



Original article

Validation and reliability of the Japanese version of the Food Allergy Quality of Life Questionnaire—Parent Form

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ARTICLE INFO

Article history:

Received 13 April 2016

Received in revised form

12 June 2016

Accepted 27 June 2016

Available online 3 September 2016

Keywords:

Anaphylaxis

Food hypersensitivity

Quality of life

Sickness impact profile

Survey

Abbreviations:

FA, food allergy; QOL, quality of life;

HRQL, health-related QOL; FAQL-PB, the

Food Allergy QOL-Parental Burden; FAQLQ-

PF, the Food Allergy QOL Questionnaire-

Parent Form; FAIM, the Food Allergy

Independent Measure; FAQLQ-PF-J, the

FQQLQ-PF in Japanese language; FAIM-J, the

FAIM in Japanese language

ABSTRACT

Background: Food allergy (FA) is a heavy burden for patients and their families and can significantly reduce the quality of life (QoL) of both. To provide adequate support, qualitative and quantitative evaluation of the parents' QoL may be helpful. The objective of this study is to develop and validate a Japanese version of the Food Allergy QoL Questionnaire—Parent Form (FAQLQ-PF-J), an internationally validated disease-specific QoL measurement of the parental burden of having a child with FA.

Methods: The FAQLQ-PF and the Food Allergy Independent Measure (FAIM), an instrument to test the construct validity of the FAQLQ-PF-J, were translated into Japanese. After language validation, the questionnaires were administered to parents of FA children aged 0–12 years and those of age-matched healthy (without FA) children. Internal consistency (by Cronbach's α) and test-retest reliability were evaluated. Construct validity and discriminant validity were also examined.

Results: One hundred twenty-seven parents of children with FA and 48 parents of healthy children filled out the questionnaire. The FAQLQ-PF-J showed excellent internal consistency (Cronbach's $\alpha > 0.77$) and test-retest reliability. Good construct validity was demonstrated by significant correlations between the FAQLQ-PF-J and FAIM-J scores. It discriminated parents of children with FA from those without. The scores were significantly higher (lower QoL) for parents of FA children with a history of anaphylaxis than those without, for those with >6 FA-related symptoms experienced than those with less FA-related symptoms.

Conclusions: The FAQLQ-PF-J is a reliable and valid measure of the parental burden of FA in children.

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Introduction

The prevalence of food allergy (FA) has increased markedly, especially in young children.^{1,2} There is no pharmacotherapy for FA, and management relies on elimination of allergenic foods from the daily diet. Accidental ingestion of an allergen can cause not only bothersome allergic symptoms such as urticaria and oral discomfort but also life-threatening anaphylaxis. Thus, patients and their families—especially the care-givers of affected young children—must vigilantly monitor the child's diet to avoid unwanted

reactions. This constant vigilance can affect the emotional and physical state of patients and their families and consequently reduce their quality of life (QOL).^{3,4} The psychological burden may be even larger for the parents than the children themselves. Adolescents with FA reportedly often “forget” their earlier experience of anaphylaxis and tend to lack self-management, consequently, parents/care-givers continue to feel anxiety about “handing over” the main responsibility for avoidance and emergency management to their children.⁵ Psychological support to reduce the burden on both parties is requisite.⁶

To provide adequate support, it is necessary to objectively evaluate various aspects of the parents' QOL in relation to the disease. Instruments for measuring the QOL of patients with FA and their families have been developed and validated.⁷ Generic health-related QOL (HRQL) questionnaires can be used to compare the QOL of FA patients with other chronic diseases such as diabetes mellitus

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Peer review under responsibility of Japanese Society of Allergy.

and asthma.⁴ However, disease-specific HRQL questionnaires are more sensitive in measuring clinically important decreases in HRQL or changes in HRQL over time in FA patients.⁸ For the parental burden due to children with FA, the Food Allergy QOL-Parental Burden questionnaire (FAQL-PB) was the first well-validated instrument and clearly showed the burden of FA on the family.⁹ The next validated instrument was the Food Allergy QOL Questionnaire-Parent Form (FAQLQ-PF), which allows parents to report their child's HRQL from the child's perspective.¹⁰ It can evaluate both the limitations on the child's life and the negative emotions caused by daily dietary restrictions. In addition, the Food Allergy Independent Measure (FAIM) was developed to evaluate the construct validity of FAQLQs.¹¹

A validated Japanese-language, FA-specific HRQL did not exist, and a locally-developed original questionnaire based on Japan's own cultural and social background was desired. However, for global cultural comparison of FA problems and development of an internationally coordinated measure for FA in the future, we realized the value of using a well-designed and validated instrument that has been translated into many languages. We thus selected the FAQLQ-PF.¹⁰ The purpose of this study was to develop and validate a Japanese version of the FAQLQ-PF. We found that the translated FAQLQ-PF was robust and accurately reflected the psychological burden on Japanese parents who have children with FA.

