ORIGINAL ARTICLE

Validation of the Spanish Version of the Food Allergy Quality of Life Questionnaire-Parent Form (S-FAQLQ-PF)

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Abstract

Background: Food allergy is an emerging health problem. Several questionnaires can be used to establish health-related quality of life (HRQOL) in food allergy patients. Current questionnaires should be translated in such a way that they take account of the culture of the country in which they are to be used.
Objective: To translate and perform a cross-sectional validation of the Food Allergy Quality of Life Questionnaire-Parent Form (FAQLQ-PF).
Methods: The parents of 54 children diagnosed with food allergy were recruited to assess the Spanish version of the FAQLQ-PF (S-FQLQ-PF).
Results: The S-FQLQ-PF was translated into Spanish according to WHO guidelines (including a forward-backward translation). The statistical analysis showed that feasibility, reliability, and internal consistency were very good for the global S-FAQLQ-PF score and for the different domains. Assessment of construct validity indicated that S-FAQLQ-PF has reduced capacity for measurement of HRQOL in younger children. Cross-sectional validation of the S-FAQLQ-PF demonstrated that HRQOL of a Spanish pediatric population was affected by patient age, severity of symptoms, and number of reactions. HRQOL was not affected by sex, food implicated, number of foods implicated, ingestion of the implicated food, or presence of anaphylaxis.
Conclusion: Translation into Spanish and cultural validation of the FAQLQ-PF demonstrated the influence of factors, such as patient age, severity of symptoms, and number of reactions on the HRQOL of a pediatric Spanish population.

Key words: Allergy. Food allergy. Quality of life. Questionnaire. Spanish. Validation.

Resumen

Introducción: La alergia a alimentos se ha convertido en un problema de salud en aumento en los últimos años. Existen múltiples cuestionarios que sirven para establecer el nivel de calidad de vida en los pacientes alérgicos a alimentos. Es importante realizar adaptaciones lingüísticas y culturares de los cuestionarios existentes a todos los idiomas.
Objetivo: Realizar una adaptación lingüística y cultural al español así como una validación transversal del cuestionario Food Allergy Quality of Life Questionnaire-Parent Form (FAQLQ-PF).
Métodos: Los padres de 54 pacientes diagnosticados de alergia a alimentos fueron reclutados para llevar a cabo la adaptación lingüística y cultural al español del cuestionario FAQLQ-PF.

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Resultados: Se realizó la traducción al español del cuestionario FAQLQ-PF (S-FAQLQ-PF) de acuerdo a las guías de la OMS. El análisis estadístico demostró que la viabilidad, fiabilidad y la consistencia interna era buena tanto para los resultados globales del S-FAQLQ-PF como para los diferentes dominios del mismo. La validez de constructo fue evaluada y los resultados sugieren que el S-FAQLQ-PF presenta peor capacidad para medir la calidad de vida en los niños de menor edad (0-3 años). Finalmente, la validación transversal del S-FAQLQ-PF ha demostrado que la edad de los pacientes, la gravedad de los síntomas o el número de reacciones sufridas afectan a la calidad de vida en una población pediátrica española, mientras que el género, el tipo o el número de alimentos, la presencia de anafilaxia y las transgresiones dietéticas no la afectan.

Conclusiones: Presentamos la adaptación lingüística y cultural al español del cuestionario de vida específico para alergia a alimentos S-FAQLQ-PF. Esta adaptación se ha utilizado para demostrar la influencia de diferentes factores, como la edad de los pacientes, la gravedad de los síntomas o el número de reacciones sufridas en la calidad de vida de una población pediátrica española.

Palabras clave: Alergia. Alergia a alimentos. Calidad de vida. Cuestionario. Español. Validación.

Introduction

Food allergy is an emerging health problem, with an alarming increase in prevalence, especially among children in developed countries [1]. Food allergy is characterized by clinical features, such as cutaneous, respiratory, and gastrointestinal symptoms, some of which can even progress to a fatal reaction [2]. Consequently, food allergy affects the health-related quality of life (HRQOL) not only of patients, but also of their families and caregivers [3,4].

