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Validation of the food allergy independent measure and the EuroPrevall food allergy quality of life questionnaire for children 8-12 years translated into Spanish

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KEYWORDS

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Abstract

Background: Different questionnaires have been developed to measure quality of life (QoL) in patients with food allergy. Our aim was to validate a Spanish translation of the Food Allergy Independent Measure (FAIM) and the EuroPrevall Food Allergy Quality of Life Questionnaire—Child Form (FAQLQ-CF) for children aged 8-12 years.

Methods: Sixty children with a diagnosis of IgE-mediated allergy to food completed the questionnaires. The internal consistency was evaluated with Cronbach's alpha. The correlation of FAQLQ-CF with FAIM was assessed to test construct validity. We compared both values with the diagnosis of anaphylaxis to evaluate discriminant validity.

Results: Cronbach's alpha was in the range of 0.654-0.863 for the four domains of FAQLQ-CF and 0.779 for FAIM. There were no criteria to remove questions from the questionnaires. Significant correlations could be found between FAQLQ-CF and the number of offending foods and the impact on social life (all $r > 0.33$, $P < 0.01$), and between FAIM and anaphylaxis.

Conclusions: The Spanish translation of FAQLQ-CF showed acceptable internal consistency, good construct validity, and capacity to discriminate patients depending on the number of foods to avoid and the impact on social life. FAIM showed good discriminant capacity for anaphylaxis.

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Introduction

Food allergy in children has become an important health problem due to its rising prevalence, severity of reactions, cost of diagnosis and treatment of the disorder, and the impact on quality of life (QoL) of patients and their families.^{1,2}

The identification of offending foods, the education on recognition and early treatment of symptoms, and the use of recent procedures such as desensitization or oral tolerance induction can have a beneficial influence on QoL.³ To evaluate these, the use of specific tools is needed.

Thus, questionnaires have been designed to measure and monitor QoL in different groups of patients. The EuroPrevall initiative,^{4,5} funded by the Framework Programme FP6 of the European Union, has developed specific questionnaires for parents of children with allergy, adolescents, and children between 8 and 12 years of age.^{6,9} Implementing the use of common questionnaires across different countries requires their translation into local language and validation in different settings. We aimed to validate the Spanish (Spain) translation of Food Allergy Independent Measure (FAIM) and EuroPrevall questionnaire on Food Allergy Quality of Life—Child Form (FAQLQ-CF) for children aged 8–12 years.⁶

Material and Methods

The English versions of FAQLQ-CF and FAIM⁶ were initially translated into Spanish by one of the authors, a pediatric allergist, fluent in English, with vast experience and attended continued daily clinical visits of food allergic children. The translated and the original versions were parallelly reviewed, question by question, by other authors, who were also practising pediatric allergists, fluent in English, to reach agreed versions. These were back translated to English by a native speaker who was a professional bilingual translator. The back translated versions were checked with the original ones, and they did not show any relevant differences, so the agreed versions were finally used. The versions were first used in a large group of children (results not included) who did not find difficulty in understanding the questions; after this, the questionnaires were used in the group of study. The selected versions are shown in the online supplement (Supplementary file 1).

Children, aged 8–12 years, with food allergy filled in the questionnaires according to the instructions shown therein. They had been diagnosed with active IgE-mediated food allergy based on compatible symptoms and demonstrated specific IgE by means of skin prick tests and/or serum-specific IgE. The patients completed the questionnaires during a visit scheduled for a food challenge with one of the offending foods, at the start of the challenge before any reactions could occur during the procedure. Patients were invited to participate regardless of the severity of previous reactions or the number of sensitizing foods to not bias the sample.

The FAQLQ-CF included 24 questions, corresponding to four domains: seven questions on allergen avoidance, five on risk of accidental exposure, six on emotional impact, and six on dietary restrictions.

A second part included FAIM, a tool that has demonstrated relevance, reliability, and face validity as independent measures (IMs) of food allergy, which has been used to measure the construct validity of the questionnaire.¹⁰ It has four questions on expectation of outcome (EO), that is, expectation of what could happen after exposure, and two questions on IM, that is, the perceived number of foods to avoid and the perceived effect on social activities. The diagnosis of anaphylaxis was collected from the electronic records of the patients. Anonymity of responders was warranted, and the study was approved by the Ethics Committee (No. 2020-003-1).

