Translation, adaptation and initial validation of Food Allergy Quality of Life Questionnaire: child form in Greek

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Abstract

The aim of the study is to determine the reliability and validity of the Greek version of the Food Allergy Quality of life Questionnaire-Child Form (FAQ-LQ-CF). After linguistic validation, the Greek FAQ-LQ-CF, Food Allergy Independent Measure (FAIM) and Pediatric Quality of Life Inventory (PedsQL™) were used by a physician to interview children diagnosed with food allergy and aged 8-12 via telephone. Cronbach’s alpha was used to evaluate reliability, and factor analysis to assess construct validity. The correlation between FAQ-LQ-CF and FAIM was moderate (rho=0.509, P<0.001) and internal consistency was strong (Cronbach’s alpha 0.905). FAQ-LQ-CF discriminated well each question’s contribution to children’s quality of life deterioration (32-80%), each child’s quality of life (17-89%), children differing in doing things with others (total score 3.55 vs 2.57, difference =0.98 > minimal clinical importance difference = 0.5; P<0.001), but not children differing in reporting anaphylaxis. The total FAQ-LQ-CF score correlated with the total PedsQL™ score and with the score of one of PedsQL™ subscales, demonstrating convergent validity. Factor analysis uncovered an underlying structure of four factors, explaining 50% of the variance. We can conclude that Greek FAQ-LQ-CF is a reliable, valid, discriminant tool for interviewing food allergic children aged 8-12, detecting those in need for immediate care.

Introduction

Food allergy in children may be a major global public health problem due to the increasing rate of prevalence (Rona et al., 2007; Mills et al., 2007; Gupta et al., 2011). The upward trend has led the scientific community on an ongoing investigation into the causes, prevention, diagnosis and methods of treatment. The quality of life of children with food allergy disturbed but the exact impact is not adequately specified. Quality of life (QoL) as defined by the World Health Organization (WHO) is the individual’s perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns (WHO, 1993). Health related quality of life (HRQL) in food allergic children has been assessed by both generic and specific questionnaires. Generic HRQL questionnaires compare patients with the normal population or patients with different diseases, but they are not sensitive to assess specific problems and cannot separate the impact on HRQL of the disease. The quality of HRQL is of the impact of comorbid diseases (Flokstra-de Blok & Dubois, 2009; Flokstra-De Blok et al., 2010). Disease specific HRQL instruments are considered more sensitive than the generic ones because they focus on domains most relevant to the disease; they detect clinically important changes in patient’s HRQL and they are used as an outcome measure (Flokstra-de Blok & Dubois, 2009). But, on the other hand, they cannot compare HRQL of patients with different diseases (Guyatt, Feeny, & Patrick, 1993). The importance of asking children themselves about their own QoL is that children and parents differ in their views, expectations and judgments about children’s QoL (van Der Velde et al., 2011). Self-report disease specific questionnaires allow children to report on their own HRQL, contribute to QoL improvement and to holistic treatment.

As part of the EuroPrevall project, a large European multicenter study on food allergy, a series of HRQL questionnaires for food allergic patients of all ages were developed and validated, named the Food...
Allergy Quality of Life Questionnaires (FAQQL) (Flokstra-de Blok & Dubois, 2012). The self-report disease specific FAQQL - Child Form (FAQQL-CF), completed by children aged 8-12 years, measures changes in HRQOL over time, compares children’s receiving different treatments HRQL, and assesses several interventions effectiveness (Factor, Mendelson, Lee, Nouman, & Lester, 2012; Flokstra-de Blok et al., 2009; van Der Velde et al., 2012). Developed in Dutch, the FAQQL-CF had an excellent internal consistency (Cronbach’s alpha 0.94), consists of 24 negative (i.e. higher scores indicate poorer HRQL) items scored 0 to 6, divided into four subscales: allergy avoidance (AA), risk of accidental exposure (RAE), emotional impact (EI) and dietary restrictions (DR), significantly (P<0.001) correlated with the Food Allergy Independent Measure (FAIM), a tool for cross-sectional validation on whether the FAQQLs measure what they are supposed to measure at one point in time (Flokstra-De Blok et al., 2009; 2010; Flokstra-de Blok & Dubois, 2012; Wassenberg et al., 2011; Wassenberg et al., 2012).