HRQOL may be the only significant outcome measure that enables us to assess the burden of food allergy; therefore, specific questionnaires have been developed in recent years. Ideally, questionnaires should be short and easy to complete so that they can become a useful tool in clinical practice. Many different questionnaires can be used to establish HRQOL in food-allergic patients. Since HRQOL differs with patient age, it is important to develop specific questionnaires for different age groups. Recently developed specific questionnaires for children are generally completed by parents [5,6], although some are completed by the children themselves [7,8]. In Europe, Food Allergy Quality of Life Questionnaires (FAQLQ) are probably the most widely used tools in children. These questionnaires were developed and validated in Europe as a part of the EuroPrevall Project and include versions for children from 0 to 18 years old and for their parents [5,7,8]. Current questionnaires should be translated in such a way that they take account of the culture and socioeconomic reality of the country in which they are to be used [9,10].

Therefore, the aim of this study was to perform translate the first disease-specific HRQOL questionnaire for children with food allergy—the Food Allergy Quality of Life Questionnaire-Parent Form (FAQLQ-PF)—into Spanish and perform a cross-sectional validation.

Methods

Questionnaires

Our study was based on 2 questionnaires: the aforementioned Food Allergy Quality of Life Questionnaire-Parent Form translated into Spanish (S-FAQLQ-PF) and the Spanish version of the Food Allergy Independent Measure (FAIM).

The FAQLQ-PF was translated to Spanish according to WHO guidelines [11], which recommend translation based on a forward-backward method (Supplementary Table 1). This kind of translation includes the following: (*1*) English to Spanish translation (forward translation), (*2*) review by an expert panel, (*3*) backward translation of the Spanish version to English by a native speaker, (*4*) pretesting and cognitive interviewing in collaboration with the Spanish Food and Latex Allergy Patients Association (AEPNAA), and (*5*) final version.

FAQLQ-PF comprises 3 domains for assessment of the impact of food allergy on HRQOL, namely, emotional impact (EI), food anxiety (FA), and social and dietary limitation (SDL). EI covers psychological experiences, FA covers fear and apprehension about food, and SDL covers everyday dietary and social restrictions [12].

Participants

The parents of 54 children aged between 0 and 12 years (median 50.5 months or 4.21 years) were recruited at the allergy outpatient clinic of a tertiary hospital in Madrid, Spain (Hospital Universitario del Sureste, Arganda del Rey, Spain). The questionnaire package was handed out to 66 child-parent pairs and returned by 54 child-parent pairs (response rate, 81.82%). The inclusion criteria were as follows: (*1*) presence of immediate allergic symptoms after the ingestion of a food and positive skin test result or elevated IgE levels to the culprit food; and (*2*) capacity to understand and complete the questionnaire. The exclusion criteria were as follows: (*1*) inability of the parents to complete the questionnaire; and (*2*) presence of another major illness that could impair HRQOL (atopic or nonatopic).

Patients were classified into 3 different age groups: 0-3 years (22 participants), 4-6 years (15 participants), and 7-12 years (13 participants). The clinical and epidemiological characteristics of these patients are summarized in Table 1. The parents (43 mothers and 11 fathers) completed the S-FAQLQ-PF (FAIM scale), as well as a generic HRQOL questionnaire in Spanish (Kindl Questionnaire [13,14]). Parents repeated the test at home (with the order of the questions altered) 10-14 days after the first completed version. The second questionnaire was sent back to our hospital by ordinary mail. The time taken and the need for help to complete the questionnaires were also documented.

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Table 1. Patients' Clinical and Epidemiological Characteristics

Variable	No. (%)
Sex	
Male	36 (66.7)
Female	18 (33.3)
Median (IQR) age, mo	50.5 (30-96)
Age, y	
0-3	23 (42.6)
4-6	17 (31.5)
7-12	14 (25.9)
Anaphylaxis	
Yes	13 (24.0)
No	41 (76.0)
Ingestion of culprit food	
Yes	21 (38.9)
No	33 (61.1)
Symptoms	
Cutaneous	32 (59.2)
Gastrointestinal	7 (13.0)
Respiratory	11 (20.4)
Multisystemic	4 (7.4)
Number of reactions	
1-4	47 (87.0)
5 +	7 (13.0)
Implicated foods	
Single	24 (44.4)
Multiple	30 (55.6)
Food[a]	
Egg	29 (53.7)
Nuts (including peanut)	19 (35.2)
Milk	15 (27.8)
Fish/shellfish	12 (22.2)
Fruits	3 (5.5)
Other	4 (7.4)

[a]Percentage higher than 100% due to multiple allergies.