Possible answers to the questions followed a graphic Likert scale, ranging from 0 to 6, with lower values associated to better QoL. Cronbach's alpha was used to test internal consistency of FAQLQ-CF domains and FAIM. Additional measures such as corrected item-total correlations and Cronbach's alpha, if an item were deleted, as well as the Spearman's correlation of the questions in FAQLQ-CF with those in FAIM, were also calculated. The values of FAQLQ-CF and FAIM were compared in children with and without the diagnosis of anaphylaxis by means of the Mann-Whitney U test. The statistical study was performed with the software programme SPSS 15.0, 2006 (Chicago, Ill, USA).

Results

The questionnaires were completed by 60 children whose characteristics are shown in Table 1. There were no missing answers.

The values of Cronbach's alpha and additional measures for the four domains of FAQLQ-CF are shown in Table 2. The values were above 0.7, except for the domain of "Risk of Accidental Exposure," which was 0.654 (>0.60 is considered acceptable by some authors, although a value of 0.70 is more often recommended). Likewise, none of corrected item-total correlations was under 0.3, and none of the changes in Cronbach's alpha, if an item were deleted, showed a marked increase. When there is any of these

Table 1 Demographic and clinical characteristics of the study groups.

Gender	Male	40 (66.6)	Offending food	n
	Female	20 (33.3)		
Age (years)	Mean	10.6 (8–12.9)	Milk	4
	(range)		Egg	10
Number of offending foods	1	24 (40)	Walnut	32
	2	14 (25)	Hazelnut	15
	3	7 (11.6)	Peanut	11
	4	6 (10)	Cashew nut	7
	5	6 (10)	Pistachio	5
	6	1 (1.7)	Kiwi	10
	7	2 (3.3)	Peach	14
Anaphylaxis	Yes	26 (43.3)	Fish	7
	No	34 (56.7)	Crustaceans	6
			Others	26

Table 2 Values of Cronbach's alpha for the whole Food Allergy Quality of Life Questionnaire–Child Form (FAQLQ-CF), its separate domains, and for the whole Food Allergy Independent Measure (FAIM) and its six separate questions (EO1–EO4, IM1, IM2).

	No. of questions	Cronbach's alpha	Cronbach's alpha if an item were deleted (range)	Corrected item/total correlation (range)
Whole FAQLQ-CF	24	0.929	0.923–0.929	0.354–0.759
Allergen avoidance	7	0.863	0.829–0.862	0.489–0.729
Risk of accidental exposure	5	0.654	0.565–0.645	0.310–0.479
Emotional impact	6	0.812	0.766–0.795	0.532–0.641
Dietary restrictions	6	0.769	0.705–0.771	0.379–0.631
Whole FAIM	6	0.789	0.707–0.794	0.402–0.731
EO1: Chance of accidental exposure			0.774	0.465
EO2: Chance of severe reaction			0.638	0.638
EO3: Change of dying			0.766	0.517
EO4: Chance of not acting effectively			0.707	0.731
IM1: Number of foods to avoid			0.753	0.567
IM2: Effect on social life			0.794	0.402

FAIM: Food Allergy Independent Measure; FAQLQ-CF: Food Allergy Quality of Life Questionnaire–Child Form.

two criteria, the removal of a question is generally recommended. The values for each specific question are shown in Supplementary file 2.

The value of Cronbach's alpha for FAIM (with six questions) was 0.779; additional measures for each question are shown in Table 2. According to the above criteria, no removal of questions would be recommended either.

The correlation between the scores of the questionnaire and FAIM, to evaluate construct validity, was significant ($r=0.453$, $P<0.001$). There was a positive correlation between the scores of each domain and the global FAIM, mainly due to correlations with the IM, but not much with EO, questions. The correlations of all questions in FAQLQ-CF and FAIM are also shown in Table 3.

The diagnosis of anaphylaxis was associated with a worse value of FAIM ($P=0.03$), but not with the value of the whole FAQLQ-CF or its domains, as shown in Table 4.

To test the floor and ceiling effect, the number of patients with possible highest and lowest scores for the whole FAQLQ-CF, for each domain, and for FAIM are shown in Table 5. In all cases, the percentage was below 15%; values under this are considered acceptable.

