Allergology International xxx (2016) 1–6

Contents lists available at ScienceDirect

Allergology International

journal homepage: http://www.elsevier.com/locate/alit

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 xxx

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 Allergology.

http://dx.doi.org/10.1016/j.alit.2016.06.013
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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 HRQLQ.[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	*P* value†
N		127	48	
Gender	M/F	90/37	23/25	0.0075
Age (y; mean ± SD)		4.2 ± 2.8	4.1 ± 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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allergenic food was egg, followed by milk and peanut (Table 1). With regard to age group, the first and second prevalent foods were the same in all the groups, the third prevalent food was wheat in 0–3 years-old group and peanut in the older 2 groups (Supplementary Table 1).

Supplementary Table 2 and Figure 1 show the FAQLQ-PF-J score distributions for the FA group parents. There were no gender differences in the total score or each subscale score (Supplementary Table 2). The total score and the subscale scores for emotional impact and food anxiety were significantly higher in the 7–12 and 4–6 year-old age groups than in the 0–3 year-old age group (Fig. 1).

Internal consistency and test-retest reliability

Cronbach's coefficient α for the total and subscale scores ranged from 0.77 to 0.97, demonstrating good internal consistency. Intraclass Spearman's correlations between the questionnaires completed twice at a 1-week interval were larger than 0.7, indicating high test-retest reliability (Table 2).

Concurrent validity

The total and three subscale scores of the FAQLQ-PF-J correlated significantly with the FAIM (Table 3). However, there were no correlations between the subscales of the FAQLQ-PF and those of the SF-8. This would be expected since the mean scores of the SF-8 subscales were very similar to those reported for healthy individuals in Japan,[12] i.e., around 50 (data not shown).

Table 2
Reliability of FAQLQ-PF-J scales in children with food allergy.

FAQLQ-PF-J	Age group (y)	Cronbach's α	Spearman's correlation coefficient between the 1st and 2nd tests
Total score	0–3	0.87	0.80
	4–6	0.92	0.96
	7–12	0.97	0.94
Subscales			
Emotional impact	0–3	0.80	0.85
	4–6	0.81	0.88
	7–12	0.93	0.97
Food anxiety	0–3	0.79	0.69
	4–6	0.87	0.94
	7–12	0.94	0.78
Social dietary limitation	0–3	0.77	0.80
	4–6	0.86	0.94
	7–12	0.94	0.93

Discriminant validity

The scores of the FAQLQ-PF-J subscales in each age group of the FA and control groups were compared (Table 4). The subscale and total scores for the corresponding age groups in the FA group were significantly higher than in the control group.

The parents of children who had experienced anaphylaxis had significantly higher scores for the total and each subscale than the parents whose children never experienced anaphylaxis (Fig. 2). Likewise, the total score and each subscale scores in the parents of