FAQQL-CF has been validated in English and French. The aim of this study was to translate it into Greek language and explore its psychometric properties.

**Materials and Methods**

**Participants**

Out of 172 physician-diagnosed food allergic children, followed-up by the Allergy Department of P&A Kyriakou Children Hospital, a national reference center serving the Athens metropolitan area, all southern Greece and the islands, 110 participated in a telephone survey (64%), aged 7.5-12.3 years [mean (SD) 10.0 (1.4)], 83 (75.5%) male, 27 (24.5%) female. All types of food allergy at different severity and symptom’s appearance were present (Supplementary Table S1).

Children with any other major chronic illness (excluding asthma, hay fever or eczema) were excluded. The data were telephone collected by ZM, during 9 May to 3 June 2013. In order to prevent any impact of external factors on children’s emotional domain, they were interviewed at a time out of school stressing program while interview process was kept as short as possible. A pilot study including nine of those children addressed some understanding difficulties. During the phone interview, no developmental or maturation differences were observed across the age range we sampled that might impact the results.

**Ethical approval**

The Scientific Committee of P&A Kyriakou Children Hospital approved the study protocol. Parents and children received written information, indicating that participation in the study was voluntary and the telephone interview was conducted after parents and their children acceptance to participate in the study.

**Measures**

The disease-specific FAQQL-CF, the validated in Greek generic Pediatric QoL Inventory™ 4.0 (PedsQL™), and the Food Allergy Independent Measure (FAIM) were used (Gkoltsiou et al., 2008; van Der Velde et al., 2012; Varni, Seid & Kurtin, 2001). FAQQL-CF properties were described in the Introduction. PedsQL™ is a 23-item self-report measure, divided into 4 subscales: physical functioning, emotions, social relationships, and school functioning, rated on a 5-point Likert scale, and asking about quality of life during the past month (Varni, Seid & Kurtin, 2001). The Greek version was found to be valid with good internal consistency (only the physical functioning subscale had a Cronbach’s α of 0.65, slightly below 0.70; see validation second paragraph, how to interpret these values) (Gkoltsiou et al., 2008).

Higher scores indicate better HRQL. FAIM is a self-report food allergy specific independent measure for children and consists of six questions scored 0 to 6. The four of them assess child’s food allergy expectation outcomes, and the other two reflect aspects of the perceived severity of food allergy. Higher scores indicate poorer HRQL. A moderate correlation coefficient (0.40-0.70) between FAQQL-CF and FAIM revealed construct validity, and a low correlation coefficient (0.10-0.30) between FAQQL-CF and PedsQL™ convergent validity (Flokstra-de Blok et al., 2009).

**Translation and culture adaptation**

Two independent Greek translators produced forward translations and one other bilingual translator backward translation according to WHO guidelines.

To ensure face validity, this version was given to nine 8-12 year old food allergy children to complete and declare item understanding. Children had some difficulties grasping the meaning of questions 10 (we added the auxiliary text That is, how much it bothers you that you have to think whether you can eat a food that you may be allergic to) and 22 (we changed the phrase never get rid of food allergy to the more easily understandable might never go away). The question How often do you eat out? was added to access discriminant validity. A cultural adaptation issue had occurred with the third question of FAIM; we changed the phrase will die with lose your life.

**Validation**

Exploratory factor analysis, applying principal components analysis, was implemented in order to uncover the underlying structure of the relatively large set of FAQQL-CF items, i.e., the underlying relationships between them, in our dataset (construct validity). Confirmatory factor analysis, via structural equation modeling using maximum likelihood estimation procedures with the relatively unaffected by sample size Tucker-Lewis Index (TLI) and Bollen’s Incremental Fit Index (IFI) (Bollen, 1990; Gerbing & Anderson, 1993; Hu & Bentler, 1995; Marsh, Balla & McDonald, 1988), was also implemented in order to test the originally proposed four-factor structure with our data (McDonald, 1978).

