



Japanese version of the food allergy quality of life questionnaire 10: An easy-to-use instrument

Shigenori Kabashima, MD, PhD^{a*}, Kiwako Hanada Yamamoto, MD, PhD^a, Yumiko Miyaji, MD^a, Yuri Endo Kram, MD^a, Mami Shimada, MD^a, Seiko Hirai, MD^a, Hiroya Ogita, MD^a, Tomoyuki Kiguchi, MD^a, Yusuke Inuzuka, MD, PhD^a, Kenji Toyokuni, MD, PhD^a, Makoto Irahara, MD, PhD^a, Fumi Ishikawa, MD^a, Miori Sato, MD^a, Mayako Saito-Abe, MD, PhD^a, Hiroki Yasudo, MD, PhD^a, Tatsuki Fukuie, MD, PhD^a, Ichiro Nomura, MD, PhD^a, Audrey DunnGalvin, PhD^b and Yukihiro Ohya, MD, PhD^{a**}

ABSTRACT

Background: The health-related quality of life (HRQL) of people with food allergies should be evaluated to provide high-quality medical care. Currently, there is no available easy-to-use and reliable instrument for assessing HRQL clinically in Japan.

Methods: The Food Allergy Quality of Life Questionnaire 10 (FAQLQ10) in English was translated into Japanese, and this was referred to as the Japanese version of the Food Allergy Quality of Life Questionnaire 10 (FAQLQ10-J). Participants aged up to 18 years, who had food allergy, and their parents were instructed to complete the FAQLQ10-J and the Food Allergy Independent Measure, a self-report instrument. For comparison, participants without food allergies were also included in the survey.

Results: The FAQLQ10-J, which included forms for individuals aged 8-12 years, teenagers, and caregivers was developed. The responders completed each form within approximately 3 min. An analysis of responses showed that each form had a good internal consistency, test-retest reliability, construct validity, and discriminant validity. Moreover, based on an examination of the relationship between demographic data and FAQLQ10-J scores, items such as possession of an adrenaline auto-injector, participant age, and number of eliminated foods might influence HRQL.

Conclusions: We developed the FAQLQ10-J, which is a simple, reliable, and effective tool for assessing HRQL among Japanese individuals with food allergy. Its use may provide a more detailed understanding of HRQL among individuals with food allergy in clinical settings and may facilitate the development of more individual-oriented treatments.

Keywords: Anaphylaxis, Caregivers, Food allergy, Quality of life, Japan

^aAllergy Center, National Center for Child Health and Development, Setagaya, Tokyo, Japan

*Corresponding author. Allergy Center, National Center for Child Health and Development; 2-10-1, Okura, Setagaya, Tokyo 157-8535, Japan, E-mail: kabashima-s@ncchd.go.jp

**Corresponding author. Allergy Center, National Center for Child Health and Development; 2-10-1, Okura, Setagaya, Tokyo 157-8535, Japan, Email: ohya-y@ncchd.go.jp

Full list of author information is available at the end of the article

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INTRODUCTION

Individuals with food allergy experience stress daily. Food allergies are commonly asymptomatic. However, the ingestion of certain foods can cause severe and sudden symptoms. Thus, certain foods must be cautiously excluded from one's daily diet. Due to constant stress, the health-related quality of life (HRQL) of individuals with food allergy and their families is deteriorating.¹

In an early report on food allergy in children, Sicherer et al (2001) reported that food allergies affect various aspects of the family, including overall health perception, emotions of the caregivers, and limitations on family activities.² Subsequent reports have indicated that various factors, including type and number of food allergens, presence of severe symptoms, age of individuals with food allergy, and household income, are associated with a deterioration in HRQL.^{3,4} Children with food allergies were reported to feel isolated in school and social settings and were more likely to be targets of bullying.^{5,6} Food allergies imposed an economic burden on both individuals and society.⁷

