Development, validation and outcome of health-related quality of life questionnaires for food allergic patients
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Health-related quality of life of food allergic patients: Comparison with other diseases and the general population

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Hein Raat
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Eric J. Duiverman

Submitted
Abstract

**Background:**
Health-Related Quality of Life (HRQL) has never been measured with generic and disease-specific questionnaires in the same group of food allergic (FA) patients.

**Objective:**
The aims of this study were to compare generic HRQL of FA patients with the general population and other diseases and to compare HRQL of FA patients as measured with generic and disease-specific questionnaires.

**Methods:**
Generic HRQL questionnaires (CHQ-CF87 and RAND-36) and disease-specific HRQL questionnaires (FAQLQ-CF, -TF and -AF) were completed by 79 children, 74 adolescents and 72 adults with FA. The generic HRQL scores were compared with scores from published studies on the general population and patients with asthma, irritable bowel syndrome (IBS), diabetes mellitus type I (DM) and rheumatoid arthritis (RA).

**Results:**
FA children and adolescents reported fewer limitations in school work due to behavioural problems (p≤0.013), but FA adolescents and adults reported more pain (p=0.020), poorer overall health (p<0.001), more limitations in social activities (p<0.001) and less vitality (p=0.002) than individuals from the general population. FA patients reported poorer HRQL than patients with DM, but better HRQL than patients with asthma, IBS and RA. In contrast to the disease-specific questionnaires, high ceiling effects were found for some generic HRQL scales.

**Conclusion:**
HRQL is impaired in FA adolescents and adults compared to the general population and is intermediate in magnitude between DM and asthma, IBS and RA. Children show the least impact on HRQL from FA. Because of high ceiling effects, generic HRQL questionnaires are less suitable to measure disease-specific, clinically important impairments in food allergy.
Introduction

Currently, there is still no cure available for patients with food allergy. Food allergic patients must carefully avoid the causal foods every day, which may be a great burden to themselves and their families. Despite taking precautions, there is always a chance of accidental exposure and for some patients such exposure may be fatal, which in turn may provoke even more anxiety. Thus, while food allergic patients may experience symptoms only intermittently, they continuously need to undertake extensive measures in order to prevent exposure to foods to which they are allergic. This has a negative impact on their health-related quality of life (HRQL).

HRQL may be defined as ‘the effects of an illness and its consequent therapy upon a patient, as perceived by the patient’. The measurement of HRQL offers the opportunity to study the impact of a disease or the effect of a treatment from the patient’s unique perspective. More importantly, HRQL is the only available measure reflecting the ongoing severity of food allergy, since no objective disease parameters are available.

There are two major types of questionnaires to measure HRQL: generic and disease-specific questionnaires. Generic questionnaires can be used to evaluate and compare different diseases. The disadvantages of generic questionnaires are that they may not focus adequately on problems specific to a particular disease and that they simultaneously measure the impact of comorbid diseases. Disease-specific instruments are targeted to a specific disease. These disease-specific questionnaires are more likely to detect clinically important changes in patients’ HRQL. However, disease-specific questionnaires do not allow comparison between different diseases.

In food allergy research, there are only a few studies that have investigated the impact of food allergy on HRQL. However, there are no studies that have compared generic HRQL of food allergic patients from childhood to adulthood with generic HRQL of the general population and patients with other chronic diseases. To our knowledge, there are two previous studies that have compared HRQL of food allergic patients with one other chronic disease (rheumathological disease and diabetes mellitus, respectively). However, the later study used non validated disease-specific questionnaires, which makes a comparison between different diseases problematic. The former study used a single Visual Analogue Scale and the Impact on Family Scale, which only covers a single domain of generic HRQL. This study is the only study in the field of food allergy that investigated the HRQL of food allergic adults. All other studies investigated food allergic children. Of these pediatric studies, there was only one study in which adolescents aged 13-21 years completed a self-administered HRQL questionnaire, while in all other pediatric studies, the HRQL questionnaires were completed by the parents. Finally, since self-administered disease-specific HRQL questionnaires for food allergic patients have become available only recently, the administration of both generic and disease-specific instruments to the same population of food allergic patients has not been possible until now.
The aims of this study were to investigate the impact of food allergy on HRQL measured with self-administered generic HRQL questionnaires in children from the age of 8 years, adolescents and adults and to compare the generic HRQL of these food allergic patients with the generic HRQL of the general population and patients with other diseases. Additionally, we compared HRQL of food allergic patients as measured with generic and disease-specific questionnaires.