The internal consistency of the instrument was assessed using Cronbach’s alpha coefficient (the total scale alpha should be at least 0.70 to be acceptable, 0.80 to be good, and 0.90 to be excellent; (Clark & Watson, 1995) and the subscale alphas should be greater than corresponding expected alphas calculated using the Spearman-Brown formula), and corrected item-total correlations (Pearson’s r for each subscale should be >0.300, otherwise the item should be removed from the questionnaire) (Field, 2011; Lyrakos, Vini, Aslani, & Drosou-Servou 2012; Norusis & SPSS Inc, 1997).

The tool’s ability to differentiate among children with various QoL levels and among various components of the QoL was checked, as well as between children who reported anaphylaxis and those who did not, as the original study did. Anaphylaxis was defined as children who ever reported two or more of the following cardiovascular symptoms: dizziness, feeling your heat beat fast, loss of vision, inability to stand, light headedness, collapse, loss of consciousness/ passing out (Flokstra-de Blok et al., 2009). In addition it was checked to children who reported multiple food allergies, many different symptoms, severe reactions, epinephrine prescription, rarely eating out, and doing less things with others, compared with children who reported less food allergies, less symptoms etc. A difference greater than a minimal clinical importance difference (MCID) of 0.5 was considered clinically significant (Flokstra-de Blok et al., 2009; Jaeschke, Singer & Guyatt, 1989; Juniper, Guyatt, Willan, & Griffith, 1994).
Results

The total and subscale FAQLQ-CF scores correlated significantly but moderately (Table 1), as expected, with the total FAIM, and with the five of the six individual FAIM questions. All but one FAQLQ-CF item correlated with at least two FAIM items. The total FAQLQ-CF and its original subscales correlated low with the total PedsQL™ and moderately with one of its subscales (emotional functioning).

The factor analysis resulted in four factors that made the most sense, explaining 50% of the variance, partly confirmed the original factors (Table 2). An expert panel (ZM, ID, GL, NP) reviewed the new factors. They could be allergen avoidance (AA, F1) and dietary restrictions (DR, F4) as in the original study, and two new ones whose names could be emotional functioning (EF, F2) and risk impact (RI, F3). All the factors had strong loadings from 0.410 to 0.768 (AA, 0.728-0.499; EF, 0.704-0.450; RI, 0.768-0.410 and DR, 0.735-0.427).

Cronbach alphas were 0.905 for the total Greek FAQLQ-CF (Table 3) and greater than expected for its subscales (except for the RAE where it was slightly less, 0.631 vs 0.665). Corrected item total correlations were between 0.387 and 0.709 for the total Greek FAQLQ-CF (Table 3) and greater than 0.300 for its subscales (except for the RAE where it was between 0.243 and 0.463). Total FAIM alpha was 0.653 (acceptable), raised to 0.703 (good) after the omission of item 5 (IM1), the corrected item total correlation of which was only 0.029, indicating that this item might be removed.

FAQLQ-CF discriminated well between children who reported different QoL levels (Supplementary Figure F2) and different QoL deterioration reasons (Supplementary Figure F2). Children’s QoL, ranged from 0.67 (11%) in the negative 0-6 scale (versely 89% of the best quality) to 4.95 (83%; reversely 17% of the best). QoL, deterioration reasons ranged 32-80% (questions 4, 14). Children who reported more than moderately affected in doing things with others were clinically and statistically more impacted than those who reported less than moderately affected (total FAQLQ-CF score 3.553 ± 2.570, difference = 0.98 > MID; P<0.001; Supplementary Table S2). The same result was found for feeling angry; difference = 0.592 > MID, P<0.003). There was an almost clinically and statistically significant difference in total FAQLQ-CF mean score between children who reported more than fairly chance to die and children eating out compared to those who reported less than fairly. The FAQLQ-CF score did not differ between children who reported anaphylaxis or various combinations of cardio-respiratory symptoms and children who did not. Things done with others was the only variable that discriminated.
Table 2. Confirmatory factor analysis: loadings (>0.4) in each of our four factors (F1 to F4) for each question (Q); the original factor (OF) for each question is also given.