Children with food allergies and their families experience reduced quality of life due to the various burdens imposed by the condition. The importance of providing care with a focus on improving HRQL is increasingly being recognized. HRQL can be assessed using general or disease-specific questionnaires. Since the early 2000s, the impact of food allergy on individuals and their families has been investigated using questionnaires developed for persons with chronic illness in general. Results showed that these individuals had impaired HRQL. General questionnaires can measure and compare HRQL regardless of disease type.⁸ However, changes in disease-specific scores can be missed.⁹ The Food Allergy Quality of Life Questionnaire (FAQLQ) is a disease-specific measuring tool that was developed from this perspective¹⁰⁻¹³ with the support of EuroPrevall. The FAQLQ had excellent validity and reliability. It was translated into European, American, and Asian languages¹⁴⁻²² and is widely used because it measures HRQL with high sensitivity in individuals with food allergy and their parents. Several disease-specific questionnaires have been developed to examine the impact of food allergies on quality of life.²³⁻²⁷ Among these,

the FAQLQ is the most widely used globally and can be considered the most important questionnaire in this field. It has a relatively large number of questions and is time-consuming. Therefore, it has been mainly applied as a research tool²⁸⁻³⁰ and rarely in clinical practice for treating patients. The same applies to other questionnaires that are specific to food allergies; no easily useable ones have been developed.

Improving HRQL for individuals with food allergy and their families is an important goal during treatment. The goals of food allergy treatment commonly include reducing the number of foods that must be avoided or increasing the amount of foods that can be consumed. However, these are considered surrogate outcomes. Health care providers must aim to directly improve HRQL. Therefore, a scale is required that easily assesses HRQL in individuals with food allergy. To meet this need, the FAQLQ10, a shortened and simpler version of the FAQLQ, was developed and used in clinical settings. The FAQLQ10 had good reliability and validity in the families of individuals with food allergy in Ireland and United States.^{31,32} Given that the FAQLQ is widely used internationally, the FAQLQ10, which is based on the FAQLQ, is expected to be used in various languages in the future.

The current study aimed to develop the Japanese version of the Food Allergy Quality of Life Questionnaire 10 (FAQLQ10-J) to provide individuals with food allergies in Japan and health care providers an easy-to-use tool for measuring HRQL. A common international tool can compare and examine HRQL of individuals with food allergy among societies with different linguistic and cultural backgrounds. For Japanese individuals, this increases the opportunity to receive care based on global standard patient-reported outcomes, whereas for non-Japanese individuals, it offers the advantage of accessing baseline HRQL data that considers regional and ethnic differences through data sharing in Japan.

METHODS

FAQLQ10-J and food allergy independent measure

We developed the FAQLQ10-J by translating the English version of the FAQLQ10 into Japanese.

The FAQLQ10 is a shortened version of the FAQLQ and was developed in English as a disease specific HRQL assessment instrument for individuals with food allergies. The original form of the FAQLQ, which is based on the individuals' age, includes the following: Child Form, Teenager Form, and Adult Form. In addition, there is Parent Form, which should be answered by the caregiver based on the child's perspective. Each form comprises 30 questions in 3 domains: emotional impact, anxiety correlated with food intake, and social life limitations. Participants were instructed to answer each question on a seven-point Likert scale, with higher scores indicating impaired HRQL. The FAQLQ10 comprises 10 questions that were created by modifying some questions or by combining multiple questions in the FAQLQ. These questions span 3 domains, similar to the FAQLQ. The respondents were instructed to answer each question on a seven-point scale. The FAQLQ10, similar to the FAQLQ, has 4 forms, which are as follows: Child Form, Teenager Form, Adult Form, and Parent Form. All FAQLQ10 forms, except for Adult Form, were translated into Japanese and created into the FAQLQ10-J Child Form, Teenager Form, and Parent Form.