Discussion

Validation of questionnaires in different languages and for different populations is essential before they can be recommended for use in clinical settings.^{10,11} This is being carried out in different countries.^{12–16} One of the EuroPrevall questionnaires on QoL in food allergy, for parents of allergic children, has been validated in Spanish by our and another group.^{17,18} In this case, we aimed to validate the questionnaire for children aged 8–12 years.

We received good results, in terms of internal consistency of FAQLQ-CF, with good or at least acceptable results in the four domains.¹⁹ It is common to find significant correlations between different questions as we did (results not shown). This could lead to consider whether the same information would be obtained if the number of questions

is reduced.^{19,20} Nevertheless, suggested criteria for removing somehow redundant questions, as described in results, were not met, so it would be recommended to keep the current questions.

The potential severity of food allergy, as perceived by the patient, is evaluated through the questions in the FAIM. This has also shown a good Cronbach's alpha, which indicates good internal consistency, and no criteria for removal of questions have been found either. It is important to state that the wording of the fourth question must have a negative sense and be highlighted, to avoid misinterpretations, as it happened to us with the questionnaire for parents, in which the wording in a positive sense led to a worse Cronbach's alpha.¹⁸ The current version in the online supplement should be recommended for use.

One way to evaluate construct validity of the questionnaire, the degree to which it measures what it tries to measure, is to test the correlation between FAQLQ-CF and independent FAIM.⁶ Our results have shown a significant correlation, which would support its validity. Nevertheless, that correlation has been good for the global values of FAQLQ-CF and FAIM (Table 3) mainly due to correlation with IM questions, with less contribution of EO questions. The everyday QoL is more related to IM questions than to EO questions, which in turn are more associated to severe allergy. Children with anaphylaxis had worse FAIM scores than those without reactions (Table 4) in only two questions, in chance of severe reaction (EO2) and in chance of dying (EO3). There was no difference in questions of chance of accidental exposure (EO1) and chance of not acting effectively (EO4), which could be interpreted as good confidence in avoiding the food and treating adequately if needed. On the other hand, there were not significant differences in the whole FAQLQ or its domains according to the diagnosis of anaphylaxis.

The floor and ceiling effects, which evaluate the number of patients with possible maximal and minimal scores, showed a low percentage (Table 5). When this exceeds 15%, the ability of a questionnaire to differentiate and classify patients is impaired.²⁰ Therefore, these findings, together

Table 3 Spearman's correlation coefficient of the Food Allergy Quality of Life Questionnaire—Child Form (FAQLQ-CF) score, domains, and Food Allergy Independent Measure (FAIM) score and its questions.

FAQLQ-CF	FAIM						
	Total	EO1	EO2	EO3	EO4	IM1	IM2
Total	0.45**	0.24	0.24	0.13	0.36**	0.51**	0.52**
Allergen avoidance	0.38**	0.14	0.13	0.09	0.33**	0.46**	0.47**
4 Read labels	0.21	0.04	0.02	0.07	0.13	0.43**	0.35**
6 Stay for a meal	0.33*	0.21	0.17	-0.02	0.32*	0.39**	0.34**
7 Try fewer	0.26*	0.01	0.08	0.07	0.16	0.36**	0.38**
8 Tell beforehand	0.32*	0.23	0.14	0.06	0.30*	0.25	0.41**
9 Check yourself	0.28*	0.11	0.10	0.02	0.31*	0.31*	0.35**
10 Hesitate eating	0.34**	0.18	0.20	0.10	0.36**	0.35**	0.22
15 Explain around	0.23	0.09	-0.03	0.07	0.19	0.34*	0.36**
Risk accidental exposure	0.43**	0.25*	0.25	0.08	0.33*	0.55**	0.47**
11 Touching foods	0.27*	0.13	0.18	-0.11	0.18	0.34**	0.34**
13 Ingredients change	0.30*	0.24	0.23	0.08	0.23	0.52**	0.15
14 Label traces of	0.28*	0.24	0.10	0.15	0.22	0.32*	0.25
16 People forget	0.28*	0.16	0.32*	0.05	0.16	0.31*	0.28*
17 Others can eat	0.20	0.01	0.09	0.08	0.18	0.33*	0.33*
Emotional impact	0.49**	0.27*	0.31*	0.28*	0.34**	0.45**	0.45**
19 Allergic reaction?	0.31*	0.24	0.24	0.22	0.21	0.30*	0.23
20 Eating wrong	0.38**	0.22	0.29*	0.34**	0.34**	0.28*	0.20
21 Never before	0.31*	0.22	0.19	0.21	0.12	0.24	0.29*
22 Never get rid	0.16	-0.05	0.12	0.09	0.10	0.31	0.26*
23 Not taking account	0.50**	0.25	0.37**	0.36**	0.34**	0.40	0.36**
24 Have food allergy	0.41**	0.22	0.21	0.11	0.31*	0.48**	0.46**
Dietary restriction	0.38*	0.24	0.27*	0.05	0.33*	0.41**	0.42**
1 Always watch	0.35**	0.25	0.32*	-0.04	0.30*	0.40**	0.32*
2 Eating fewer things	0.23	0.10	0.19	-0.13	0.26*	0.42**	0.28*
3 Limited in buying	0.33**	0.22	0.14	0.03	0.36**	0.19	0.49**
5 Refuse food	0.23	0.11	0.13	0.12	0.21	0.37**	0.32*
12 Don't get treats	0.12	0.09	0.22	0.11	0.07	0.22	0.03
18 Don't know taste	0.25*	0.11	0.23	0.32*	0.11	0.23	0.17