Methods

Participants
The current study is part of a larger study on the development and validation of food allergy specific HRQL questionnaires and the measurement of the impact of food allergy on HRQL. This larger study was reviewed by the local medical ethics review commission (METc 2005/051) who deemed that the study did not fall under the range of the Medical Research Involving Human Subjects Act and that therefore approval was not needed. Participants in the present study were part of the studies on the cross-sectional validation of the Food Allergy Quality of Life Questionnaire-Child Form, -Teenager Form and -Adult Form (FAQLQ-CF, -TF and -AF)\textsuperscript{18-20}. These participants, aged 8 years and older with a physician-diagnosed food allergy for at least one food, were recruited from our outpatient (paediatric) allergy clinic or were recruited through food allergy support organisations (the Dutch Foundation for Food Allergy and the Dutch Anaphylaxis Network) and by advertisement in local newspapers. All common food allergies and different types and severities of symptoms were represented\textsuperscript{18-20}.

Procedure
A letter of invitation, the questionnaires (the age appropriate generic and disease-specific HRQL questionnaire) and descriptive questions on age, sex, type and number of food allergies, type of symptoms and diagnosis were sent by mail to be completed at home. The letter of invitation stressed that participation was completely voluntary. Participants were not paid for their participation. The children and their parents were instructed that the children should fill out the questionnaires by themselves. Parents were allowed to explain a question when needed, but they were not allowed to tell the child which answer to give. For completing the descriptive questions parents were allowed to help their child when needed.

Questionnaires

Generic HRQL questionnaires
In children and adolescents, the Child Health Questionnaire-Child Form (CHQ-CF87) was administered\textsuperscript{21,22}. This questionnaire is self-administered by the child and contains 87 items divided into twelve scales (Table 1). After recoding the raw
Generic quality of life of food allergic patients

Table 1. CHQ-CF87 and RAND-36 scales, items per scale and definition of the scales.

<table>
<thead>
<tr>
<th>Generic HRQL scales</th>
<th>No. of items</th>
<th>Definition of the scales</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CHQ-CF87</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical functioning (PF)</td>
<td>9</td>
<td>Limitations in physical activities</td>
</tr>
<tr>
<td>Role functioning-emotional (RE)</td>
<td>3</td>
<td>Limitations in school work or activities with friends due to emotional problems</td>
</tr>
<tr>
<td>Role functioning-behaviour (RB)</td>
<td>3</td>
<td>Limitations in school work or activities with friends due to behavioural problems</td>
</tr>
<tr>
<td>Role functioning-physical (RP)</td>
<td>3</td>
<td>Limitations in school work or activities with friends due to physical problems</td>
</tr>
<tr>
<td>Bodily pain (BP)</td>
<td>2</td>
<td>Severity, frequency of pain and limitations due to pain</td>
</tr>
<tr>
<td>General behaviour (BE)</td>
<td>17</td>
<td>The degree to which the child exhibits aggressive, immature or delinquent behaviour</td>
</tr>
<tr>
<td>Mental health (MH)</td>
<td>16</td>
<td>The degree of positive and negative feelings, including anxiety, depression, peacefulness and happiness.</td>
</tr>
<tr>
<td>Self-esteem (SE)</td>
<td>14</td>
<td>The degree of satisfaction with abilities, looks, family/peer relationship and life overall</td>
</tr>
<tr>
<td>General health (GH)</td>
<td>12</td>
<td>Perceptions of overall health</td>
</tr>
<tr>
<td>Change in health*</td>
<td>1</td>
<td>Change in health compared to 1 year ago</td>
</tr>
<tr>
<td>Family activities (FA)</td>
<td>6</td>
<td>The degree to which the child’s health limits or interrupts family activities or is a source of family tension</td>
</tr>
<tr>
<td>Family cohesion (FC)</td>
<td>1</td>
<td>The ability of the family to get along with each other</td>
</tr>
<tr>
<td><strong>RAND-36</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical functioning (PF)</td>
<td>10</td>
<td>Limitations in physical activities</td>
</tr>
<tr>
<td>Social functioning (SF)</td>
<td>2</td>
<td>Limitations in social activities</td>
</tr>
<tr>
<td>Role functioning-physical (RP)</td>
<td>4</td>
<td>Limitations in work or daily activities due to physical problems</td>
</tr>
<tr>
<td>Role functioning-emotional (RE)</td>
<td>3</td>
<td>Limitations in work or daily activities due to emotional problems</td>
</tr>
<tr>
<td>Mental health (MH)</td>
<td>5</td>
<td>The degree of positive and negative feelings, including anxiety, depression, peacefulness and happiness.</td>
</tr>
<tr>
<td>Vitality (VT)</td>
<td>4</td>
<td>The degree of vitality and liveliness</td>
</tr>
<tr>
<td>Bodily pain (BP)</td>
<td>2</td>
<td>Severity, frequency of pain and limitations due to pain</td>
</tr>
<tr>
<td>General health (GH)</td>
<td>5</td>
<td>Perceptions of overall health</td>
</tr>
<tr>
<td>Change in health (CH)</td>
<td>1</td>
<td>Change in health compared to 1 year ago</td>
</tr>
</tbody>
</table>