The FAQLQ10 was translated into Japanese according to the following procedure: First, the English version of the FAQLQ10 was translated into Japanese by 2 native Japanese speakers. Then, the Japanese translation was prepared by making revisions via a discussion among translators. The Japanese translation was presented to individuals with food allergy and their caregivers, who were questioned about problems regarding ease of understanding or answering. Next, further revisions were made. The FAQLQ10-J created via this procedure was then back-translated into English by 2 native and native-equivalent English speakers. The back-translated FAQLQ10 was checked by the developer of the English version of the FAQLQ10 to ensure that there were no linguistic errors or cultural biases. Based on the aforementioned procedure, the FAQLQ10-J was created.

Moreover, this study developed a Japanese version of the Food Allergy Independent Measure (FAIM), which is a tool used to validate the FAQLQ10-J. The FAIM is an independent measurement instrument developed to confirm the

results of the food allergy-specific questionnaires,³³ and it has been used to validate several HRQL scales.¹⁰⁻¹³ It comprises 6 questions rated on a seven-point scale. As with the FAQLQ, the FAIM includes questions about the number of foods that should be avoided and restrictions on social life as well as questions about the likelihood of accidental ingestion, the likelihood that an accidental ingestion will trigger a strong reaction, and the likelihood that an appropriate response will not be possible when an allergic reaction occurs. In developing the FAQLQ10-J, the FAIM was used to examine construct validity. Therefore, the Japanese version of the FAIM forms (FAIM-J Child Form, Teenager Form, and Parent Form) were developed using the same procedure as in establishment of the PAQLQ10-J.

Participants and procedure

We recruited individuals with food allergy and their caregivers in the order of their visits from June 18, 2020, to November 5, 2020, who attended the Allergy Department of National Center for Child Health and Development and were diagnosed with food allergies based on documented histories of clear immediate-type allergic reactions or positive results from oral food challenge tests. In total, 100 participants (aged 8-12 and 13-18 years) were recruited and instructed to complete the Child Form and Teenager Form of FAQLQ10 J-. The caregivers (n = 100) of participants aged 12 years or younger were recruited and instructed to fill out the FAQLQ10-J Parent Form. Moreover, all participants were asked to complete the relevant FAIM-J. To examine the test-retest reliability, the first 40 participants recruited were instructed to complete the second form after 10-14 days. To test the discriminant validity, we randomly recruited participants from other departments of the same institution who did not have food allergies and were not under dietary restrictions, and requested them to complete the FAQLQ10-J.

When the children filled out the forms, the caregivers were allowed to explain the question. However, they should not provide answers to the child. Further, they were instructed to answer a form asking about participant's age, sex, type of food allergy, number of foods eliminated, history of anaphylaxis, possession of adrenaline auto-

injector (AAI), and comorbidities (atopic dermatitis, bronchial asthma, and allergic rhinitis).

Statistical analysis

The internal consistency of the forms was assessed using Cronbach's alpha (α). Generally, Cronbach's α is interpreted as follows: ≥ 0.9 indicates excellent reliability, 0.8–0.9 indicates good reliability, and 0.7–0.8 indicates acceptable reliability.³⁴ To assess the test-retest reliability, intraclass correlation coefficients were examined using the forms completed by participants who were instructed to respond twice. Intraclass correlation coefficients are interpreted as follows: ≥ 0.90 indicates excellent reliability, 0.75–0.90 indicates good reliability, and 0.50–0.75 indicates moderate reliability.³⁵ To examine the construct validity, the Spearman correlation coefficient between the FAQLQ10-J and FAIM-J was calculated. Spearman correlation coefficient is interpreted as follows: 0.80–1.00 indicates very strong correlation, 0.60–0.80 indicates strong correlation, and 0.40–0.60 indicates moderate correlation.³⁶ To examine the discriminant validity, the Mann-Whitney *U* test was used to compare the food allergy and control groups. In addition, analysis of covariance was performed to determine whether participant age, sex, number of foods eliminated, history of anaphylaxis, possession of AAI, and comorbidities were associated with the FAQLQ10-J scores. Finally, the FAQLQ10-J Child Form and Parent Form scores were evaluated to compare the HRQL assessed by participants themselves and their caregivers. The correlations between the 2 were examined using the Spearman coefficient, and differences were examined using the dependent *t*-test. All statistical analyses were performed using the Statistical Package for the Social Sciences software version 19.0 (IBM Inc.).