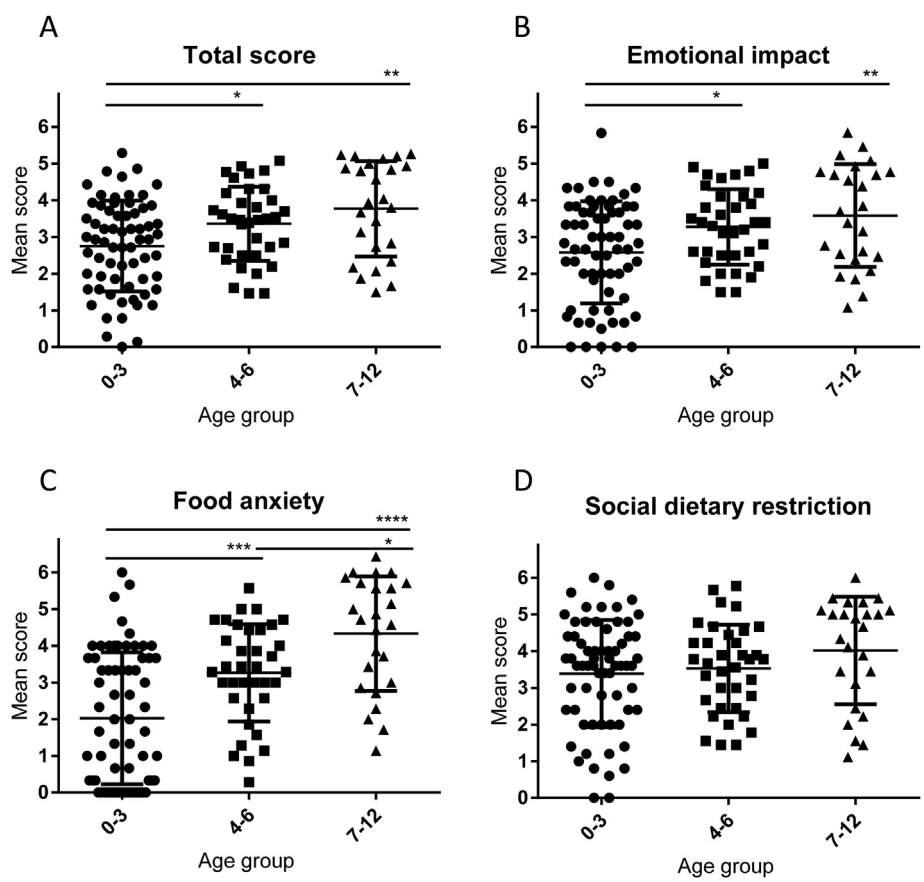

Fig. 1. Total **(A)** and subscale scores (**B**, emotional impact; **C**, food anxiety; and **D**, social dietary restriction) of FAQLQ-PF-J in FA children aged 0–3 years, 4–6 years and 7–12 years. Scores of each individual are plotted, and mean scores and ranges of SD are depicted with horizontal lines. *P* values of one-way ANOVA for **A**, **B**, **C** and **D** are 0.0008, 0.0018, <0.0001 and 0.1585, respectively. * indicates $P < 0.05$, ** indicates $P < 0.01$, *** indicates $P < 0.001$ and **** indicates $P < 0.0001$ with Holm-Sidak's multiple-comparison test.

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Table 3
Spearman's correlations between the FAQLQ-PF-J, SF-8, and FAIM-J.

FAQLQ-PF-J	SF-8										FAIM-J
	Physical functioning	Role physical	Bodily pain	General health	Vitality	Social functioning	Role emotional	Mental health	Physical component summary	Mental component summary	
Total score	−0.092	−0.022	−0.061	−0.104	−0.088	−0.211	−0.079	−0.037	−0.073	−0.112	0.560*
Subscales											
Emotional impact	−0.062	0.003	−0.157	−0.093	−0.141	−0.075	−0.031	−0.127	−0.075	−0.096	0.393*
Food anxiety	−0.041	0.042	−0.018	−0.137	−0.064	−0.256	−0.071	−0.044	−0.022	−0.153	0.639*
Social dietary limitation	−0.076	0.005	−0.088	−0.133	−0.109	−0.224	−0.080	−0.074	−0.067	−0.144	0.627*

*$P < 0.01$.

Table 4
Comparison of FAQLQ-PF-J scores between children with food allergy and the healthy controls.

Age group (y)	FAQLQ-PF-J	Mean score (SD)		*P* value
		FA	Control	
0–3	Total	2.8 (1.2)	0.5 (0.8)	<0.0001
	Subscales			
	Emotional impact	2.6 (1.4)	0.4 (1)	<0.0001
	Food anxiety	2 (1.8)	0.8 (1)	0.003
	Social dietary limitation	3.4 (1.5)	0.6 (1)	<0.0001
4–6	Total	3.4 (1.0)	0.7 (1.5)	<0.0001
	Subscales			
	Emotional impact	3.3 (1)	0.8 (1.6)	<0.0001
	Food anxiety	3.3 (1.3)	0.6 (1.3)	<0.0001
	Social dietary limitation	3.5 (1.2)	0.7 (1.6)	<0.0001
7–12	Total	3.8 (1.3)	0.4 (0.8)	<0.0001
	Subscales			
	Emotional impact	3.6 (1.4)	0.4 (0.9)	<0.0001
	Food anxiety	4.3 (1.6)	0.4 (0.9)	<0.0001
	Social dietary limitation	4 (1.5)	0.4 (0.9)	<0.0001
All ages	Total	3.1 (1.3)	0.5 (1)	<0.0001
	Subscales			
	Emotional impact	3 (1.4)	0.5 (1.1)	<0.0001
	Food anxiety	2.8 (1.9)	0.6 (1)	<0.0001
	Social dietary limitation	3.6 (1.4)	0.5 (1.1)	<0.0001

