

# Validity and reliability of the Thai version of Food Allergy Quality of Life Questionnaire – Adult Form (FAQLQ-AF) and Food Allergy Independent Measure – Adult Form (FAIM-AF)

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## Abstract

**Background:** Food allergy affects the patient's quality of life (QoL) and leads to anxiety and depression. In addition to routine treatment, QoL evaluation should also be performed in patients with food allergies. The validated Food Allergy Quality of Life Questionnaire - Adult Form (FAQLQ-AF) and Food Allergy Independent Measure - Adult Form (FAIM-AF) have been well accepted and available in many languages.

**Objectives:** Translate FAQLQ-AF and FAIM-AF into Thai and perform reliability and validity tests in Thai adult patients with food allergies.

**Methods:** The translation process was performed according to the ISPOR Task Force for Translation and Cultural Adaptation. Participants 18 years or older and with physician-diagnosed food allergies were included in the study. Thai versions of FAQLQ-AF and FAIM-AF were administered to participants at baseline and after two weeks. The intraclass correlation coefficient and Cronbach's  $\alpha$  coefficient were evaluated to demonstrate both questionnaires' test-retest reliability and internal consistency.

**Results:** The study included 104 participants. The Thai version of FAQLQ-AF and FAIM-AF demonstrated good reliability, with intraclass correlation coefficients of 0.83 (95%CI 0.76, 0.88) and 0.85 (95%CI 0.79, 0.90), respectively. The validity was excellent, with Cronbach's  $\alpha$  coefficient of 0.91 and 0.92, respectively. Both questionnaires were moderately correlated ( $r = 0.69$ ,  $P < 0.001$ ), but poorly correlated with the 36-Item Short Form Survey, which is usually used to evaluate general health status.

**Conclusion:** To evaluate the QoL in adult patients with food allergies, the Thai versions of FAQLQ-AF and FAIM-AF are valid, reliable, and more suitable than the general questionnaire.

**Key words:** adult, food allergy, quality of life, questionnaire, Thai, reliability, validity, FAQLQ, FAIM

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### Abbreviations:

|          |   |
|----------|---|
| FAQLQ-AF | Food Allergy QoL Questionnaire – Adult Form   |
| FAIM-AF  | Food Allergy Independent Measure – Adult Form |
| IQR      | Interquartile range                           |
| ICC      | Intraclass correlation                        |
| OR       | Odd ratio                                     |
| QoL      | Quality of life                               |
| SF-36    | 36-Item Short Form Survey                     |
| SD       | Standard deviation                            |
| Th       | Thai  |

## Introduction

The global prevalence of food allergy is increasing, affecting up to 10% of the population in all age groups.<sup>1,2</sup> While food allergy in children has been extensively studied, there is a growing need to address the prevalence of adult food allergies worldwide.<sup>3</sup> The population-based prevalence of food allergy in adults was 6% in Europe,<sup>4</sup> 6.4% in Taiwan,<sup>5</sup> and 10.8% in the United States.<sup>6</sup> In Thailand, a population-based prevalence study was conducted on preschool children in northern Thailand, estimated at 5.5%, but there was no report on Thai adults.<sup>7</sup>

Clinical manifestations of food allergies in adults ranged from mild to severe life-threatening conditions. A significant number of children and adults in the US experienced at least one anaphylaxis episode.<sup>6</sup> The mainstay treatment is dietary avoidance. Patients must carefully read the food label and avoid food allergens that are sometimes not mentioned on the labels. These affect the quality of life (QoL) and social activities and may lead to psychological disorders.<sup>2</sup> Previous studies showed that food allergy is associated with increased stress and anxiety disorders.<sup>8</sup> It is also a risk of depression with an odd ratio (OR) of 1.64-2.27. This risk is much higher if there are multiple food allergies.<sup>9</sup> Therefore, focusing on patient quality of life, in addition to medical management, is essential to holistic food allergy care.