* This single-item scale was not used in this study.

Scores, scale scores are computed and transformed into a 100-point scale. Higher scores indicate better HRQL.

In adults we administered the RAND-36, which is the Dutch translation of the MOS 36-item Short-Form Health Survey \(^{23,24}\). The RAND-36 consists of 36 items divided into nine scales (Table 1). After recoding the raw scores, scale scores are computed and transformed into a 100-point scale. Higher scores indicate better HRQL.
Chapter 7

Disease-specific HRQL questionnaires
The disease-specific HRQL questionnaires used in this study were the Food Allergy Quality of Life Questionnaire-Child Form (FAQLQ-CF) for children aged 8-12 years, the Food Allergy Quality of Life Questionnaire-Teenager Form (FAQLQ-TF) for adolescents aged 13-17 years and the Food Allergy Quality of Life Questionnaire-Adult Form (FAQLQ-AF) for adults aged 18 years and older. All 3 questionnaires were validated in the Netherlands and showed excellent reliability. These questionnaires consist of 24, 23 and 29 items, respectively. The raw FAQLQ scores 0 to 6 were recoded as 1 to 7. The total score is the mean of all items of each questionnaire and ranges from 1 (minimal impairment of HRQL) to 7 (maximal impairment of HRQL). Thus higher scores indicate poorer HRQL.

Comparative studies
Norm values of the Dutch population were obtained from the validation studies of the generic questionnaires in the Netherlands. The original database of the Dutch school population was obtained and used to calculate CHQ-CF87 scores for children and adolescents separately. As comparative diseases we chose asthma, irritable bowel syndrome (IBS), diabetes mellitus type I (DM) and rheumatoid arthritis (RA). These diseases were chosen because they are chronic with sufficient parallels with food allergy and were used as comparative disease in previous studies on HRQL in food allergy.

Selection of comparative studies
To compare the impact of food allergy on HRQL with the general population and patients with other diseases, we searched PubMed for comparative studies on generic HRQL. Comparative studies were identified through a search from 1998 to 2008 using the search terms ‘Child Health Questionnaire Child Form 87’ or ‘CHQ-CF87’ for the children and adolescents and ‘RAND-36’, ‘SF-36’ or ‘Medical Outcomes Study Short Form 36’ for the adults, together with disease-specific terms. Only studies in Dutch populations were included, since the current study of food allergic patients was carried out in the Netherlands. For inclusion in the comparison, the studies had to report the mean (SD) scores for each of the CHQ-CF87 subscales or RAND-36 subscales. Because the focus of the comparison was the effect of disease on HRQL, baseline or pre-treatment scores were required. If multiple studies met the selection criteria, the study with the largest sample size was chosen.