Correlation is significant at the *0.05/**0.01 level. EO1: Chance of accidental exposure; EO2: Chance of severe reaction when accidentally exposed; EO3: Chance of dying when accidentally exposed; EO4: Chance of not acting effectively when accidentally exposed; IM1: Number of foods one needs to avoid; IM2: Effect of food allergy on social life.

with the significant correlation with IM questions, point out at good discriminant validity.

There were some limitations in our study. We did not compare the studied questionnaire with generic health-related QoL questionnaires. This approach is adequate for comparison between different diseases,^{11,21} but agreement between generic and disease-specific questionnaires is low^{12,21}, and disease-specific questionnaires are more suitable to assess relevant changes in QoL of children with food allergy.^{11,21} We did not assess test-retest reliability. For this, a stable unchanged condition is needed. In our study, the questionnaires were filled in at our clinics when children attended for a challenge test, and the results of this could have a striking positive or negative effect on their perception of QoL, and this effect would change the child's condition and the retest results. Evaluation of this reliability is generally assessed through telephone interviews or mailed questionnaires on occasions 1 week to 3 months

apart and has shown good to excellent results for questionnaires for food allergic children, adolescents, and adults in English, Japanese, Dutch, and Spanish,^{8,9,12-14} while there are no results for French or Greek.^{15,16}

Conclusion

In summary, this version of the FAQLQ-CF in Spanish has some limitations, but it has shown adequate internal consistency, construct validity, and discriminant capacity through correlations with other aspects of QoL. The translation of the FAIM also had good internal consistency and discriminant capacity for children with anaphylaxis. Thus, they can be used as validated tools for the evaluation of QoL in children with food allergy, at diagnosis and during follow-up periods, and to assess the effectiveness of diagnostic and therapeutic procedures.

Table 4 Values of the whole Food Allergy Quality of Life Questionnaire–Child Form (FAQLQ-CF), its domains, and the Food Allergy Independent Measure (FAIM) and its questions according to diagnosis of anaphylaxis.

	Mean rank		U	P
	Anaphylaxis (no) (n=36)	Anaphylaxis (yes) (n=24)		
Whole FAQLQ-CF	30.10	30.81	431	0.88
Allergen avoidance	29.71	31.10	421	0.76
Risk of accidents	31.33	29.87	420	0.32
Emotional impact	30.29	30.66	436	0.92
Dietary restrictions	31.44	29.78	417	0.71
Whole FAIM	25.88	36.54	285	0.02
EO1: Chance of accidental exposure	29.28	32.10	400	0.53
EO2: Chance of severe reaction	24.65	38.15	243	0.002
EO3: Chance of dying	25.44	37.12	270	0.008
EO4: Chance of not acting effectively	28.85	32.65	386	0.40
IM1: Number of foods to avoid	28.87	32.63	387	0.39
IM2: Effect on social life	28.16	33.56	363	0.23

Table 5 Number (percentage) of patients with possible highest and lowest scores in the whole Food Allergy Quality of Life Questionnaire–Child Form (FAQLQ-CF) the Food Allergy Independent Measure (FAIM) and domains in FAQLQ-CF.