| Q | OF  | F1    | F2    | F3    | F4    | Item                                      |
|---|-----|-------|-------|-------|-------|-------------------------------------------|
| 3 | DR  | 0.735 |       |       |       | Limited in buying                          |
| 2 | DR  | 0.726 |       |       |       | Eating fewer things                        |
| 18| DR  | 0.628 |       |       |       | Refuse food                                |
| 20| DR  | 0.591 |       |       |       | Don’t get treats                           |
| 6 | AA  | 0.545 |       |       |       | Try fewer things                           |
| 1 | DR  | 0.427 |       |       |       | Always watch                               |
| 23| EI  | 0.704 |       |       |       | Never get rid                              |
| 22| RAE | 0.681 |       |       |       | Don’t know taste                           |
| 24| EI  | 0.414 | 0.631 |       |       | Have food allergy                          |
| 17| EI  | 0.583 |       |       |       | Not taking account                         |
| 5 | AA  | 0.492 |       |       |       | Stay for a meal                            |
| 10| RAE | 0.450 |       |       |       | Ingredient change                          |
| 15| EI  | 0.768 |       |       |       | Eating wrong                               |
| 14| EI  | 0.747 |       |       |       | Allergic reaction                          |
| 9 | RAE | 0.590 |       |       |       | Touching foods                             |
| 16| EI  | 0.578 |       |       |       | Never eat                                  |
| 21| RAE | 0.496 |       |       |       | People forget                              |
| 8 | AA  | 0.492 |       |       |       | Hesitate eating                            |
| 11| RAE | 0.410 |       |       |       | Label traces of ...                        |
| 12| AA  | 0.728 |       |       |       | Explain around                             |
| 19| AA  | 0.723 |       |       |       | Tell beforehand                            |
| 4 | AA  | 0.456 | 0.561 |       |       | Read labels                                |
| 7 | AA  | 0.499 |       |       |       | Check yourself                             |

Table 3. Cronbach’s alpha and corrected item-total correlation for Food Allergy Quality of life Questionnaire-Child Form (FAQLQC-F), Pediatric Quality of Life Inventory (PedsQL™), and Food Allergy Independent Measure (FAIM).

| Scale/Subscale                  | It | Obs | Cronbach’s alpha (α) | Corrected item-total correlation** |
|---------------------------------|----|-----|----------------------|------------------------------------|
| FAQLQC-F (total scale)          | 24 |     | 0.905                | 0.94                               |
| Allergen avoidance              | 7  |     | 0.775                | 0.735                              |
| Risk of accidental exposure     | 5  |     | 0.631°               | 0.665                              |
| Emotional impact                | 6  |     | 0.738                | 0.705                              |
| Dietary restrictions             | 6  |     | 0.747                | 0.705                              |
| Factor 1 (DR)                   | 6  |     | 0.775                | 0.705                              |
| Factor 2 (EF)                   | 7  |     | 0.826                | 0.735                              |
| Factor 3 (RI)                   | 7  |     | 0.764                | 0.735                              |
| Factor 4 (AR)                   | 4  |     | 0.713                | 0.615                              |
| First half (questions 1-12)     | 12 |     | 0.845                | 0.827                              |
| Second half (questions 13-24)   | 12 |     | 0.837                | 0.827                              |
| Odd (questions 1, 3, 5, …, 23)  | 12 |     | 0.805                | 0.827                              |
| Even (questions 2, 4, 6, …, 24) | 12 |     | 0.836                | 0.827                              |
| PedsQL™ (total scale)           | 23 |     | 0.887°               | >0.70**                            |
| Physical functioning            | 8  |     | 0.775°               | 0.732                              |
| Emotional functioning           | 5  |     | 0.734°               | 0.631                              |
| Social functioning              | 5  |     | 0.809                | 0.631                              |
| School functioning              | 5  |     | 0.717°               | 0.631                              |
| FAIM (total scale)              | 6  |     | 0.653°               | 0.70**                            |
| OE                              | 4  |     | 0.706                | 0.616                              |
| IM                              | 2  |     | 0.194                | 0.445                              |