Statistical analysis
One-sample t-tests were used to compare the scores of the food allergic patients on the CHQ-CF87 and RAND-36 with Dutch populations and specific disease populations previously studied. Because we obtained the original database of the Dutch child and adolescent populations, we used the Mann-Whitney test to compare the scores of the food allergic children and adolescents on the CHQ-CF87 with the scores of the Dutch child and adolescent populations (not normally
distributed). Additionally, floor and ceiling effects (percentage of patients with minimal or maximal score, respectively) of the generic and disease-specific questionnaires were investigated. The floor and ceiling of the generic CHQ-CF87 and RAND-36 were score 0 and score 100. The floor and ceiling of the diseasespecific FAQLQ-CF, -TF and -AF were score 1 and score 7. Statistical analyses were performed with SPSS for Windows 14.0 (SPSS Inc., Chicago, IL, USA).

**Results**

**Participants**

The questionnaire packages including the FAQLQ-CF, -TF or -AF and the age appropriate generic HRQL questionnaires were sent to 312 participants divided over the three age groups. Response rates were high: children 84/111 (73%), adolescents 75/98 (77%) and adults 80/100 (80%). A few returned questionnaires were excluded from the analysis because a) no current food allergies were reported (three children and one adult) or b) no physician-diagnosed food allergy was reported (seven adults) or c) the descriptive characteristics were missing (one child and one adolescent) or d) the generic questionnaire was not completed (one child). Therefore, 225 participants were included in the final analysis. Table 2 shows the descriptive characteristics of these participants.

**Comparative studies**

The following numbers of articles were reviewed for each generic questionnaire and each disease:

- CHQ-CF87, children and adolescents: asthma, 3; IBS, 0; DM, 5; RA, 11;
- RAND-36, adults: asthma, 7; IBS, 1; DM, 19; RA, 16;

A summary of the selected articles (population based and disease based) is shown in Table 3.

**CHQ-CF87: food allergy versus population**

Food allergic children scored significantly higher on the scale RB (p=0.005) than children from the general population 22, indicating better HRQL for the food allergic children on this scale (Figure 1). Also food allergic adolescents scored significantly higher on the scale RB (p=0.013), but lower on the scales BP (p=0.020) and GH (p<0.001) than adolescents from the general population 22, indicating better HRQL on one scale for the food allergic adolescents and poorer HRQL on the other two scales (Figure 2a).

**CHQ-CF87: food allergy versus other diseases**

No studies in asthma, IBS, DM or RA were found that examined the CHQ-CF87 in children aged 8 to 12 years. Only two studies examined the CHQ-CF87 in adolescents with asthma 26 and DM 27. Asthmatic adolescents scored significantly
Table 2. Descriptive characteristics of the food allergic participants (n=225).