A tool to evaluate QoL in food allergy was self-answered questionnaires that depended on age. Unlike children and teenagers, there are a few tools for adults.<sup>10</sup> The Food Allergy QoL Questionnaire – Adult Form (FAQLQ-AF) and Food Allergy Independent Measure – Adult Form (FAIM-AF) was developed for patients 18 years and older. The FAQLQ-AF comprises 29 questions and is divided into 4 domains: allergen avoidance and dietary restrictions, emotional impact, risk of accidental exposure, and food allergy-related health.<sup>11</sup> The FAIM-AF was developed to establish independent measurements in food allergy and used to evaluate the construct validity of the FAQLQ-AF.<sup>12</sup> It had four expectation of results questions (EO 1-4) and two independent measure questions (IM1-2). Both questionnaires were reliable and valid for assessing the QoL in food-allergic adults.<sup>11,12</sup> These are currently available in many languages.<sup>13</sup> The Food Allergy QoL Questionnaire-Parent Form was translated and validated in Thailand. Unfortunately, it is used for Thai food-allergic children aged 0-12 years.<sup>14</sup>

This study aimed to translate the FAQLQ-AF and FAIM-AF English into Thai. Furthermore, we aim to test reliability and validity in Thai adult food-allergic patients.

## Methods

This study was conducted in the outpatient clinic of the Division of Allergy and Immunology, Department of Medicine, Siriraj Hospital. Ethical approval was obtained from the Siriraj Institutional Review Board (SIRB), Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand (certificate of approval no. 263/2563[IRB4]). This study was conducted following the principles outlined in the Declaration of Helsinki. Written informed consent was obtained from all participants, ensuring their anonymity

and granting permission to publish their information in this article.

## Translation Process

We obtained permission from the questionnaire developer. Then followed the recommendation of the International Society for Pharmacoeconomics and Outcomes Research Task Force for Translation and Cultural Adaptation.<sup>15</sup> Briefly translated into Thai by two board-certified American Thai allergists fluent in English. Translated backward into English by a native English speaker fluent in Thai. After that, the backward translation questionnaires were sent to the developer for approval. The Thai version of both questionnaires was tested for cognitive debriefing on ten participants. The expert panel consisted of three allergists with extensive familiarity with patients suffering from food allergies and a profound understanding of Thai culture. This panel was responsible for thoroughly reviewing, providing constructive feedback, revising, and finalizing the questionnaires.

## Participants

Eligible criteria were 1) 18 years of age or older, 2) participants must experience food allergic events, and sensitization must be confirmed by at least one of the following, positive skin prick or serum specific IgE to culprit food at least 0.35 KUA/L or positive oral food challenge, and 3) can read and write the Thai language. All participants who met all three criteria were included. On the first date, participants were asked to complete three questionnaires, including the Thai version (Th) of FAQLQ-AF, FAIM-AF, and the 36-Item Short Form Survey (SF-36), which evaluated quality of life in the general population. Two weeks apart, participants were asked again to complete the ThFAQLQ-AF and ThFAIM-AF. Demographic data and clinical characteristics of food allergy were also collected.

## Statistical analysis

The sample size calculation was determined based on a previously conducted study and a reported formula.<sup>11,16,17</sup> The planning value for the intraclass correlation coefficient ( $\rho_i$ ) was 0.95, and the Cronbach's  $\alpha$  ( $P_j$ ) was 0.7.<sup>11</sup> The chosen values for type I and type II errors were 0.05 and 0.02, respectively. Based on these considerations, a minimum of 96 patients were required for this study.

Demographic data were presented as mean with standard deviation (SD) for continuous data and frequency with proportion for categorical data. The detailed questions in FAQLQ-AF were demonstrated in the original study.<sup>11</sup> The 6 questions of FAIM-AF were EO1, the chance of accidental exposure; EO2, the chance of severe reaction when accidentally exposed; EO3, the chance of dying when accidentally exposed; EO4, the chance of not acting effectively when accidentally exposed; IM1, the number of foods to avoid; IM2, the impact of food allergy on social life.<sup>12</sup> The FAQLQ-AF and FAIM-AF scores were recorded as 1 to 7. The total score of FAQLQ-AF and FAIM-AF was calculated according to the developer's instructions,

ranging from 1 (no impairment/ low perceived disease severity) to 7 (maximal impairment/high perceived disease severity).<sup>13</sup> The total score of SF-36 was calculated according to the instructions. The score ranges from 0 (the maximum impaired quality of life) to 100 (no impaired quality of life). Statistical analyses were performed with IBM SPSS Statistics 21 (SPSS Inc., Chicago, IL, USA).

#### Reliability tests

The test-retest reliability and internal consistency were performed using intraclass correlation (ICC) and Cronbach's  $\alpha$ , respectively.

#### Validity tests

The correlation between the ThFAQLQ-AF, ThFAIM-AF, and SF-36 was evaluated using Pearson's correlation coefficients for convergent validity. We explored the discriminant validity of the ThFAQLQ-AF, ThFAIM-AF, and SF-36 using the Mann-Whitney test between sex, age, the number and type of food allergens, allergic comorbidity, and clinical presentation.