Ethical considerations

This study was approved by the ethics committee of National Center for Child Health and Development (reception no.: 2019-038). The participants and their caregivers were informed about the study prior to completing the forms. Children aged 7 years and older signed an assent form, and those aged 16 years and older and their caregivers provided a signed consent form indicating their

agreement for the publication of the research results as a paper.

RESULTS

Participants

In total, 98, 99, and 100 participants with food allergy and their caregivers responded to the FAQLQ10-J Child Form, Teenager Form, and Parent Form, respectively. Then, 50 participants without food allergies and their caregivers also answered each form.

Demographic data

Table 1 shows the demographic data of the participants. The number of male participants who answered the 3 forms was higher than that of female participants. The most common causative food was egg, followed by milk, peanut, and wheat. The proportion of participants (74%) with egg allergy who responded to the FAQLQ10-J Parent Form, which is the youngest participant population, was particularly high. Hence, younger participants might likely present with egg allergy and undergo remission with increasing age. Conversely, the cumulative incidence of participants who experienced anaphylaxis increased with age: 59.0%, 64.3%, and 77.6% based on the FAQLQ10-J Parent Form, Child Form, and Teenager Form, respectively. Overall, these data may reflect the epidemiological characteristics of Japanese pediatric patients with food allergies.^{37,38}

FAIM-J

First, we examined the internal consistency, test-retest reliability, and discriminant validity of the FAIM-J. Based on responses from each participant, Cronbach's α values for the FAIM-J Child Form, Teenager Form and Parent Form were 0.841, 0.789, and 0.863, respectively. The intraclass correlation coefficients for the test-retest method were 0.771, 0.863, and 0.865, respectively. The Mann-Whitney test showed that, in all groups, the scores were significantly higher for individuals with food allergies than those without. These results confirm that the FAIM-J has good reliability and validity.

	FAQLQ10-J Parent Form	FAQLQ10-J Child Form	FAQLQ10-J Teenager Form
Participants (n)	100	98	98
Sex, (M/F)	66/34	67/31	61/36
Age, range (years)	0-12	8-12	13-18
Age, mean in years (SD)	6.71 (3.70)	9.81 (1.49)	15.14 (1.88)
Food allergy, n (%)			
Egg	74 (74.0)	64 (65.3)	48 (49.0)
Milk	41 (41.0)	46 (46.9)	34 (34.7)
Wheat	18 (18.0)	15 (15.3)	17 (17.3)
Peanut	26 (26.0)	27 (27.6)	29 (29.6)
Others	41 (41.0)	53 (54.1)	63 (64.3)
Number of foods eliminated, n (%)			
1 food	33 (33.0)	23 (23.5)	24 (24.5)
2 foods	13 (13.0)	15 (15.3)	15 (15.3)
3 foods	17 (13.0)	20 (20.4)	8 (8.2)
>3 foods	30 (30.0)	32 (32.7)	43 (43.9)
Number of previous anaphylactic episodes, n (%)			
0 episode	42 (42.0)	34 (34.7)	22 (22.4)
1 episode	22 (22.0)	21 (21.4)	23 (23.5)
2 episodes	15 (15.0)	20 (20.4)	13 (13.3)
3 episodes	10 (10.0)	8 (8.2)	9 (9.2)
>3 episodes	11 (10.0)	14 (14.3)	31 (31.6)
Any episode	59 (59.0)	63 (64.3)	76 (77.6)
Possession of AAI	59 (59.0)	73 (74.5)	74 (75.5)
Comorbidity			
Atopic dermatitis	69 (69.0)	59 (60.2)	68 (69.4)
Bronchial asthma	39 (39.0)	37 (37.8)	29 (29.6)
Allergic rhinitis	56 (56.0)	68 (69.4)	66 (67.3)