<table>
<thead>
<tr>
<th></th>
<th>Children</th>
<th>Adolescents</th>
<th>Adults</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients (n)</td>
<td>79</td>
<td>74</td>
<td>72</td>
</tr>
<tr>
<td>Sex (m/f)</td>
<td>45/34</td>
<td>34/40</td>
<td>18/54</td>
</tr>
<tr>
<td>Age, mean (years)</td>
<td>10.2 (1.3)</td>
<td>14.7 (1.3)</td>
<td>37.2 (14.3)</td>
</tr>
<tr>
<td>Age, range (years)</td>
<td>8−12</td>
<td>13−17</td>
<td>18−72</td>
</tr>
<tr>
<td>Type of food allergies, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peanut</td>
<td>59 (74)</td>
<td>57 (77)</td>
<td>42 (58)</td>
</tr>
<tr>
<td>Tree nut</td>
<td>57 (72)</td>
<td>56 (76)</td>
<td>42 (58)</td>
</tr>
<tr>
<td>Egg</td>
<td>29 (37)</td>
<td>26 (35)</td>
<td>16 (22)</td>
</tr>
<tr>
<td>Milk</td>
<td>22 (28)</td>
<td>29 (39)</td>
<td>19 (26)</td>
</tr>
<tr>
<td>Fish</td>
<td>2 (3)</td>
<td>13 (18)</td>
<td>11 (15)</td>
</tr>
<tr>
<td>Shell fish</td>
<td>7 (9)</td>
<td>12 (16)</td>
<td>12 (17)</td>
</tr>
<tr>
<td>Wheat</td>
<td>10 (13)</td>
<td>5 (7)</td>
<td>12 (17)</td>
</tr>
<tr>
<td>Sesame</td>
<td>14 (18)</td>
<td>8 (11)</td>
<td>13 (18)</td>
</tr>
<tr>
<td>Soy</td>
<td>12 (15)</td>
<td>17 (23)</td>
<td>13 (18)</td>
</tr>
<tr>
<td>Celery</td>
<td>1 (1)</td>
<td>3 (4)</td>
<td>11 (15)</td>
</tr>
<tr>
<td>Fruits</td>
<td>29 (37)</td>
<td>38 (51)</td>
<td>35 (49)</td>
</tr>
<tr>
<td>Vegetables</td>
<td>14 (18)</td>
<td>22 (30)</td>
<td>27 (38)</td>
</tr>
<tr>
<td>Other*</td>
<td>15 (19)</td>
<td>20 (27)</td>
<td>30 (42)</td>
</tr>
<tr>
<td>Number of food allergies, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 food</td>
<td>15 (19)</td>
<td>9 (16)</td>
<td>12 (17)</td>
</tr>
<tr>
<td>2 foods</td>
<td>15 (20)</td>
<td>12 (41)</td>
<td>14 (19)</td>
</tr>
<tr>
<td>3 foods</td>
<td>16 (20)</td>
<td>15 (11)</td>
<td>8 (11)</td>
</tr>
<tr>
<td>&gt;3 foods</td>
<td>32 (41)</td>
<td>38 (51)</td>
<td>38 (53)</td>
</tr>
<tr>
<td>Type of symptoms, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiovascular symptoms¹</td>
<td>28 (35)</td>
<td>31 (58)</td>
<td>44 (61)</td>
</tr>
<tr>
<td>Respiratory symptoms¹</td>
<td>56 (71)</td>
<td>61 (82)</td>
<td>60 (83)</td>
</tr>
<tr>
<td>Gastrointestinal symptoms¹</td>
<td>49 (62)</td>
<td>47 (64)</td>
<td>48 (67)</td>
</tr>
<tr>
<td>Skin symptoms¹</td>
<td>69 (87)</td>
<td>60 (81)</td>
<td>55 (76)</td>
</tr>
<tr>
<td>Other¹</td>
<td>66 (84)</td>
<td>66 (89)</td>
<td>62 (86)</td>
</tr>
</tbody>
</table>

* E.g. lupine, kernels and seeds, herbs and spices, meat.
¹ dizziness, feeling your heart beat fast, loss of vision, inability to stand, light headedness, collapse, loss of consciousness / passing out
² tightening throat, difficulty swallowing, hoarseness / hoarse voice, difficulty breathing in, shortness of breath, wheezing, cough
³ nausea, stomach cramps, vomiting, diarrhea
⁴ itchy skin, red rash, urticaria, worsening eczema, swelling of the skin
⁵ oral allergy, swollen tongue or lips, symptoms of the nose or eyes
lower on the scales PF (p=0.049), BE, MH, FA and FC (all p<0.001) than those with food allergy, indicating better HRQL for food allergic adolescents than asthmatic adolescents. Adolescents with DM scored significantly higher on to the scales PF (p=0.039), BP (p=0.012), MH (p=0.034) and SE (p=0.014) than those with food allergy, indicating poorer HRQL for food allergic adolescents than diabetic adolescents (Figure 2b).

**RAND-36: food allergy versus population**

Food allergic adults scored significantly lower on the scales SF (p<0.001), VT (p=0.002) and GH (p<0.001) than adults from the general population 23, indicating poorer HRQL for food allergic adults (Figure 3a).

**RAND-36: food allergy versus other diseases**

Adults with DM 28 scored significantly higher on five scales than those with food allergy (SF, p<0.001; RP, p=0.014; VT, p=0.002; BP, p=0.001; GH, p<0.001), indicating poorer HRQL for food allergic adults than diabetic adults. Adults with asthma 28 scored significantly lower on all scales, except one (MH), than those with food allergy (all p<0.01), indicating better HRQL for food allergic adults than asthmatic adults. Also adults with RA 10 scored significantly lower on six scales than those with food allergy (PF, p<0.001; RP, p<0.001; RE, p=0.008; VT, p=0.031; BP, p<0.001; GH, p=0.048), indicating better HRQL for food allergic adults than adults with RA. Finally, adults with IBS 31 scored significantly lower on all scales than those with food allergy (all p<0.01), indicating better HRQL for food allergic adults than adults with IBS (Figure 3b).