Methods

Translation and language validation of the FAQLQ-PF and FAIM in Japanese language (FAQLQ-PF-J and FAIM-J)

The FAQLQ-PF consists of 30 items that are categorized into three domains: emotional impact, food anxiety and social dietary limitations. Respondents are asked to rate the impact of each item on a 6-point Likert scale from "not at all" to "extremely", in which the higher score indicates the larger clinical impact or worse QOL. In view of child development, some of the items deal with emotions or activities seen only in older children, not in younger children. Thus, the parents of children aged 3 or less answer only 14 questions, the parents of children aged 4 to 6 answer 26 questions, and the parents of children aged 7 to 12 answer all 30 questions.¹⁰ The FAIM consists of four questions, also rated on a 6-point scale, and assesses the parents' expectation of the outcome for the child with FA.¹⁰

Two investigators of this study (YM and YO) requested and received consent from the author of the FAQLQ-PF and FAIM (AD) to develop Japanese versions of those documents. Two native Japanese translators independently translated the original versions of the FAQLQ-PF and FAIM into Japanese and then finalized the translations through discussions. The translated questionnaires were then reviewed by two mothers of children with FA for language clarity and understandability and were accordingly modified to give final Japanese versions, FAQLQ-PF-J and FAIM-J. Next, those Japanese versions were back-translated to English by bilingual native English speakers and reviewed by the author of the original versions (AD). The original author confirmed that there was no cultural bias between the original and translated questionnaires.

Study participants

Parents of children (0–12 years old) with FA being treated at the allergy clinic of Mie National Hospital were invited to participate in the study (FA group). After giving informed consent, they filled out the FAQLQ-PF-J, FAIM-J and the 8-item Short Form Survey (SF8), a generic HRQL.¹² A randomly selected subgroup of the participants filled the forms out a second time one week later at home to examine the test-retest reliability. Parents of healthy children

(0–12) without FA were also recruited (control group) and filled out the FAQLQ-PF-J and FAIM-J in order to test the discriminant validity. The study was approved by the Ethics Committee of Mie National Hospital (Study registration ID: 23-9).

Statistical analysis

The internal consistency of the questionnaire was evaluated using Cronbach's α . Test-retest reliability was examined using the intra-class correlation coefficient (Spearman) between repeated measures of the FAQLQ-PF-J. Concurrent validity was examined using Spearman correlation coefficients between the FAQLQ-PF-J and SF-8 scale scores, and also between the FAQLQ-PF-J and FAIM scale scores. Discriminant validity was evaluated by unpaired test to compare the FA and control groups. Clinical validation was performed using the number of FA symptoms and history of anaphylaxis as indicators of the severity of FA. Unpaired *t* test and one-way ANOVA followed by Holm-Sidak's multiple comparisons test were used for known-group validation. All statistical analyses were performed using SPSS Statistics version 23 (IBM, Armonk, NY, USA).

Results

Characteristics of participants

One-hundred and sixty-five participants were enrolled in the FA group and 48 in the control group. In the FA group, 38 sets of incomplete questionnaires were excluded, and 127 completed questionnaires were used for analysis. The age and gender distributions of the children did not differ between the excluded and included sets (data not shown). In the control group, all questionnaires were completed. Ninety-nine percent of the FA group respondents were the mothers, while all the control group respondents were the mothers. Table 1 shows the demographics of the participants' children. About 40% of the patients had history of anaphylaxis. The majority had experienced several food-induced symptoms except for 16 patients (13%) who had been on allergen-elimination diet because of documented food sensitization and infantile atopic dermatitis. Half of them avoided 1 or 2 kinds of food and the rest avoided 3 or more. The most prevalent

Table 1
Demographics of children of the participants.

		FA	Control	<i>P</i> value*
N		127	48	
Gender	M/F	90/37	23/25	0.0075
Age (y; mean \pm SD)		4.2 \pm 2.8	4.1 \pm 2.6	0.8301
Age groups (y)	0–3	66 (52%)	20 (42%)	0.6428
	4–6	36 (28%)	11 (23%)	0.9777
	7–12	25 (20%)	17 (35%)	0.7914
History of anaphylaxis	Yes	52 (41%)	0 (0%)	<0.0001
	No	75 (59%)	48 (100%)	
Number of food-induced symptoms	0	16 (13%)	N.A.	
	1–6	43 (34%)		
	7+	68 (54%)		
Number of foods to avoid	1–2	64 (50%)	N.A.	
	3–6	30 (24%)		
	7–10	7 (6%)		
	10+	7 (6%)		
	unknown	19 (15%)		
Allergenic food	Egg	105 (83%)	N.A.	
	Milk	63 (50%)		
	Peanut	34 (27%)		
	Wheat	26 (20%)		
	Other	72 (57%)		

%, Percent of total number of subjects in each group; N.A., Not applicable.

* Chi-square test.

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