Table 1. Demographic characteristics of the participants AAI: *adrenalin auto-injector*

FAQLQ10-J Child Form

Participants aged 8-12 completed the FAQLQ10-J Child Form. We calculated Cronbach's α to confirm the internal consistency of the form. Among the collected forms, 96 were included in the analysis, because they were fully completed without missing data. Cronbach's α was 0.894, indicating that the Child Form has good internal consistency (Table 2). Subsequently, we examined the test-retest reliability of the Child Form. In total, 37 forms were fully completed with responses at 2 time points, 10-14 days apart. We compared the results from the first and second responses and calculated the intraclass correlation coefficient, which was 0.783, suggesting good test-retest reliability. To confirm construct validity, we compared

the scores of the Child Form of FAQLQ10-J and FAIM-J. Among the participants, 95 completed both forms without any missing data, and were included in the analysis. The calculation resulted in a Spearman coefficient of 0.707, indicating strong correlation and confirming the construct validity of the FAQLQ10-J Child Form. Finally, we assessed discriminant validity. Among the responses obtained from participants without food allergies, 49 were fully completed without any missing data. We compared these results with those from participants with food allergies using the Mann-Whitney test. The results showed that the scores were significantly higher for participants with food allergies than those without, suggesting good discriminant validity of the Child Form.

	FAQLQ10-J Parent Form	FAQLQ10-J Child Form	FAQLQ10-J Teenager Form
Internal consistency			
Number of samples, n	99	96	98
Cronbach's α	0.88	0.89	0.92
Test-retest reliability (10-14-day reproducibility)			
Number of samples, n	39	37	40
Interclass correlation coefficient	0.78	0.78	0.75
Construct validity (correlation with FAIM)			
Number of samples, n	97	95	96
Spearman's correlation coefficient	0.63	0.71	0.66
Discriminative validity			
Number of samples (with/without FA), n	99/50	96/49	98/50
Average score (with/without FA)	3.20/0.35	2.50/0.15	2.90/0.63
Significance level ^a	<0.001	<0.001	<0.001

Table 2. Validity and reliability of the FAQLQ10 FA: food allergy. ^aMann-Whitney U test

FAQLQ10-J Teenager Form

Participants aged 13-18 years completed FAQLQ10-J Teenager Form. The analysis was similar to that for the Child Form. Cronbach's α was calculated using 98 forms. The calculated value of Cronbach's α was 0.919, confirming excellent reliability. For test-retest analysis, 40 forms had complete responses at 2 time points. The value of calculated intraclass correlation coefficient was 0.750, suggesting good test-retest reliability. In participants aged 13-18 years, 95 completed the Teenager Form for both FAQLQ10-J and FAIM-J without any missing data and were included in construct validity analysis. The Spearman coefficient was 0.662, indicating a strong correlation. In total, 48 individuals without food allergies fully completed FAQLQ10-J Teenager Forms with no missing data. The result of Mann-Whitney test showed that the scores of individuals with food allergies were significantly higher, indicating that the FAQLQ10-J Teenager Form has discriminant validity.

FAQLQ10-J Parent Form

The caregivers of individuals aged ≤ 12 years completed the FAQLQ10-J Parent Form, which was then analyzed using the same methods as the Child Form and Teenager Form. In total, 99 forms were used to calculate Cronbach's α . The calculated value of Cronbach's α was 0.876, confirming good reliability. The number of forms with

complete responses at 2 time points for the test-retest analysis was 39. The calculated intraclass correlation coefficient was 0.782, suggesting good test-retest reliability. Of the Parent Form obtained from caregivers of participants without food allergies, 50 were fully completed with no missing data. The Mann-Whitney test confirmed significantly higher scores of caregivers of individuals with food allergies than those without, indicating that the Parent Form has discriminant validity.