Table 3. Description of studies included in the comparison.

<table>
<thead>
<tr>
<th>Reference</th>
<th>Disease</th>
<th>Patients, n*</th>
<th>Age, mean (SD)</th>
<th>Age, range</th>
<th>Male, %</th>
<th>Sample source</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHQ-CF87</td>
<td>Population</td>
<td>444</td>
<td>12.8 (1.7)</td>
<td>9-17</td>
<td>50.5</td>
<td>School children</td>
</tr>
<tr>
<td>Raat et al. 22</td>
<td>Asthma</td>
<td>72</td>
<td>15 (0.7)</td>
<td>14-17</td>
<td>27.8</td>
<td>School children</td>
</tr>
<tr>
<td>Mohangoo et al. 26</td>
<td>DM</td>
<td>91</td>
<td>14.9 (1.1)</td>
<td>13-16.5</td>
<td>47</td>
<td>Outpatient clinic</td>
</tr>
<tr>
<td>Van de Zee et al. 23</td>
<td>Population</td>
<td>1063</td>
<td>44.1 (17.5)</td>
<td>18-89</td>
<td>35</td>
<td>Dutch population</td>
</tr>
<tr>
<td>Willems et al. 29</td>
<td>Asthma</td>
<td>27</td>
<td>45.9 (15.9)</td>
<td>NA</td>
<td>33.3</td>
<td>Outpatient clinic</td>
</tr>
<tr>
<td>Ten Berg et al. 30</td>
<td>IBS</td>
<td>169</td>
<td>55.0 (17.1)</td>
<td>NA</td>
<td>22.8</td>
<td>Medical database</td>
</tr>
<tr>
<td>Hart et al. 28</td>
<td>DM</td>
<td>274</td>
<td>38.2 (12.4)</td>
<td>NA</td>
<td>54.4</td>
<td>Outpatient clinic</td>
</tr>
<tr>
<td>Rupp et al. 31</td>
<td>RA</td>
<td>679</td>
<td>59.6 (13.8)</td>
<td>NA</td>
<td>29</td>
<td>Diagnostic register</td>
</tr>
</tbody>
</table>

DM=diabetes mellitus type I
RA=rheumatoid arthritis
IBS=irritable bowel syndrome
NA=not available

*represents the number of patients included in the analysis of the generic HRQL questionnaire
Figure 1. CHQ-CF87 scores of children with food allergy and a sample of children from the general population. *p<0.01. Higher scores indicate better HRQL. FA, not available for the sample of children from the general population. See table 1 for the definition of the scales.

Figure 2a. CHQ-CF87 scores of adolescents with food allergy and a sample of adolescents from the general population. *p<0.05; **p<0.001. Higher scores indicate better HRQL. FA, not available for the sample of adolescents from the general population. See table 1 for the definition of the scales.

Figure 2b. CHQ-CF87 scores of adolescents with food allergy, asthma and diabetes mellitus type 1 (DM). *p<0.05; **p<0.01. Higher scores indicate better HRQL. RE and RB not available for asthma, FA not available for DM. See table 1 for the definition of the scales.
Generic quality of life of food allergic patients

Generic versus disease-specific HRQL questionnaires: Floor and ceiling effects

The FAQLQ-CF, -TF and -AF showed minimal if any floor or ceiling effects (Table 4), indicating that almost no food allergic patients reported the minimal score (best HRQL) or maximal score (worst HRQL) on the FAQLQ. In children, the CHQ-CF87 showed almost no floor effects because the minimal score (worst HRQL) was seldom reported. However, remarkable ceiling effects were seen for the scales RE, RB, RP, where more than 80% of the children reported the maximal score (best HRQL). A similar pattern was seen in adolescents. In adults, the RAND-36 showed some floor effects (adults with the minimal score, thus worst HRQL), but more pronounced were the ceiling effects (adults with the maximal score, thus best HRQL), especially for the scale RE (79%).
Chapter 7

Discussion

In this study we found that food allergic children and adolescents reported less impairment on the scale role functioning-behaviour (RB) than general pediatric and adolescent populations. However, food allergic adolescents reported more impairment on the scales bodily pain (BP) and general health (GH) than a general adolescent population and food allergic adults reported more impairment on the scales self-esteem (SE), vitality (VT) and general health (GH). Compared with other chronic diseases, food allergic patients reported poorer generic HRQL than patients with DM, but better generic HRQL than patients with asthma, IBS and RA. Finally, we found very high ceiling effects for some scales of the generic questionnaires. No significant floor or ceiling effects were found for the disease-specific FAQLQs.