patients who had experienced 7 or more food-induced symptoms were significantly higher than those who experienced less symptoms (Fig. 3). Differences in the score for each allergenic food was not evident (Supplementary Table 3). Number of food avoided also did not affect the scores (data not shown).

Finally, higher FAQLQ-PF-J scores in older age group (Fig. 1) prompted us to examine whether prevalence of anaphylaxis and number of food-induced symptoms are higher in older age groups since the two factors appeared to have impact on the FAQLQ-PF-J scores as shown above. As expected, proportion of the patients with anaphylaxis was significantly different among three age groups (Chi-square test $P < 0.0001$), higher proportion in older age group (Fig. 4A), and number of FA symptoms in older age groups were significantly larger than younger age groups (Fig. 4B). The two factors were not different among allergenic food (Supplementary Table 3).

Discussion

We developed and validated a Japanese version of the FAQLQ-PF, an HRQL questionnaire for FA in children that parents complete from the child's perspective.[10] We found that the FAQLQ-PF-J for Japanese parents had good construct validity, internal consistency and discriminant validity. Even if there is diversity in eating habits and prevalent food allergens among countries,[1] FA is a significant burden for the patients and their families everywhere. Thus, international comparisons are meaningful to develop coordinated countermeasures and treatments for FA by using internationally validated tools to measure the QoL. The FAQLQ-PF has been validated in Europe and the US, and now for the first time in Asia in this study.

It is difficult to apply HRQL questionnaires to young children because their cognitive and expressive abilities change with age. FA affects children over a wide range of ages, from infants—who cannot be surveyed directly—to school children and adolescents—who have varying abilities to express themselves. On the other hand, mothers can "sense" or understand the burden on children, and questionnaires completed by mothers can elucidate the HRQL of children. The present HRQL questionnaire, which we translated into Japanese, was designed to identify the burden from the child's perspective by starting each question with "Because of food allergy my child…", followed by "feels different from other children", etc.[10] Mothers are asked to imagine items relating to their child's HRQL. In this regard, it is reasonable that we found that