Ethics Disclosure

The study was approved by the Ethics Committee of University Hospital Gregorio Marañón on September 30, 2013 (Acta 11/2013). Full written parental consent was provided. Parents and children received written information, indicating that participation in the study was voluntary.

Statistical Analysis

The main statistics were calculated based on patient data (Supplementary Table 2). The crude S-FAQLQ-PF and FAIM scores 0 to 6 were recoded as 1 to 7 to facilitate the statistical analyses. The analysis was performed using Stata 14.1 for Windows (Stata Corp).

Feasibility and Reliability

Feasibility was measured as the percentage of fully completed S-FAQLQ-PFs.

Test-retest reliability was evaluated by comparing the original S-FAQLQ-PF and a second version containing the same items in an altered order about 10 to 14 days later. Reliability was calculated using the interclass correlation coefficient (ICC).

Internal Consistency and Floor/Ceiling Effect

The Cronbach α was used to assess the internal consistency of the S-FAQLQ-PF. Internal consistency evaluates whether all the items included in the questionnaire yield similar results.

The floor/ceiling effect refers to the percentage of participants with the lowest/highest score in the questionnaire. A high percentage indicates that the questionnaire cannot evaluate differences between patients. The criteria for acceptability included <15% floor and ceiling effects for global score and various domains [16].

Construct Validity

Construct validity was analyzed by comparing the S-FAQLQ-PF results and the results of a validated HRQOL questionnaire (FAIM on this occasion). The Spearman correlation coefficient of both questionnaires was compared to establish the construct validity of S-FAQLQ-PF. A comparison with a generic HRQOL questionnaire (Kindl questionnaire [17]) was also performed to confirm the construct validity results.

Discriminant Validity

The Mann-Whitney and Kruskal-Wallis tests were performed to assess the influence of the epidemiological and clinical characteristics of the participants for the global S-FAQLQ-PF score and for all the 3 domains in order to evaluate the discriminant validity of the questionnaire. Differences with respect to sex, age, presence/absence of anaphylaxis (recorded in the clinical history), ingestion the implicated food, related symptoms, number of reactions, and number of foods implicated were evaluated.

Results

Feasibility and Reliability

Feasibility was evaluated in 54 questionnaires, of which 52 (96.3%) were fully completed and 2 (3.7%) were only partially completed. One of the partially completed questionnaires was almost fully completed (1 item missing), whereas in the other, only 1 item was completed because the parents reported that the remaining items were not applicable for a child younger than 3 years. Less than a quarter of the parents (11) needed assistance to complete the questionnaire.

A total of 50 patients fully completed both S-FAQLQ-PF (first at the visit where they were included in the study, and second, about 10 to 14 days later, when the items were included in a different order). Reliability was calculated for the 3 different age groups: 0-3 years (22 patients, because of the patient who completed only 1 item), 4-6 years (15 patients),

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Table 2. Reliability, Internal Consistency, and Floor/Ceiling Effect

S-FALQL-PF	Age Group, y	No.	Item	Mean (SD)	Cronbach α	%Min/%Max (Floor/Ceiling)	ICC
Global score	0-3	22	14	2.1 (1.0)	0.897	13.6/0	0.898
	4-6	17	26	2.8 (1.3)	0.960	0/0	0.902
	7-12	14	30	3.0 (1.1)	0.952	0/0	0.973
EI score	0-3	22	6	1.6 (0.9)	0.882	40.9/0	0.772
	4-6	17	10	2.6 (1.0)	0.856	5.9/0	0.790
	7-12	14	13	2.9 (1.0)	0.896	0/0	0.928
FA score	0-3	22	3	2.1 (1.3)	0.823	45.4/0	0.799
	4-6	17	7	3.2 (1.7)	0.946	11.7/0	0.932
	7-12	14	8	3.4 (1.5)	0.895	0/0	0.957
SDL score	0-3	22	5	2.6 (1.4)	0.809	13.6/0	0.822
	4-6	17	9	2.7 (1.5)	0.916	5.9/0	0.859
	7-12	14	9	2.6 (1.2)	0.830	14.3/0	0.954

Abbreviation: ICC, interclass correlation coefficient; EI, emotional impact; FA, food anxiety; SDL, social and dietary limitation; S-FAQLQ-PF, Spanish Food Allergy Quality of Life Questionnaire – Parent Form.

and 7-12 years (13 patients), and for the different domains of the S-FAQLQ-PF, including EI, FA, and, SDL. The ICC for the different age groups varied from 0.898 to 0.973, and the ICC for the different domains showed a value higher than 0.75 in all age groups (Table 2).