Association between demographic characteristics and FAQLQ10-J scores

Table 3 shows the covariance analysis results for sex, age, number of eliminated foods, number of anaphylaxis episodes, possession of AAI, and comorbidities. Possession of AAI was associated with higher scores in the FAQLQ10-J Child Form and Teenager Form. In addition, participant age, bronchial asthma, and number of foods eliminated were associated with higher scores of the Parent Form, Child Form, and Teenager Form, respectively.

Comparison of FAQLQ10-J Child Form and Parent Form scores

We instructed 50 pairs of participants and their caregivers to complete the FAQLQ10-J Child Form and Parent Form. The scores of the 49 pairs who had complete responses for both forms were

compared. The Pearson coefficient of the 2 scores was 0.364, indicating mild correlation. However, the mean Child Form and Parent Form scores were 2.38 (standard deviation [SD]: 1.43) and 3.67 (SD: 1.14), respectively. The score of Parent Form was significantly higher based on the analysis of independent samples using the *t*-test ($p < 0.001$). Therefore, caregivers might have a more impaired perception regarding HRQL than individuals with food allergies (aged 8–12 years).

DISCUSSION

This study developed a simple instrument for assessing disease-specific HRQL in individuals with food allergies in Japan by translating the original FAQLQ10 written in English into Japanese and validating its efficacy. The FAQLQ10-J had good performance in terms of internal consistency, test-retest reliability, construct validity, and discriminant validity, and was found to be effective when used for Japanese individuals.

The original FAQLQ10, a short version of the FAQLQ, which is an internationally used, food allergy-specific HRQL measurement tool, was developed to facilitate the assessment of HRQL in individuals with food allergy. Most reports have used the FAQLQ for examining HRQL for research purposes, and only few studies have assessed HRQL in clinical settings and treated patients based on survey results. The FAQLQ is not routinely used in clinical settings probably because it has a relatively large number of questions and is time-consuming. In our study, participants filled out the FAQLQ10-J forms within approximately 3 min. The FAQLQ10-J, which can be completed within a short period, is an effective and simple tool that can be used in actual treatment settings.

In this study, the FAQLQ10-J had a good test-retest reliability. Mizuno et al. created a Japanese version of the FAQLQ Parent Form and evaluated its validity.²⁰ In addition, they examined its test-retest reliability by asking participants to respond

	Parent Form			Child Form			Teenager Form		
	B	<i>p</i> value	95 % CI	B	<i>p</i> value	95 % CI	B	<i>p</i> value	95 % CI
Sex	−0.131	0.57	−0.59 to 0.33	0.16	0.57	−0.41 to 0.73	0.01	0.99	−2.21 to 2.23
Age	0.09	0.04 ^a	0.00 to 0.17	−0.054	0.57	−0.24 to 0.13	0.38	0.19	−0.19 to 0.95
Number of foods eliminated	0.08	0.36	−0.09 to 0.25	0.12	0.27	−0.09 to 0.33	0.83	0.03 ^a	0.10 to 1.55
Number of previous anaphylactic episodes	0.17	0.09	−0.03 to 0.36	0.05	0.69	−0.18 to 0.28	0.33	0.40	−0.44 to 1.10
Possession of AAI	−0.328	0.27	−0.92 to 0.26	−0.797	0.04 ^a	−1.55 to −0.04	−3.853	0.01 ^a	−6.66 to −1.05
Atopic dermatitis	−0.187	0.44	−0.67 to 0.29	0.17	0.63	−0.52 to 0.85	−1.877	0.18	−4.64 to 0.88
Asthma	−0.089	0.72	−0.58 to 0.40	0.77	0.01 ^a	0.19 to 1.35	−2.291	0.07	−4.74 to 0.16
Allergic rhinitis	−0.094	0.73	−0.64 to 0.45	−0.451	0.21	−1.16 to 0.25	2.75	0.07	−0.27 to 5.77

Table 3. Factors influencing FAQLQ10 scores AAI: adrenalin auto-injector. ^aSignificance, $p < 0.05$.

twice at an interval of 1 week. Results showed a high correlation coefficient (0.8–0.96). This indicated that its reliability was higher than that in the current study. This finding might be attributed to the fact that the FAQLQ had 3 times more questions than the FAQLQ10, which makes the results more stable. DunnGalvin et al. examined changes in the FAQLQ Parent Form scores in pediatric individuals before and after the food challenge test, which was conducted at an interval of 6 months. Results revealed long-term reliability.³⁹ Prior to the use of the FAQLQ10-J for the long-term management of patients, more studies must be conducted to validate whether it can identify long-term changes in HRQL in a stable manner.