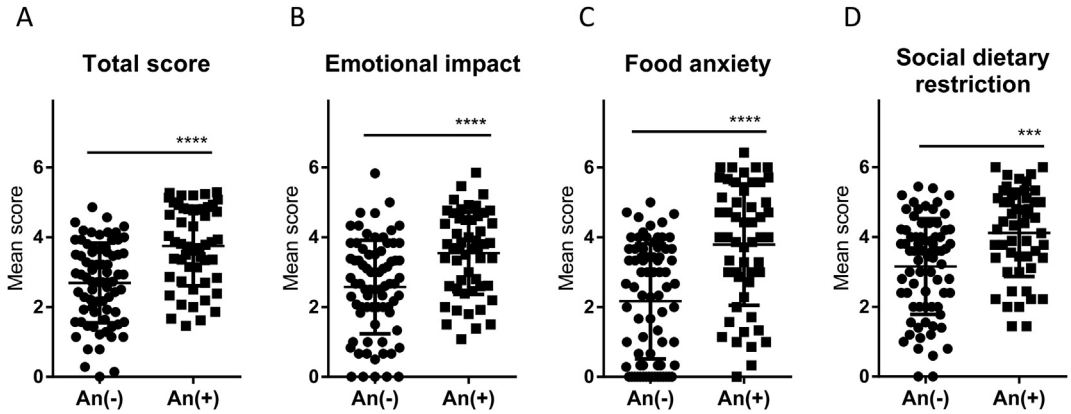

Fig. 2. Total **(A)** and subscale scores (**B**, emotional impact; **C**, food anxiety; and **D**, social dietary restriction) of FAQLQ-PF-J in FA children with and without history of anaphylaxis (An). *** indicates $P < 0.01$ and **** indicates $P < 0.001$ with the unpaired *t* test.

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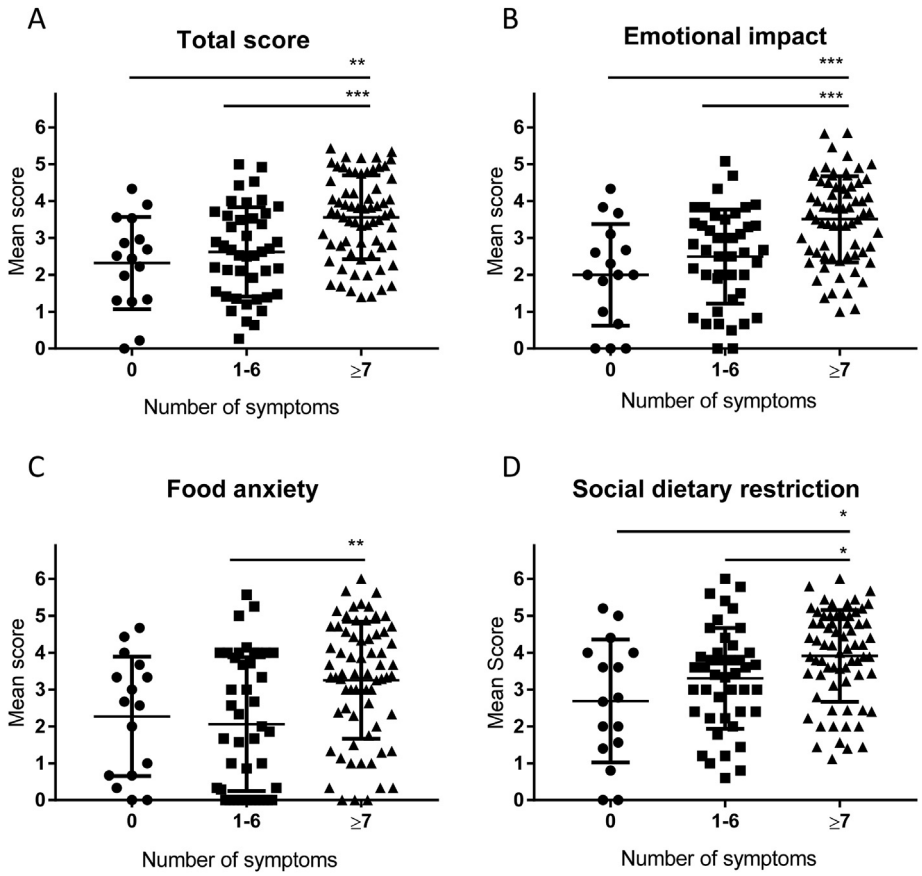

Fig. 3. Total **(A)** and subscale scores (**B**, emotional impact; **C**, food anxiety; and **D**, social dietary restriction) of FAQLQ-PF-J in FA children grouped by number of food-induced symptoms; 0, 1–6 and ≥7. Scores of each individual are plotted, and mean scores and ranges of SD are depicted with horizontal lines. *P* values of one-way ANOVA for **A**, **B**, **C** and **D** are <0.0001, <0.0001, 0.0018, and 0.0048, respectively. * indicates $P < 0.05$, ** indicates $P < 0.01$, and *** indicates $P < 0.001$ with Holm-Sidak's multiple-comparison test.

the FAQLQ-PF-J scores correlated well with the FAIM-J, but not with the SF-8 in the analysis of concurrent validity, since the latter asks about the health status of the mother, whereas the FAQLQ-PF-J asks mainly about the status of the child.