Internal Consistency and Floor/Ceiling Effect

A questionnaire is considered to have good internal consistency when the Cronbach α is higher than 0.8. In our study, all the results were higher than 0.8 both for the different age groups (0.897 to 0.90) and for the different domains (0.809 to 0.946).

As regards the floor/ceiling effect, none of the questionnaires presented the highest possible score (ceiling effect). However, 3 patients in the 0-3 year group (5.5% of the total) completed the questionnaire with the lowest score (floor effect) (Table 2).

Construct Validity

A significant correlation was observed between the S-FAQLQ-PF and FAIM scales in the 4-6 and 7-12 year groups for the global S-FAQLQ-PF score and for all the different domains (Supplementary Table 3), except for the SDL domain in the 7-12 year group. In the other group (0-3 year group), only the EI and the SDL domains presented a significant correlation with the mean score of the FAIM scale.

Moreover, with regards to the comparison between the S-FAQLQ-PF and the Kindl Questionnaire (Kiddy Kindl for children aged 4-6 years and Kid Kindl for children aged 7-12 years), the only statistically significant correlation was between the EI domain in S-FAQLQ-PF and the Family domain in Kiddy-Kindl (data not shown).

Discriminant Validity (Table 3)

The Mann-Whitney test revealed no differences between the sexes. Statistical significant differences were observed for the 7-12 year group in the global S-FAQLQ-PF score and for the EI and FA domains, as well as for the 4-6 year group in the EI and FA domains (close to statistical significance in the global S-FAQLQ-PF score) when the different age groups were compared. The parents of the 0-3 year age group group reported a lower score and better HRQOL in the global S-FAQLQ-PF score than the 4-6 year and 7-12 year groups (no statistically significant differences were observed between the last 2 groups). The parents of the 4-6 year and 7-12 year groups reported a higher mean score for EI (difference of 1.0 [P=.001] and 1.3 [P<.001], respectively) and for FA (difference of 1.1 [P=.027] and 1.4 [P=.002], respectively). The difference in the number of reactions that the patients had experienced was also evaluated. Patients with a lower number of reactions (1-4 reactions) presented better HRQOL than those with 5 or more reactions (in the global S-FAQLQ-PF score [P=.004] and for all the domains: EI, P=.011; FA, P=.004; SDL, P=.019). When the Kruskal-Wallis test was used to evaluate differences according to symptoms, patients with respiratory and gastrointestinal symptoms presented worse HRQOL in the global S-FAQLQ-PF score (P=.011 and P=.060 respectively), and patients with anaphylaxis had a worse global S-FAQLQ-PF score in all the domains, although the differences were not statistically significant.

No differences were observed between patients for presence or absence of anaphylaxis, transgression with the implicated food, or the number of foods implicated. Similarly, no differences were observed in the global S-FAQLQ-PF when the foods implicated were analyzed.

Discussion

Measuring HRQOL helps to evaluate the impact of a disease. HRQOL is also important in patients with food allergy [3,18,19]. Cultural, culinary, and socioeconomic differences may influence the ability of the questionnaires to identify essential items for pediatric food-allergic patients in the Spanish-speaking population. Our objective was to obtain a culturally equivalent Spanish version of the FAQLQ-PF in

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Table 3. Discriminant Validity