Our data showed that the demographic characteristics of participants might affect the FAQLQ10-J scores. The FAQLQ10-J Parent Form score increased with participant age. This trend is consistent with the results of several previous studies about the FAQLQ Parent Form.^{10,19,21,22,40} Thus, as the individual grows older, the range of their activities becomes wider, which can relatively increase the restrictions they face in daily life.^{10,19,21,22,40} Participants with comorbidities including bronchial asthma had higher FAQLQ10-J Child Form scores. Individuals with bronchial asthma often have memories of painful experiences associated with attacks in the past. These individuals are prone to strong allergic symptoms upon consuming allergic foods. Hence, these past experiences and knowledge may have influenced their HRQL. The FAQLQ10-J Teenager Form scores increased with the number of foods avoided. As children get older and present with more opportunities to manage their own diet, the complexity of removing a large number of foods from one's diet likely becomes a burden. Some studies have reported that the FAQLQ Parent Form and Adult Form scores increased with the number of allergenic foods and the number of foods that should be eliminated.^{13,16,41} Meanwhile, some studies have shown that the number of allergenic foods did not affect HRQL.¹⁴ The differences in study results could be attributed to varying patient population and cultural background. Ramos et al. reported significant differences between racial groups in the results of responses to several questions on the FAQLQ10 Parent Form, even within the same study cohort.³²

Interestingly, possession of AAI was significantly associated with high FAQLQ10-J Child Form and Teenager Form scores, which were assessed by individuals themselves. However, it did not affect the Parent Form scores, which were assessed by their caregivers. Multiple studies have reported similar results.^{14,42} This finding is attributed to the fact that some individuals are aware about their condition and the importance of bringing AAI at all times and that they are cautious that injections might be required in case of emergency. Some studies have reported that a history of anaphylaxis is associated with higher FAQLQ scores^{13,14,15,20}. Meanwhile, others have reported that it had no effect.^{11,12,18,21} More detailed studies have evaluated the differences in HRQL based on whether individuals had a severe response affecting their circulatory dynamics. We did not ask the participants about specific symptoms. Hence, the severity of anaphylaxis was not validated. To determine the impact of allergic reactions on HRQL, the actual symptoms should be evaluated in detail.

In participants aged 8–12 years, the HRQL assessed by the participants themselves was compared with that evaluated by their caregivers, and the HRQL investigated by the caregivers was lower. Velde et al. reported that in a Dutch parent-child pair, the Child Form scores were higher than the Parent Form scores,⁴³ and there was no difference between the Teenager Form and Parent Form scores.⁴⁴ Moreover, the FAQLQ scores may be affected by several factors, including age, linguistic environment, and cultural background. Moreover, they emphasized the importance of assessing HRQL from the perspectives of individual with food allergy and their caregivers. This study compared HRQL scores of patients and caregivers, and the results were in contrast to those of other studies. This might be attributed to the fact that the study was conducted in an environment with a completely different linguistic and cultural background.