Nonetheless, we should have used a generic HRQL questionnaire for children, to be answered by parents, instead of the SF-8 to test for concurrent validity. This may be a limitation of our study. The original study of the FAQLQ-PF[10] used CHQ-PF28,[13] a generic HRQL questionnaire that covers the physical, emotional and social well-being of children. However, there was no validated Japanese translation of the CHQ-PF28.

The FAQLQ-PF-J clearly discriminated parents of children with FA from those without. Within the FA group, the scores were significantly higher for parents of FA children with a history of

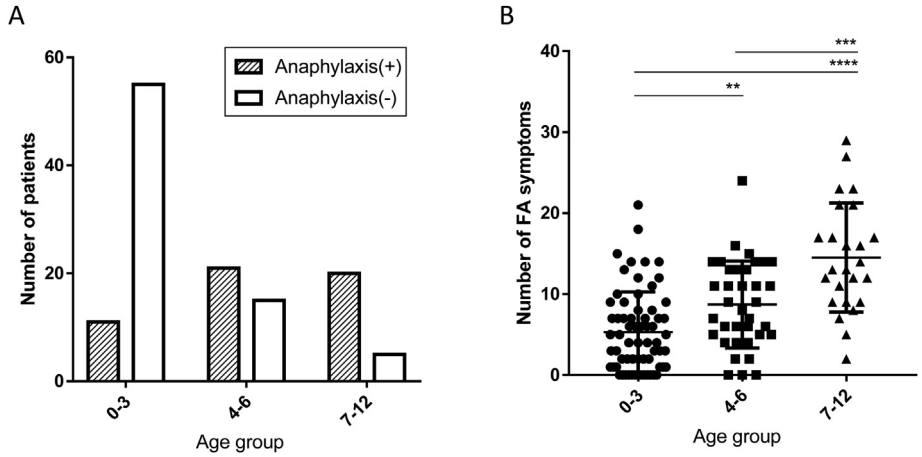

Fig. 4. **(A)** Number of FA children with (+) or without (−) history of anaphylaxis in age groups of 0–3 years, 4–6 years and 7–12 years. Proportions of anaphylaxis were significantly different between the age groups. $P < 0.0001$ with Chi-square test, **(B)** Number of FA symptoms in FA children aged 0–3 years, 4–6 years and 7–12 years. Data of each individual are plotted, and mean and ranges of SD are depicted with horizontal lines. *P* values of one-way ANOVA was <0.0001. ** indicates $P < 0.01$, *** indicates $P < 0.001$ and **** indicates $P < 0.0001$ with Holm-Sidak's multiple-comparison test.

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anaphylaxis than for those without. The scores were significantly higher for those with large number (7 or more) of food-induced symptoms than those with none or less than 7 symptoms. These results suggest that the FAQLQ-PF-J accurately reflects the severity of FA.

We found that the total score and subscale scores for emotional impact and food anxiety of FAQLQ-PF-J were significantly higher (lower QOL) in the two older age groups. We suspect that the higher score may be explained by higher prevalence of anaphylaxis and larger number of symptoms in the older age groups. In addition, an older FA child may encounter more difficulty at school and out-of-home situations because food-related activities such as school lunches and eating-out-with-friends increases as he/she gets older. And when the caregiver is not around, the child must decide for himself or herself what is safe to eat. This places a large amount of stress on the child. Perhaps the burden could be reduced by implementation of social support measures such as awareness training for non-FA children and teachers regarding FA and the proper way to assist in the case of food-induced anaphylaxis. The FAQLQ-PF may be useful for evaluating the effectiveness of such social support measures in improving FA children's QOL.

In conclusion, the Japanese version of the FAQLQ-PF is a valid instrument for measuring the HRQL of food-allergic children in Japan. The FAQLQ-PF-J can assist clinicians in optimizing management strategies for children with FA and their care-givers. In addition, it is useful to perform international collaborative studies.