Variable		No.	Global S-FAQLQ Score	*P*	EI	*P*	FA	*P*	SDL	*P*
Sex	Male	35	2.6 (1.2)	.977	2.3 (1.1)	.792	2.8 (1.6)	.940	2.7 (1.4)	.763
	Female	18	2.6 (1.2)		2.3 (1.1)		2.8 (1.6)		2.6 (1.4)	
Age, y	0-3 (ref.)	22	2.1 (1.0)		1.6 (0.9)		2.1 (1.3)		2.6 (1.4)	
	4-6	17	2.8 (1.3)	.074	2.6 (1.0)	.001[a]	3.2 (1.7)	.027[a]	2.7 (1.5)	.921
	7-12	14	3.0 (1.1)	.008[a]	2.9 (1.0)	<.001[a]	3.5 (1.4)	.002[a]	2.6 (1.4)	.820
Anaphylaxis	Yes	13	2.8 (1.2)	.301	2.6 (0.8)	.108	3.1 (1.5)	.367	2.8 (1.7)	.877
	No	40	2.5 (1.2)		2.2 (1.2)		2.7 (1.6)		2.6 (1.3)	
Ingestion	Yes	21	2.9 (1.3)	.161	2.5 (1.0)	.127	3.1 (1.6)	.323	3.0 (1.4)	.321
	No	32	2.4 (1.2)		2.2 (1.1)		2.6 (1.6)		2.4 (1.1)	
Symptoms	Cutaneous (ref.)	31	2.2 (1.1)		2.0 (1.1)		2.3 (1.5)		2.3 (1.1)	
	Gastrointestinal	7	3.2 (1.0)	.060	2.6 (0.9)	.107	3.9 (1.7)	.030[a]	3.0 (1.0)	.079
	Respiratory	11	3.2 (1.2)	.011[a]	3.0 (1.0)	.003[a]	3.5 (1.4)	.021[a]	3.0 (1.7)	.213
	Multisystemic	4	3.1 (1.6)	.276	2.5 (1.3)	.359	2.9 (1.7)	.461	3.9 (2.0)	.113
Number of reactions	1-4	46	2.4 (1.1)	.004[a]	2.1 (1.0)	.011[a]	2.6 (1.5)	.004[a]	2.5 (1.3)	.019[a]
	5+	7	3.9 (1.1)		3.4 (0.9)		4.5 (1.2)		3.9 (1.5)	
Implicated foods	Single	23	2.3 (1.1)	.146	2.2 (1.1)	.372	2.6 (1.6)	.279	2.2 (1.0)	.074
	Multiple	30	2.8 (1.3)		2.4 (1.1)		3.0 (1.6)		3.0 (1.4)	
Egg/milk allergy	Yes	33	2.5 (1.2)	.359	2.1 (1.1)	.036[a]	2.6 (1.6)	.203	2.7 (1.4)	.65
	No	20	2.8 (1.2)		2.7 (1.0)		3.1 (1.5)		2.5 (1.3)	
Nut allergy	Yes	19	2.6 (0.9)	.504	2.7 (0.9)	.019[a]	3.0 (1.2)	.267	2.1 (0.9)	.098
	No	34	2.6 (1.4)		2.1 (1.2)		2.7 (1.8)		2.9 (1.5)	

Abbreviations: EI, emotional impact; FA, food anxiety; SDL, social and dietary limitation; S-FAQLQ-PF, Spanish Food Allergy Quality of Life Questionnaire – Parent Form.
[a]Statistically significant.

and to demonstrate that it is useful for evaluation of HRQOL in a Spanish pediatric population.

The first step in our process was a translation into Spanish according to WHO guidelines (including a forward-backward translation) [11]. The parents of 54 food-allergic children aged between 0 and 12 years completed the S-FAQLQ-PF on 2 occasions (at the first visit and 10 to 14 days afterwards), the FAIM scale, and a generic quality of life questionnaire (Kindl Questionnaire). Finally, the clinical and epidemiological characteristics and results of the questionnaires were analyzed and evaluated. A remarkable strength of our study is that the clinical symptoms of anaphylaxis and the indication of epinephrine were obtained from the clinical history and not from patient self-reports.

Our statistical analysis showed that the feasibility, reliability, and internal consistency were very good for global S-FAQLQ-PF and for the different domains. Therefore, S-FAQLQ-PF is an optimal tool for measuring HRQOL and could be used in the Spanish pediatric population (patients aged 0 to 12 years). Measurement of the floor/ceiling effect revealed that a small percentage of patients (5.5%) completed the questionnaire with the lowest score. Since these patients were in the 0-3 year group, the low score is probably due to the small amount of relevant items.

Finally, construct validity was assessed by comparing S-FAQLQ-PF results using a specific HRQOL questionnaire (FAIM scale) and a generic HRQOL questionnaire (Kindl Questionnaire). The results obtained with the FAIM scale were statistically significant for the 4-6 year and 7-12 year groups (except for the SDL domain in the 7-12 year group), but not for the 0-3 year group, where only the EI and the SDL domains were statistically significant. These results may imply that the S-FAQLQ-PF is less able to measure HRQOL in younger children. Our data reinforce the idea that specific HRQOL questionnaires should be designed to improve the quality of assessment; this aspect should be addressed in future studies in younger children. No correlation was observed in the comparison between the S-FAQLQ-PF and the generic Kindl Questionnaire, except for the EI domain in S-FAQLQ-PF and the Family domain in Kiddy-Kindl. It has been demonstrated that generic HRQOL questionnaires are not valid for measuring the effect of food allergy on HRQOL, because this type of questionnaire focuses on the daily or frequent fluctuations in physical status, whereas food allergy causes severe symptoms at specific times, but not on a day-to-day basis [20,21].