Individuals with food allergy are subjected to different interventions in clinical settings, and the FAQLQ10-J can be used to examine the impact of such interventions. Some reports showed significant improvement in the FAQLQ Child Form, Teenager Form, and Adult Form scores in individuals who underwent double blind placebo-controlled food challenge (DBPCFC) with peanut

or certain nuts and showed negative results.⁴⁵ However, others have shown poor improvement in HRQL in individuals who underwent DBPCFC with cashews, even when the results were negative.⁴⁶ Therefore, the differences may be attributed to the combined effect of various factors on changes in HRQL, including the level of impairment at baseline. These reports showed that there are individual differences in changes in HRQL associated with food challenge and that there is a need for individualized assessments to examine the impact of these changes. When we focus on the impact of oral immunotherapy, HRQL is generally believed to improve when the amount of tolerable allergic food is increased or the types of foods that should be eliminated is decreased. However, in some cases, oral immunotherapy was found to temporarily worsen HRQL.⁴⁷ Health care providers should aim to reduce the burdens and limitations of persons in real-world settings and to provide treatments that can improve HRQL. Repeatedly assessing and monitoring HRQL with the FAQLQ10-J may improve the quality of treatment provided to individuals with food allergy.

The strength of the current study is, that we developed 3 forms (the FAQLQ10-J Child Form, Teenager Form, and Parent Form) based on the participant's age, which covers the HRQL assessment of all young people aged up to 18 years and their caregivers. However, this study also had limitations. For example, the characteristics of participants such as history of anaphylaxis and comorbidities were assessed via self-report. Although the subjective perceptions of participants influence HRQL, objective assessment of participant reports could have potentiated the reliability of our study. Additionally, although this study examined the relationship between the number of foods requiring elimination and patient HRQL, it did not investigate the impact of the types of foods being eliminated. In reality, eliminating commonly consumed foods such as eggs and wheat is presumed to have a greater impact on HRQL than removing other foods. The type of food eliminated cannot be ignored when considering its impact on HRQL. Among the participants in this study, there were differences in the types of foods eliminated across age groups. Further

investigations are needed to understand how various demographic factors affect HRQL.

In conclusion, we developed the FAQLQ10-J, which is a simple instrument for assessing HRQL, in individuals with food allergy in Japan clinically, by translating FAQLQ10 into Japanese. This tool could measure the HRQL in young people aged up to 18 years from the perspective of the patients and their caregivers. The internal consistency, test-retest reliability, construct validity, and discriminant validity of the FAQLQ10-J were evaluated. Results showed that it was valid and reliable. Therefore, this tool could be utilized for developing better patient education and treatment methods that can improve HRQL of individuals with food allergy.

Abbreviations

AAI: adrenaline auto-injector; DBPCFC: Double Blind Placebo-Controlled Food Challenge; FAIM: Food Allergy Independent Measure; FAIM-J: Japanese version of the Food Allergy Independent Measure; FAQLQ: Food Allergy Quality of Life Questionnaire; FAQLQ10: Food Allergy Quality of Life Questionnaire 10; FAQLQ10-J: Japanese version of the Food Allergy Quality of Life Questionnaire 10; HRQL: Health-related quality of life

Availability of data and materials

We have not made the data publicly available.

Authors' consent for publication

All authors have reviewed this manuscript and consent to its publication.

Ethics approval

This study was approved by the ethics committee of the National Center for Child Health and Development (reception no.: 2019-038).

Author contribution

SK and YO designed the study and wrote the manuscript. KHY and YM contributed to the translation and revision of the questionnaire. ADG supervised the study and development of the questionnaire. SK, KHY, YEK, MS, SH, HO, TK, YI, KT, FI, MI, MS, MS, HY, TF, and IN contributed to data collection. All authors read and approved the final manuscript.

Declaration of generative AI and AI-assisted technologies in the writing process

During the preparation of this work the authors used ChatGPT in order to check the readability of the English text in a portion of the manuscript. After using this tool, the

authors reviewed and edited the content as needed and take full responsibility for the content of the publication.

Confirmation of unpublished work

This manuscript is original, has not been published before, is not currently being considered for publication elsewhere, and has not been posted to a preprint server.

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Declaration of competing interest

The authors report no competing interests.

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Author details

^aAllergy Center, National Center for Child Health and Development, Setagaya, Tokyo, Japan. ^bSchool of Applied Psychology, University College Cork, Cork, Ireland.

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