One of the advantages of generic HRQL questionnaires is that they can be used to compare healthy individuals with patients with a chronic disease. We compared food allergic patients with individuals from the general population and found that food allergic children and adolescents reported fewer limitations in school work or activities with friends due to behavioural problems (RB). This may be explained by the fact that having a food allergy demands that the child be conscious of his or her behaviour, especially regarding to situations involving food, with an emphasis on avoidance of impulsive behaviour. These disease managing demands may result

Table 4. Percentage of floor and ceiling effects of FAQLQ-CF, -TF and -AF, CHQ-CF87 and RAND-36.

<table>
<thead>
<tr>
<th>Children</th>
<th>Adolescents</th>
<th>Adults</th>
</tr>
</thead>
<tbody>
<tr>
<td>Floor %</td>
<td>Ceiling %</td>
<td>Floor %</td>
</tr>
<tr>
<td>FAQLQ</td>
<td>1.3 0</td>
<td>0 1.4</td>
</tr>
<tr>
<td>CHQ-CF87</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PF</td>
<td>0 64.8</td>
<td>0 58.1</td>
</tr>
<tr>
<td>RE</td>
<td>1.3 81.0</td>
<td>1.4 73.0</td>
</tr>
<tr>
<td>RB</td>
<td>0 82.3</td>
<td>0 81.1</td>
</tr>
<tr>
<td>RP</td>
<td>0 86.1</td>
<td>2.7 85.1</td>
</tr>
<tr>
<td>BP</td>
<td>0 41.8</td>
<td>1.4 20.3</td>
</tr>
<tr>
<td>BE</td>
<td>0 5.1</td>
<td>0 0</td>
</tr>
<tr>
<td>MH</td>
<td>0 2.6</td>
<td>0 0</td>
</tr>
<tr>
<td>SE</td>
<td>0 6.3</td>
<td>0 0</td>
</tr>
<tr>
<td>GH</td>
<td>0 3.8</td>
<td>0 0</td>
</tr>
<tr>
<td>FA</td>
<td>0 31.6</td>
<td>0 24.3</td>
</tr>
<tr>
<td>FC</td>
<td>0 25.3</td>
<td>0 23.0</td>
</tr>
</tbody>
</table>

See table 1 for the definition of the scales.

Floor effect = percentage of patients with minimal score.
Ceiling effect = percentage of patients with maximal score.

Floor and ceiling of the FAQLQ-CF, -TF and -AF are score 1 (best HRQL) and 7 (worst HRQL), respectively.
Floor and ceiling of CHQ-CF87 and RAND-36 are score 0 (worst HRQL) and 100 (best HRQL), respectively.
in more consciousness about behaviour in other situations as well, resulting in less
behavioural problems than in children of the general population. In addition to RB,
trends were seen for food allergic children to report better HRQL scores on RE and
FC and also in food allergic adolescents and adults to report better HRQL scores
on the scales RB and PF, respectively. However, the overall trend was that food
allergic patients reported poorer HRQL on most scales than the general population.
Compared to the older age groups, food allergic children reported the least impact
of food allergy on generic HRQL and their scores were comparable to the scores of
the children in the general population. As in this age group parents are responsible
for the management of the food allergy, children probably do not experience
much impact of their food allergy on their generic HRQL. Alternatively, the generic
questionnaire used in children may be less responsive than the corresponding
questionnaires in adolescents and adults.

Food allergic adolescents reported significantly more pain and limitations
due to pain (BP) and poorer perceptions of overall health (GH) than adolescents
from the general population. It is remarkable that food allergic adolescent reported
significantly lower scores on BP than those from the general population, since pain
is not a feature of food allergy. However, the questions included in BP ask about
bodily pain or symptoms. While symptoms are generally not a feature of food
allergy outside of accidental exposures, they are a feature of frequent comorbid
conditions such as asthma. Since generic questionnaires do not separate the
impact on HRQL of the disease in question from the impact of comorbid diseases,
this may have influenced the responses to questions in this domain. Food allergic
adults reported significantly more limitations in social activities (SF), less vitality
and liveliness (VT) and poorer perceptions of overall health (GH) than adults from
the general population. Overall, food allergic patients tend to report poorer HRQL
than individuals from the general population, apart from the exceptions indicated
above.