Cross-sectional validation of the S-FAQLQ-PF generates important information about HRQOL in the study population. First, no differences were observed when sex, food implicated, number of implicated foods, and ingestion of the implicated food were compared. The relationship between these factors should be reviewed, because inconsistent results have been observed in various studies [22]. The presence of anaphylaxis did not affect HRQOL, although the number of patients who presented it is lower than that of those who did not, thus potentially leading to bias [23]. As for population age, patients in the 0-3 year group presented better HRQOL than

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older patients, as reported in a Swiss population [24]. Patients who presented more severe symptoms (gastrointestinal, respiratory, or multisystemic) have a lower HRQOL than those who presented cutaneous symptoms [20,22]. Finally, the relationship between HRQOL and number of reactions presented by patients was also evaluated. Patients who presented 5 or more reactions to foods reported worse values than those with 4 or fewer reactions, as observed elsewhere [25].

In summary, we report our results on a culturally equivalent Spanish version of of the specific food allergy HRQOL questionnaire, FAQLQ-PF. We also performed a cross-sectional validation of this questionnaire. S-FAQLQ-PF presents results similar to those obtained in the original version and was used to demonstrate the influence of factors such as patients' age, severity of symptoms, and number of reactions on the HRQOL of a Spanish pediatric population. We found that S-FAQLQ-PF was less useful in patients aged 0 to 3 years, thus suggesting that new specific questionnaires should be designed for this age group.

S-FAQLQ-PF is an interesting tool for evaluation of HRQOL in the Spanish food-allergic population and could even be used for Spanish speakers throughout the world (about 500 million people in recent years) until specific questionnaires are created for each Spanish-speaking country. The questionnaire could also be used to evaluate the influence of food avoidance, oral provocation challenges [5], and new treatments such as food immunotherapy [26,27] on patients' HRQOL. We adapted S-FAQLQ-PF not only to the Spanish language but also to Spanish culture, expectations, and socioeconomic characteristics.

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Conflicts of Interest

The authors declare that they have no conflicts of interests.

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Supplementary Table 1. WHO recommendations for Forward-Backward translation

Step 1	English to Spanish translation (Forward translation)
Step 2	Questionnaire review by expert panel
Step 3	Backward translation to English of the Spanish version by a native speaker
Step 4	Pre-testing and cognitive interviewing in collaboration with the Spanish Food and Latex Allergy Patients Association (AEPNAA)
Step 5	Final version of the questionnaire

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Supplementary Table 2. HRQL concepts (modified from Antolín-Amerigo D et al [15])

Concept	Definition
Reliability	Extent to which the questionnaire is repeatable and consistently produces the same results.
Internal Consistency	How well the items of a questionnaire relate to each other and to the total questionnaire. It is most commonly evaluated by Cronbach's alpha. An alpha≥0.70 indicates good internal consistency.
Test-Retest	Reproducibility of the questionnaire over time. The questionnaire is completed on two occasions by the same patients in whom no change in the condition has taken place. It is most commonly evaluated by the intraclass correlation coefficient (ICC). An ICC≥0.70 indicates good test–retest reliability.
Validity	Degree to which the questionnaire measures what it is intended to measure.
Internal Validity	Internal structure of the questionnaires and is usually evaluated by factor analysis, inter-item correlations and floor and ceiling effects.
Discriminant Validity	Assessed by calculating the correlation between the questionnaire and measures of similar or dissimilar constructs. Type of External Validity.
Construct Validity	Ascertained by calculating the correlation between the questionnaire and an independent measure, which reflects the severity of the disease in question. Type of External Validity.

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Supplementary Table 3. Spearman correlations between S-FAQLQ-PF and FAIM scale

Group (years)	EI score	FA score	SDL score	HRQL score
0 – 3	0.440(*)	0.126	0.571(*)	0.365
4 – 6	0.581(*)	0.773(*)	0.444(*)	0.687(*)
7 – 12	0.666(*)	0.547(*)	0.510	0.644(*)

(*)P – value< 0.05

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