	Lowest possible score	Highest possible score
FAQLQ (whole)	0	0
Allergen avoidance	1 (1.6)	0
Risk of accidental exposure	2 (3.3)	0
Emotional impact	0	0
Dietary restrictions	1 (1.6)	0
Whole FAIM	0	1 (1.7)

Conflict of interest

The authors declare no potential conflicts of interest with respect to publication of this article.

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FAIM: Food Allergy Independent Measure- Child form (8-12 años)

Medida independiente de la alergia a alimentos - Versión niños (8-12 años)

Las siguientes cuatro preguntas se refieren a lo que piensas del riesgo de que te pase algo a causa de tu alergia a alimentos. Escoge una de las respuestas. Luego hay dos preguntas más sobre tu alergia. Responde, por favor, cada pregunta marcando con una "x" en la respuesta adecuada

	0	1	2	3	4	5	6						
	Ninguno (0% de riesgo)	Muy poco riesgo	Poco riesgo	Riesgo intermedio	Bastante riesgo	Mucho riesgo	Todo (100% de riesgo)						
¿En tu opinión, cuánto riesgo hay de que ...							0	1	2	3	4	5	6
a	por error comas algo a lo que tienes alergia?					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b	tengas una reacción grave si, por error, comes algo a lo que tienes alergia?					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c	puedas morir si, por error, comes algo a lo que tienes alergia?					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d	<u>no</u> puedas tratar correctamente tu reacción alérgica si, por error, comes algo a lo que tienes alergia?					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e													
¿Cuántos alimentos tienes que evitar a causa de tu alergia a alimentos?													
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>						
Casi ninguno	Muy pocos	Pocos	Algunos	Muchos	Muchísimos	Casi todos							
f													
Todo el mundo comparte actividades con otras personas, como jugar con amigos, ir a un cumpleaños, ir de visita, quedar con alguien para comer o salir a comer fuera. Tu alergia a alimentos ¿cuánto afecta a estas actividades?													
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>						
Tan poco que ni lo noto	Muy poco	Poco	Regular	Bastante	Mucho	Muchísimo							

Table E1 Modifications in Cronbach's alpha for each question in the domain of allergen avoidance (Cronbach's alpha = 0.863).

	Cronbach's alpha when an item was deleted	Corrected item/total correlation
4 Read labels	0.840	0.657
6 Stay for a meal	0.862	0.489
7 Try fewer	0.853	0.559
8 Tell beforehand	0.839	0.660
9 Check yourself	0.829	0.729
10 Hesitate eating	0.847	0.607
15 Explain around	0.830	0.723

Table E2 Modifications in Cronbach's alpha for each question in the domain of risk of accidental exposure (Cronbach's alpha = 0.654).

	Cronbach's alpha when an item was deleted	Corrected item/total correlation
11 Touching foods	0.594	0.423
13 Ingredients change	0.624	0.356
14 Label traces	0.645	0.310
16 People forget	0.572	0.471
17 Others can eat	0.565	0.479

Table E3 Modifications in Cronbach's alpha for each question in the domain of emotional impact (Cronbach's alpha = 0.812).

	Cronbach's alpha when an item was deleted	Corrected item/total correlation
19 Allergic reaction?	0.777	0.613
20 Eating wrong	0.786	0.565
21 Never before	0.795	0.532
22 Never get rid	0.783	0.569
23 Not taking into account	0.787	0.557
24 Have food allergy	0.766	0.641

Table E4 Modifications in Cronbach's alpha for each question in the domain of dietary restriction (Cronbach's alpha = 0.769).

	Cronbach's alpha when an item was deleted	Corrected item/total correlation
1 Always watch	0.745	0.469
2 Eating fewer things	0.708	0.631
3 Limited in buying	0.723	0.556
5 Refuse food	0.705	0.623
12 Don't get treats	0.771	0.379
18 Don't know taste	0.751	0.459