Acknowledgements

The authors thank the translators and participants for preparing the Japanese version of the FAQLQ-PF. This research is supported by a Grant-in-Aid from Ministry of Health, Labour and Welfare, Japan, and a Grant-in-Aid from the Japan Agency for Medical Research and Development (AMED).

Appendix A. Supplementary data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.alit.2016.06.013.

Conflict of interest

The authors have no conflict of interest to declare.

Authors' contributions

YM, YO, ADG and TF designed the study and wrote the manuscript. MN and YM contributed to data collection. YO, MN and TF performed the statistical analysis and interpretation of the results. All authors read and approved the final manuscript.

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Supplementary Table 1

Prevalence of allergenic food in each age group.

	Age group (y)		
Allergenic food	0-3	4-6	7-12
Egg; n (%)	54 (82%)	30 (83%)	21(84%)
Milk; n (%)	32 (48%)	13 (36%)	18 (72%)
Peanuts; n (%)	13 (20%)	11 (31%)	10 (40%)
Wheat; n (%)	16 (24%)	6 (17%)	4 (16%)
others; n (%)	24 (36%)	12 (33%)	14 (56%)

n, number of patients; %, percent of total number of subjects in each group.

Supplementary Table 2

Score distribution of the FAQLQ-PF-J for parents of children with food allergy.

FAQLQ-PF-J	Age group (y)	Gender	Mean score (SD)	P^*
Total	0-3	M	2.8 (1.2)	0.333
		F	2.5 (1.2)	
	4-6	M	3.4 (1.1)	0.921
		F	3.3 (0.9)	
	7-12	M	3.6 (1.4)	0.349
		F	4.1 (1.1)	
	all ages	M	3.1 (1.2)	0.812
		F	3.1 (1.3)	
Subscales				
Emotional impact	0-3	M	2.6 (1.4)	0.688
		F	2.5 (1.4)	
	4-6	M	3.3 (1.1)	0.842
		F	3.3 (0.8)	
	7-12	M	3.4 (1.5)	0.519
		F	3.8 (1.1)	
	all ages	M	3 (1.4)	0.928
		F	3 (1.3)	
Food anxiety	0-3	M	2.2 (1.8)	0.362
		F	1.7 (1.7)	
	4-6	M	3.2 (1.4)	0.862
		F	3.3 (1.3)	
	7-12	M	4.2 (1.7)	0.653
		F	4.5 (1.3)	
	all ages	M	2.9 (1.9)	0.756
		F	2.8 (1.9)	
Social dietary limitation	0-3	M	3.5 (1.4)	0.246
		F	3.1 (1.6)	
	4-6	M	3.6 (1.2)	0.557
		F	3.3 (1.4)	
	7-12	M	3.7 (1.5)	0.127
		F	4.6 (1.3)	
	all ages	M	3.6 (1.3)	0.781
		F	3.5 (1.6)	

Supplementary Table 3

Prevalence of anaphylaxis, number of FA symptoms and total and subscale scores of FAQLQ-PF-J for each allergenic food.

Allergenic food	n	Anaphylaxis †	Number of FA symptoms	FAQLQ-PF-J score‡			
				Total	Subscale		
					Emotional impact	Food anxiety	Social dietary limitation
Egg	105	44 (42)	9.0 (6.3)	3.2 (1.3)	3.1 (1.3)	2.8 (1.8)	3.7 (1.3)
Milk	63	34 (54)	10.4 (6.5)	3.2 (1.3)	3.2 (1.4)	2.7 (1.9)	3.8 (1.3)
Peanut	34	20 (59)	11.4 (1.2)	3.5 (1.2)	3.4 (1.3)	3.2 (1.5)	3.8 (1.3)
Wheat	26	14 (54)	9.1 (6.9)	3.2 (1.2)	3.1 (1.4)	2.3 (1.9)	4.1 (1.0)

†n (%) ; ‡ Mean (SD).