A further advantage of generic HRQL questionnaires is that they can be used
to compare different diseases. We compared food allergy with four other chronic
diseases and found that food allergic patients reported poorer HRQL than patients
with DM, but better HRQL than patients with asthma, IBS and RA. While this may
indicate that these diseases differ in their impact on HRQL, other factors may have
played a role as well. Firstly, HRQL in adults is age-dependent and it has been found
that HRQL as measured with the scales PF, RB, BP and GH decreases with age. On
average, the food allergic adults in our study were younger than the adult patients
with asthma, IBS and RA, which may have led to diminished HRQL being reported
by these patient groups. The adults with DM had approximately the same age as
the food allergic adults, and thus this comparison is probably not influenced by
the described age effect. Another possibility is that generic questionnaires may be
biased to being responsive in diseases characterised by daily chronic symptoms
such as asthma, IBS and RA. Conversely, generic HRQL questionnaires tend to
ignore limitations of lifestyle and psychological burden caused by disease managing
activities more characteristic for diseases such as food allergy and DM. This may
also have influenced the HRQL reported by these patient groups and could have led to an underestimation of the impact on generic HRQL in DM and food allergy.

The disadvantages of generic questionnaires are that they are by design comprehensive, so they may not focus adequately on problems specific to a particular disease and that they do not separate the impact on HRQL of the disease in question from the impact of comorbid diseases. In previous studies on the development and validation of the FAQLQ-CF, -TF and -AF we already showed that the correlations between the generic and disease-specific questionnaires were only low to moderate \(^{18-20}\). This indicates that the generic and disease-specific questionnaires are not measuring exactly the same thing. Additionally, we found very high ceiling effects for some scales of the generic questionnaires in this study, which means that a substantial part of the food allergic patients reported no problems in these areas. This indicates that, as expected, some areas measured by generic questionnaires are irrelevant to food allergy. In contrast, no floor or ceiling effects were observed for the disease-specific FAQLQ-CF, -TF and -AF. This indicates that these questionnaires are responsive to the specific concerns of food allergic patients and it underscores the internal validity of these questionnaires. In addition, it illustrates the general desirability of using disease-specific HRQL questionnaires when studying specific diseases.

This study may also have some limitations. We decided to only include comparative studies that were performed in the Netherlands, since the HRQL measurement in food allergic patients was done in the Netherlands. This may decrease the generalisability of the results to other countries and cultures. However, for the comparisons within this study, it was important to include only Dutch studies to prevent bias caused by different languages or cultures. The FAQLQs used in this study will be validated in other countries as well, so they can be used for international disease-specific studies of food allergy. Further comparative studies in other counties and cultures will show if the same patterns are seen as in our study. In addition, it should be mentioned that the comparison between the different diseases is restricted to the patients included in the selected studies. Patients within these different studies could not be perfectly matched on demographic variables which might influence the impact of these diseases on HRQL.

In conclusion, this study showed that food allergic children reported the least impact of food allergy on generic HRQL, which was even better than in children in the general population in some respects. In contrast, food allergic adolescents and adults reported overall poorer generic HRQL than the general population. The HRQL impact of food allergy is intermediate in magnitude between DM and asthma, IBS and RA. Generic HRQL questionnaires may thus be useful to compare the impact of food allergy on HRQL with the general population and other chronic diseases. However, the very high ceiling effects that were found for some generic scales may indicate that generic HRQL questionnaires are not sufficiently responsive to measure disease-specific but potentially clinically important impairments in food allergy. For measuring these disease-specific effects in food allergic patients, it is preferable to use disease-specific questionnaires.
Acknowledgements
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Reference list

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20. Flokstra-de Blok BMJ, van der Meulen GN, DunnGalvin A et al. Development and validation of the Food Allergy Quality of Life Questionnaire-Adult Form (FAQLQ-AF). Allergy 2009;In press:


