

Short communication

Development, validity and reliability of the food allergy independent measure (FAIM)

Background: The Food Allergy Quality of Life Questionnaire-Child Form, -Teenager Form and -Adult Form (FAQLQ-CF, -TF and -AF) have recently been developed. To measure construct validity in the FAQLQs, a suitable independent measure was needed with which FAQLQ scores could be correlated. However, in food allergy, no appropriate independent measure existed, which could be used for this purpose.

Aims of the study: The aim of this study was to describe the development of a Food Allergy Independent Measure Child-Form, -Teenager Form and -Adult Form (FAIM-CF, -TF and -AF) and to assess their validity and reliability.

Methods: The FAIMs were developed using previously established methodology to capture the patients' expectation of outcome (EO). Face validity was determined by expert opinion. FAIM questions showing no correlation to any potential items in the FAQLQs were considered irrelevant and eliminated.

To measure test-retest reliability, one-hundred and one patients were included and completed the FAIM twice with a 10–14 day interval. The intraclass correlation coefficient (ICC), Lin's concordance correlation coefficient (CCC) and Bland-Altman plots were used to assess test-retest reliability.

Results: Six FAIM questions were developed and considered relevant for the FAIM-CF and -AF, and five questions were relevant for the FAIM-TF. The FAIMs showed good reliability with ICCs and CCCs above 0.70 and with mean differences all close to zero.

Conclusions: Food allergy independent measures were developed for children, adolescents and adults and were shown to be valid, relevant and reliable. This supports the suitability of the FAIMs for evaluating construct validity.

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In Health Related Quality of Life (HRQL) research, construct validity is the only approach possible to establish validity (1). Construct validity refers to whether the questionnaire is measuring what it is supposed to measure and can be assessed by correlating a new questionnaire with an independent measure, which reflects disease severity.

To measure construct validity in the recently developed Food Allergy Quality of Life Questionnaire-Child Form, -Teenager Form and -Adult Form (FAQLQ-CF, -TF and -AF) (2–4), we needed to demonstrate that the FAQLQs were measuring only that part of HRQL affected by food allergy and not general quality of life aspects. However, in food allergy, no appropriate independent measure existed, which could be used for this purpose. Therefore, a Food Allergy Independent Measure-Child Form, -Teenager Form and -Adult Form (FAIM-CF, -TF and -AF) were developed. This study describes the development, validity and reliability of the FAIMs.

Methods

Development

Development of a Dutch independent measure was carried out using Expectation of Outcome (EO) questions, previously described by Oude Elberink (5, 6). The EO questions capture the perceived expectation of patients of the chance of accidental exposure and the perception of what will happen following accidental exposure. This is likely to be the source of quality of life differences in anaphylactic disorders and is therefore an appropriate independent measure (6). Each question was scored on a seven-point scale. A consultant for sick children, psychologist and a linguist reviewed the FAIMs for clarity and ease of use.

Validity and relevance

Face validity was determined by expert opinion. Three experts participated in and agreed on the validity of the possible FAIM questions. FAIM questions were considered valid if they addressed aspects of food allergy outcomes that patients were likely to

perceive as determining the severity of their condition. Questions showing no correlation to any potential FAQLQ item were not considered relevant and therefore eliminated.

Reliability

Patients and procedures. Dutch children (8–12 years), adolescents (13–17 years) and adults (≥ 18 years) with food allergy were recruited from our clinic or by advertisement from January 2007 to May 2007. Patients with the most prevalent food allergies were included. The FAIMs were sent by mail to be completed at home. Participation was completely voluntary. Regarding the FAIM-CF, parents were instructed that they were allowed to explain a question when needed, but they were not allowed to tell the child which answer to give. All patients who completed the first questionnaires (test) received the second questionnaires (re-test) 10–14 days after completion of the first. Patients who did not respond within 14 days were excluded from the study as well as patients who reported a clinically important change in health state [defined as a food allergic reaction of grade 3 or 4 according to the Mueller classification (7)] between the measurements or within two months before the study. This study ran in parallel with the test-retest reliability study of the FAQLQs (8). The study was approved by the local medical ethics review commission (METc 2005/051).

Statistical analysis. Data were analysed using SPSS software for Windows (Version 14.0). The intraclass correlation coefficient (ICC), using a one-way ANOVA (9) and Lin's concordance correlation coefficient (CCC) (10), were calculated to investigate test-retest reliability. ICCs and CCCs should be above 0.7 for group comparison studies (11). *P*-values < 0.05 were considered to be significant. The different components of the CCC (Pearson correlation coefficient, location shift and scale shift) were calculated. A value of 0 represents no location shift. A value of 1 represents no scale shift. The first measurement was plotted against the second measurement and we used major axis analyses to calculate the best fitting line (12). Visual assessment was obtained by the use of Bland-Altman plots. Mean differences were calculated and should be close to zero. Limits of agreement were calculated as mean difference $\pm 1.96 \times \text{SD}$ of the mean difference. Ninety-five percentage of the differences (calculated as measurement 1 – measurement 2) should lie between these limits. A regression coefficient was calculated to estimate a relationship between the difference and the mean.

Results

Development

The original FAIM-CF, -TF and -AF contain six questions (Fig. 1). The wording of the questions was changed for children to improve understanding. EO questions 2 and 3 were adapted from questions, which were successfully developed for validation of the Vespil allergy Quality of Life Questionnaire (VQLQ) (5) and the Food Allergy Quality of Life-Parental Burden questionnaire (FAQL-PB) (13). Two other EO questions (1 and 4) were developed, which were likely to be an additional source of HRQL differences in food allergic patients. Additionally, two independent measure questions (IM 1 and 2) were

developed, which reflect aspects of the perceived severity of food allergy not captured by the other four questions.

Validity and relevance

EO question 3 did not correlate with any of the items of the FAQLQ-TF (3) and was therefore eliminated. Additionally, EO question 4 did not correlate with any of the items of the FAQLQs. This was considered to be due to the original positive formulation of this question versus the negative formulation of the other EO questions. The positive formulation (...can effectively deal...) and a negative formulation (...cannot effectively deal...) were compared in an additional analysis of 28 children, 34 adolescents and 32 adults and showed significantly better correlations of the negative formulation with the total FAQLQ-CF, -TF and -AF scores than the positive formulation (data not shown). Therefore, we finally included EO question 4 in its negative formulation. The other questions were shown to be relevant. The final mean FAIM scores correlated significantly with the individual items of the FAQLQs (2–4).

Reliability

Patients. We contacted 148 patients, of which 131 patients completed and returned the first questionnaires and 114 responded to the second questionnaires. Thirteen patients were excluded because they did not respond in time or had a grade III or IV allergic reaction between the first and second measurement or within two months before the first measurement. This resulted in 101 patients (31 children, 34 adolescents and 36 adults) who were eligible for analyzing test-retest reliability. Table 1 shows types and numbers of food allergies.

Analysis. Table 2 shows the results of the test-retest analysis. ICCs were 0.87, 0.86 and 0.76 for FAIM-CF, -TF and -AF respectively. Concordance correlation coefficients were nearly identical. Location shift and scale shift could all be considered minimal according to Lin's examples (10). Pearson correlation could be considered moderate for FAIM-CF and -TF and acceptable for FAIM-AF according to Lin's examples (10). Figure 2 illustrates the correlation between the first and second measurement. Major Axis analysis revealed no significant difference of the slope and the intercept of the best fitting line from the concordance line for the FAIMs. The slope and intercept of the best fitting lines of all FAIMs did not differ significantly from each other. Bland-Altman plots are shown in Fig. 3. Mean differences of both scores were all close to zero. About 95% of the differences lie within the 1.96 SD limits of agreement. Limits of agreement of the FAIM-AF were wide. There is no significant correlation between the mean of both scores and the difference of both scores.

A The Food Allergy Independent Measure – Child Form (8-12 years)

The following four questions are about the chance that you think you have of something happening to you because of your food allergy. Choose one of the answers. This is followed by two more questions about your food allergy. Answer every question by putting an 'x' in the box next to the proper answer.

0 Never (0% chance)	1 Very small chance	2 Small chance	3 Fair chance	4 great chance	5 Very big chance	6 Always (100% chance)					
How big do you think the chance is that you ...					0	1	2	3	4	5	6
EO1. will accidentally eat something to which you are allergic?					☐	☐	☐	☐	☐	☐	☐
EO2. will have a severe reaction if you accidentally eat something to which you are allergic?					☐	☐	☐	☐	☐	☐	☐
EO3. will die if you accidentally eat something to which you are allergic?					☐	☐	☐	☐	☐	☐	☐
EO4. Can <u>not</u> do the right things for your allergic reaction, should you accidentally eat something to which you are allergic					☐	☐	☐	☐	☐	☐	☐
IM1. How many foods are you unable to eat because of your food allergy?					IM2. Everyone does things with other people, such as: playing with friends, going to a birthday party, visiting, staying over with someone for a meal or eating out. How much does your food allergy affect things you do with others?						
☐ almost none					☐ so little I don't actually notice it						
☐ very few					☐ very little						
☐ a few					☐ a little						
☐ some					☐ moderately						
☐ many					☐ a good deal						
☐ very many					☐ a great deal						
☐ almost all					☐ a very great deal						

B The food Allergy Independent Measure-Teenager Form (13-17 years) and Adult Form

The following four questions are about the chance that you think you have of something happening to you because of your food allergy. Choose one of the answers provided. This is followed by two more questions about your food allergy. Answer every question by putting an 'x' in the box next to the appropriate answer.

0 never (0% chance)	1 very small chance	2 small chance	3 fair chance	4 great chance	5 very great chance	6 always (100% chance)					
How great do you think the chance is that you ...					0	1	2	3	4	5	6
EO1. will accidentally eat something to which you are allergic?					☐	☐	☐	☐	☐	☐	☐
EO2. will have a severe reaction if you accidentally eat something to which you are allergic?					☐	☐	☐	☐	☐	☐	☐
EO3.* will die if you accidentally eat something to which you are allergic?					☐	☐	☐	☐	☐	☐	☐
EO4. can <u>not</u> effectively deal with an allergic reaction should you accidentally eat something to which you are allergic					☐	☐	☐	☐	☐	☐	☐
IM1. How many products must you avoid because of your food allergy?					IM2. How great is the impact of your food allergy on your social life?						
☐ almost none					☐ negligibly small						
☐ very few					☐ very small						
☐ a few					☐ small						
☐ some					☐ moderate						
☐ many					☐ great						
☐ very many					☐ very great						
☐ almost all					☐ extremely great						

Figure 1. The FAIM-CF (A) and the FAIM-TF and -AF (B). *EO question 3 was not considered to be an appropriate independent measure questionnaire for food allergy in adolescents.

Discussion

This article describes the development, face validity and test-retest reliability of the FAIMs. Questions were

chosen for good face validity and selected on the basis of relevance. Six questions were considered relevant for the FAIM-CF and -AF and five questions were considered relevant for the FAIM-TF. The FAIMs

Table 1. Type and number of food allergies

	Children (<i>n</i> = 31)	Adolescents (<i>n</i> = 34)	Adults (<i>n</i> = 36)
Type food allergy, <i>n</i> (%)			
Peanut	25 (81)	30 (88)	25 (69)
Nut	17 (55)	28 (82)	25 (69)
Milk	15 (48)	15 (44)	15 (42)
Egg	14 (45)	16 (47)	7 (19)
Wheat	5 (16)	4 (12)	7 (19)
Soy	9 (29)	13 (38)	8 (22)
Sesame	7 (23)	9 (26)	6 (17)
Fish	2 (6)	5 (15)	9 (25)
Shell fish	6 (19)	8 (24)	12 (33)
Celery	0 (0)	4 (12)	8 (22)
Fruit	14 (45)	13 (38)	26 (72)
Vegetables	6 (19)	6 (18)	10 (28)
Others	25 (81)	24 (71)	13 (36)
Number of food allergies, <i>n</i> (%)			
1 food	6 (19)	3 (9)	1 (3)
2 foods	4 (13)	4 (12)	3 (8)
3 foods	4 (13)	8 (24)	10 (28)
>3 foods	17 (55)	19 (56)	22 (61)

Table 2. Test-retest reliability results of the food allergy independent measure-child form, -teenager form and -adult form (FAIM-CF, -TF and -AF)

	FAIM-CF	FAIM-TF	FAIM-AF
M1 (SD)	3.72 (0.93)	4.15 (0.93)	3.97 (1.05)
M2 (SD)	3.80 (1.10)	4.10 (1.09)	4.04 (1.20)
Mean of both scores (SD)	3.76 (0.99)	4.13 (0.97)	4.00 (1.05)
Mean difference (SD) (M1-M2)	-0.08 (0.52)	0.05 (0.55)	-0.07 (0.79)
Limits of agreement (MD $\pm$ 1.96 SD)	-1.09 to 0.93	-1.02 to 1.12	-1.61 to 1.47
ICC (95% CI)	0.87 (0.76–0.94) <i>P</i> < 0.001	0.86 (0.74–0.93) <i>P</i> < 0.001	0.76 (0.58–0.87) <i>P</i> < 0.001
Error variance	0.13	0.15	0.31
CCC (95% CI)	0.87 (0.79–0.95) <i>P</i> < 0.001	0.85 (0.76–0.94) <i>P</i> < 0.001	0.75 (0.61–0.90) <i>P</i> < 0.001
Scale shift	1.17	1.18	1.14
Location shift	-0.08	0.05	-0.06
Pearson	0.88	0.87	0.76

M1, total score measurement one; M2, total score measurement two; MD, mean difference; ICC, intraclass correlation coefficient; CCC, concordance correlation coefficient.

showed good reliability with ICCs and CCCs above 0.70 and with mean differences all close to zero. There was little evidence for scale shift and location shift supporting the accuracy of the FAIM.

Generally, independent measures used to validate HRQL questionnaires are some sort of objective measurement of the severity of a disease. An objective measurement is often related to the burden of symptoms characterizing the disease. However, in food allergy, no such clinical measure based on symptoms exists. Moreover, such a clinical measure would even be inappropriate because food allergic patients only experience symptoms

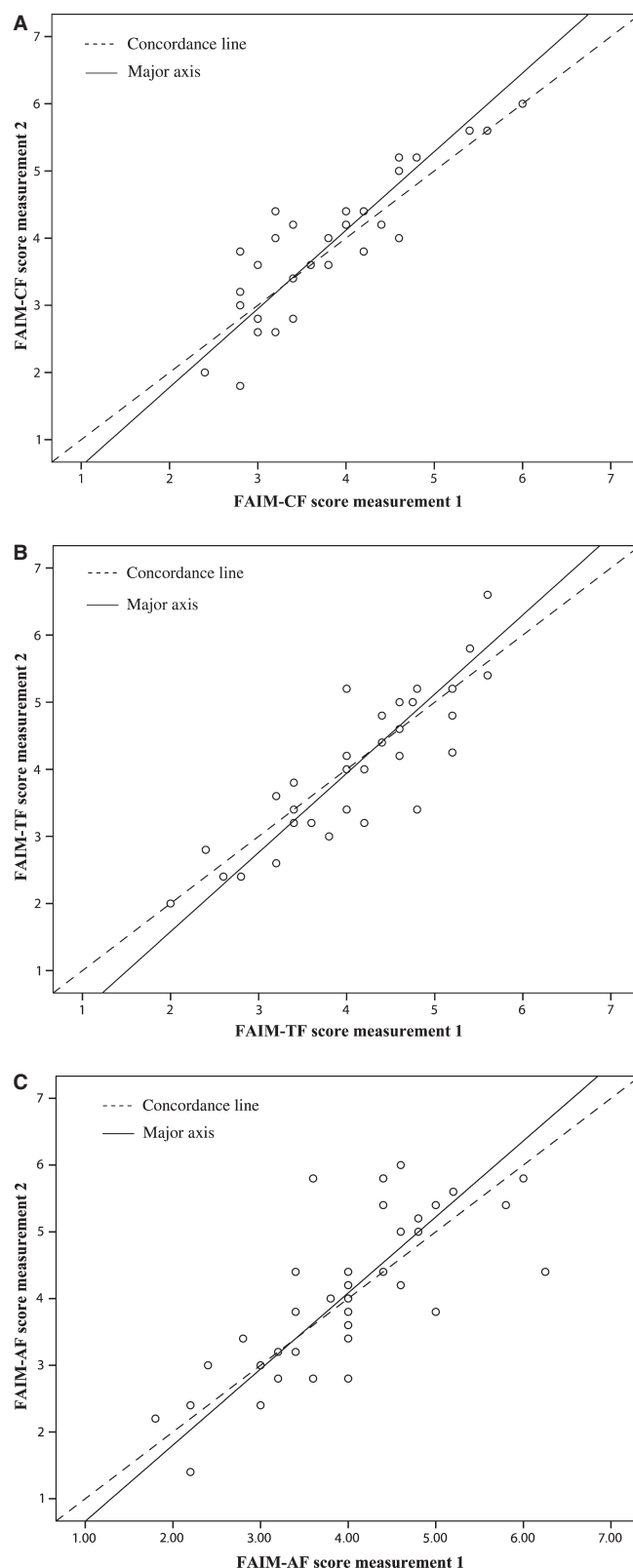


Figure 2. FAIM score of the first measurement against FAIM score of the second measurement in (A) children, (B) adolescents and (C) adults.

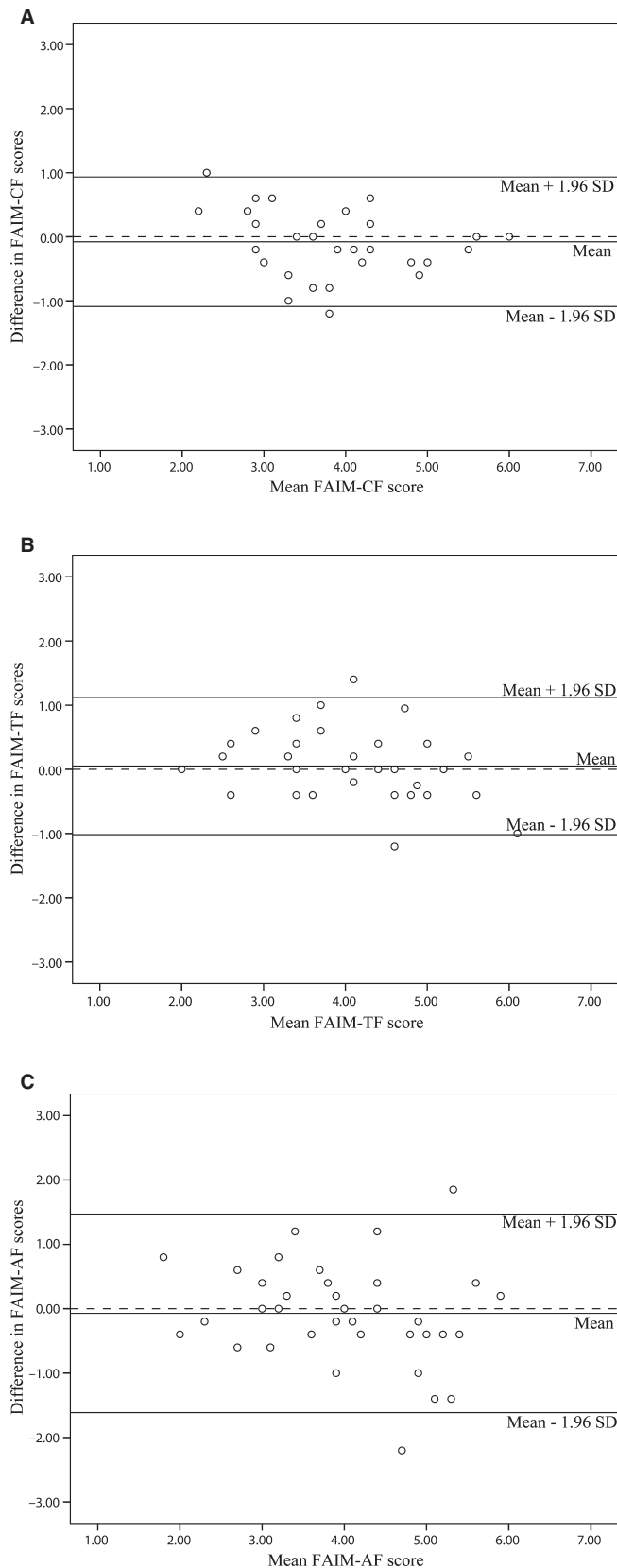


Figure 3. Bland-Altman plots for the FAIMs in (A) children, (B) adolescents and (C) adults.

on accidental exposure, while their HRQL is continuously affected by their condition. An independent measure based on food allergic outcomes attempts to capture the aspects of disease severity, which drive HRQL in an ongoing way. HRQL instruments built upon the method of EO questions have proved to be useful and consistent in measuring HRQL (5, 13).

It was an unexpected finding that in adolescents EO question 3 was not correlated with any of the items of the FAQLQ-TF. As this question has successfully been used before in other age groups, we expected the question to be valid and relevant. However, this finding might indicate that adolescents are not afraid of dying of anaphylaxis and underestimate exposure in contrast to adults and children. Previously, it has been reported that adolescents perceived their anaphylaxis as 'no big deal' (14) despite the fact that they are at the highest risk of dying from food allergy (15).

Another remarkable finding was shown in the results of the validity of EO question 4. These results illustrate that the wording of a question is very important. Changes in wording may result in misreading of the question or misdirection of the answer in sometimes unexpected ways.

According to the reliability results, the FAIM-AF showed the lowest ICC and CCC and the widest limits of agreement. This may have been caused by two outliers in the FAIM-AF. This assumption was supported by a re-analysis excluding the two outliers, which showed an ICC of 0.84 ($P < 0.001$), a nearly identical CCC and limits of agreement of -1.31 to 1.19 . Another explanation might be that children and adolescents are more used to filling out questionnaires as they are frequently examined at school, causing higher reliability statistics.

A limitation of the method of EO questions might be that EO questions are subjective and therefore prone to inaccuracy. However, expectations are likely to be the driving force in HRQL (i.e. patients who expect to die after exposure would be expected to have a poor HRQL, independent of the truth of this expectation.) (16). Moreover, there is no appropriate objective measure in food allergy. Therefore, the FAIMs are the best independent measures for food allergy thus far.

In summary, we described the development of a food allergy specific independent measure for children, adolescents and adults. Overall, the FAIMs showed good face validity, relevance and reliability. Therefore, these results support the suitability of the FAIMs for evaluating construct validity of the FAQLQs.

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