) | 0.83 | 0.407 ($P<.0001$) |
| FAQLQ_RAE | 1.00 | 6.88 | 4.37 (1.46) | 0.85 | 0.422 ($P<.0001$) |
| FAQLQ_FAH | 2.67 | 7.00 | 5.58 (1.20) | 0.66 | 0.390 ($P<.0001$) |

Abbreviations: AADR, allergen avoidance and dietary restrictions; AF, Adult form; EI, emotional impact; FAH, food allergy related health; FAIM, Food Allergy Independent Measure; FAQLQ, Food Allergy Quality of Life Questionnaire; RAE, risk of accidental exposure; S-, Spanish.

Convergent and Discriminant Validity

The total S-FAQLQ-AF score was weakly and nonsignificantly correlated with the SF-12 scales (Spearman correlation coefficient for S-FAQLQ-AF and SF-12 mental health domain, -0.17 and SF-12 physical health domain, -0.04).

Discriminative Ability

Patients who had reported anaphylaxis (cardiovascular symptoms) tended to have worse HRQOL (higher S-FAQLQ-AF score) than those who had not (total S-FAQLQ-AF score 4.7 vs 4.45, $P=.06$). In addition, total S-FAQLQ-AF score was significantly higher in patients who reported more than 1 allergy (3.54 vs 2.88, $P=.04$). HRQOL impairment did not differ significantly between men and women (total S-FAQLQ-AF score 4.15 vs 4.69; $P=.06$) or between patients with different atopic conditions, such as rhinoconjunctivitis (4.72 vs 4.44; $P=.4$), asthma (4.38 vs 4.64, $P=.4$), atopic dermatitis (4.79 vs 4.50, $P=.6$), and drug hypersensitivity (4.73 vs 4.51, $P=.7$).

Reliability

The total S-FAQLQ-AF score intraclass correlation coefficient was 0.83 (95% $P<.0001$), indicating excellent test-retest reliability.

Discussion

We have reported on the cultural and linguistic adaptation and cross-sectional validation of the first disease-specific HRQOL questionnaire for adults with food allergy in Spanish, the S-FAQLQ-AF [11].

Our analysis demonstrates that the S-FAQLQ-AF has good construct validity and excellent internal consistency for measuring the impact of food allergy on quality of life. Moreover, it discriminates between patients with and without anaphylaxis, between patients who differ in number of food allergies, between difference levels of disease severity, and between different levels of patient education [23–28]. Finally, the S-FAQLQ-AF showed convergent/discriminant validity. Considering that Spanish is spoken by around 500 million people worldwide and that food allergy is a growing problem with a major impact on patient quality of life, it can be safely said there is a real need for a disease-specific HRQOL questionnaire to assess Spanish-speaking food-allergic adults. Moreover, validation in other cultural settings where Spanish is spoken is now possible, highlighting even further the importance of the S-FAQLQ-AF.

Overall, the content of the S-FAQLQ-AF considers the pivotal aspects that food-allergic patients have to cope with in their daily life and that interfere with their quality of life. These issues constitute important objectives for governments, healthcare providers, industries, etc., in terms of enhancing quality of life through targeted interventions.

Total S-FAQLQ-AF score was weakly correlated with the SF-12 mental health scale, and the correlations with the other SF-12 scales were not significant. This was expected as the S-FAQLQ-AF is a disease-specific questionnaire, whereas

the SF-12 is a generic questionnaire (discriminant validity). The domains of the S-FAQLQ-AF showed weak correlation with a few SF-12 scales. As expected, most correlations were found for the FAH domain, as this is the most general domain of the disease-specific S-FAQLQ-AF (convergent validity).

Patients who reported anaphylaxis tended to have more severely impaired quality of life than patients who did not. The difference in total S-FAQLQ-AF score between these 2 groups was 0.36, so it did not reach the minimal importance difference (MID) of approximately 0.5 proposed for HRQOL questionnaires in the literature [21]. Although this MID is a robust estimate for HRQOL questionnaires with a 7-point scale [21], the specific MID of the S-FAQLQ-AF remains to be estimated in a longitudinal survey. The difference in total S-FAQLQ-AF score for patients who reported more than 1 food allergy compared with patients who reported just 1 food allergy was 0.66 ($P<.05$), which exceeded the MID, indicating significantly greater HRQOL impairment in patients with more allergies.

The higher total S-FAQLQ-AF mean score in patients who had experienced food-induced anaphylaxis and a comparison of these results with those from children and adolescents suggest that as individuals age, they probably become more aware of the severity of symptoms and of the potential dangers of food allergy [22].

We observed a trend, albeit insignificant, towards poorer quality of life in patients who had experienced anaphylaxis (total S-FAQLQ-AF score 4.7 vs 4.45 in those who had not experienced anaphylaxis; $P=.06$). The lack of a significant difference may be due to factors inherent to our sample or to the fact that a large sample might be needed to detect significant differences in patients with a high mean level of HRQOL impairment. Further studies with larger series of patients may provide a clearer picture.

The S-FAQLQ-AF was meticulously translated into English using the guidelines of the World Health Organization [12] and the questionnaire was adapted and validated in Spanish. Our study, though, may have certain limitations. While the validity of the English-language version of the questionnaire has been proven and the questionnaire is a suitable and important instrument for the assessment of quality of life in food allergy [1,7–11,13,17,18,27,32–34], as stated earlier, cultural differences may influence the ability of the questionnaire to identify essential items for food-allergic patients in Spanish-speaking countries or regions outside Spain due to different cultural, culinary and/or socioeconomic settings [7,33,34].

In summary, we have reported on the cultural and linguistic validation of the first Spanish-language disease-specific HRQOL questionnaire for food-allergic adults: the S-FAQLQ-AF. The questionnaire shows excellent measurement properties, discriminates between different severities of allergic reactions, and is short and easy to use. It seems to be a promising instrument to evaluate the effect of treatments, such as food immunotherapy, monoclonal antibody therapy, and interventional measures such as specific avoidance measures [7,34,35]. The S-FAQLQ-AF complements existing food allergy questionnaires for children, adolescents, parents, and adults [1,3,7–11,15,18,20, 22,23,27,33,34].

The S-FAQLQ-AF is therefore suitable for the assessment of the quality of life of Spanish-speaking food-allergic adults,

whose characteristics, culture, culinary habits, socioeconomic situation, and expectations may differ from the population for which the English version of the questionnaire was developed [7,27].

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Conflicts of Interest

The authors declare that they have no conflicts of interest.

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