**Expected subscale alphas were calculated using the Spearman-Brown formula \( \alpha_{sub} = \frac{k \alpha_{tot}}{1+(k-1)\alpha_{item}} \), where \( k \) is the number of items of the subscale divided by the number of items of the overall scale.1,2°  | 0.351-0.542 | 0.290-0.682 |bern correlation coefficients \( r \). For example, in the first line, the 24 \( r \) coefficients for the FAQLQC-F (total scale) range 0.397 (for the question 11: How much trouble is it, because of your food allergy, that the label states: “May contain traces of….”?) to 0.701 (for the question 24: How disappointed do you feel because you have a food allergy?). Similarly the 23 \( r \) coefficients for the PedsQL™ (total scale) range 0.216 to 0.848. And the 6 \( r \) coefficients for the FAIM (total scale) range 0.029 (for the questions 5: How many foods are you unable to eat because of your food allergy?) to 0.601 (for the question 2: How big do you think the chance is that you will have a severe reaction if you accidentally eat something to which you are allergic?).° 0.631 increased to 0.644 (greater than expected 0.615) if item 17 was deleted; 0.887 to 0.890 if item 23 was deleted; 0.775 to 0.788 if item 7 was deleted; 0.734 to 0.736 if item 11 was deleted; 0.717 to 0.730 if item 22 was deleted; and 0.653 to 0.703 if item 5 was deleted; no other observed alpha increased after deletion of any of the items for any of the other scales or subscales. °° All self-report and proxy-report scales of PedsQL™ 4.0, except for physical functioning self-report (α = 0.65), exceeded the minimum reliability standard of 0.70.14
that affected clinically and statistically the mean FAIM-OE score (the difference disappeared if the IM1 question was added), and the mean PedsQL™ score. The statistically (P=0.035) significantly worse mean PedsQL™ score in older children was also clinically significant [absolute (−0.18)>0.1744 = MID].

Discussion

Content validity, the extent to which a measure represents all facets of a given social construct, perhaps the most important thing of a questionnaire, was addressed by the original study. Thus, we focused on questionnaire’s translation and cultural adaptation in Greek.

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 (van der Velde et al., 2010). The significant correlation between FAQLQ-CF and FAIM assures construct validity, fits with Floskra de Blok and Wassenberg, and demonstrates that Greek FAQLQ-CF is measuring the food allergy affected QoL (Flokstra-de Blok et al., 2009; Wassenberg et al., 2011). As in the original study, we supplemented statistical factoring by face validity (Flokstra-de Blok et al., 2009).

Cronbach alpha for the total Greek FAQLQ-CF (0.905) indicates an excellent reliability (Fayers & Machin, 2000). Tavakol and Dennick argue that an alpha >0.90 may suggest redundancies and show that the tool’s length should be shortened (Tavakol & Dennick, 2011). No alpha if item deleted was greater than without deletion, an indication of no redundancies. Item-total Pearson’s correlations showed that all items are well related (r>0.300), an indication of no need for any item to be removed (except an item in RA with r=0.243, considered by the expert panel as important for the questionnaire).

The questionnaire discriminates between various QoL levels and various QoL components. Thus, it could serve as a helpful additional tool, as a good first step, for clinicians to manage children’s allergy. It also discriminates well between children who reported more than and less than moderately affected in doing things with others. There was no difference according to eating out, chance to die, feeling angry and age.

Children who reported anaphylaxis did not differ with children who did not report anaphylaxis, as also Floskra de Blok et al. found (Flokstra-de Blok et al., 2009). One possible explanation could be that the children who reported anaphylaxis were only four; however we found no differences according to eating out, chance to die, feeling angry and age.

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Conclusions

Concluding this study showed that the Greek FAQLQ-CF, the European standard questionnaire on food allergic children, has satisfactory validity, reliability, and discriminant ability. The tool could help clinicians to detect children in need for immediate care and children’s deterioration reasons.
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