## Results

One hundred and four participants were included. All participants can complete ThFAQLQ-AF and ThFAIM-AF. Demographic data are shown in **Table 1**. Most participants were female, with a mean age of  $35.2 \pm 8.2$  years, and were allergic to at least of two foods. Sixty-four participants (61.5%) had at least one comorbidity. Allergic rhinitis was the most common comorbidity. Food allergy was diagnosed primarily by a suggestive clinical history and a positive skin test or specific IgE for culprit food allergens. Only 14.4% underwent an oral food challenge test. The most common culprit of food allergens are fruits, particularly bananas. Cutaneous symptoms (itching, urticaria, lip swelling) were commonly found in almost participants (94.2%). Severe symptoms such as cardiovascular symptoms (hypotension, dizziness) were found in 42 participants (40.4%). Sixty-four participants (61.5%) experienced anaphylaxis in the previous year, and 84.6% experienced at least one anaphylaxis.

#### Reliability

The ThFAQLQ-AF showed good test-retest reliability (ICC = 0.83, 95%CI 0.76,0.88) and excellent internal consistency (Cronbach's  $\alpha$  = 0.91). The ThFAIM-AF showed good test-retest reliability (ICC = 0.85, 95%CI 0.79,0.90) and excellent internal consistency (Cronbach's  $\alpha$  = 0.92). The domain analysis of the ThFAQLQ-AF and ThFAIM-AF is shown in **Table 2**. The highest score on ThFAQLQ-AF and ThFAIM-AF was in the food allergy-related health domain and the EO2 question, respectively.

**Table 1. Demographic data. (n = 104)**

| Characteristics                    | n (%)          |
|------------------------------------|----------------|
| Female                             | 83 (79.8)      |
| Age (mean $\pm$ SD)                | 35.2 $\pm$ 8.2 |
| <b>Comorbidity</b>                 |                |
| Presence of at least 1 comorbidity | 64 (61.5)      |
| Allergic rhinitis                  | 49 (47.1)      |
| Drug allergy                       | 7 (6.7)        |
| Asthma                             | 6 (5.8)        |
| Atopic dermatitis                  | 3 (2.9)        |
| <b>Evidence of sensitization</b>   |                |
| Skin test to culprit foods         | 94 (90.4)      |
| Specific IgE to culprit foods      | 25 (24.0)      |
| Oral food challenge test           | 15 (14.4)      |
| <b>Food allergens</b>              |                |
| Number of food allergens           |                |
| 1                                  | 51 (49%)       |
| 2                                  | 9 (8.7)        |
| $\geq 3$                           | 44 (42.3)      |
| Type of culprit foods              |                |
| Fruits                             | 63 (60.6)      |
| Shellfish                          | 29 (27.9)      |
| Wheat                              | 20 (19.2)      |
| Other allergens                    | 1 (1)          |
| <b>Clinical presentation</b>       |                |
| Anaphylaxis in the previous year   | 64 (61.5)      |
| Cutaneous symptoms                 | 98 (94.2)      |
| Respiratory symptoms               | 70 (67.3)      |
| Gastrointestinal symptoms          | 51 (49.0)      |
| Cardiovascular symptoms            | 42 (40.4)      |

**Abbreviations:** SD, standard deviation; IgE, immunoglobulin E; IQR, interquartile range.

**Table 2. Reliability of the Thai version of FAQLQ-AF and FAIM-AF.**

|                               | Mean score ± SD | ICC (95% CI)     | Cronbach's α |
|-------------------------------|-----------------|------------------|--------------|
| <b>Total ThFAQLQ-AF score</b> | 4.43 ± 1.03     | 0.83 (0.76,0.88) | 0.91         |
| AADR                          | 4.30 ± 1.06     | 0.82 (0.74,0.87) | 0.90         |
| EI                            | 4.67 ± 1.05     | 0.79 (0.70,0.85) | 0.88         |
| RAE                           | 4.18 ± 1.36     | 0.80 (0.72,0.86) | 0.89         |
| FAH                           | 5.05 ± 1.44     | 0.72 (0.62,0.80) | 0.84         |
| <b>Total ThFAIM-AF score</b>  | 4.24 ± 1.24     | 0.85 (0.79,0.90) | 0.92         |
| EO1                           | 4.42±1.51       | 0.65 (0.53,0.75) | 0.79         |
| EO2                           | 4.94±1.55       | 0.73 (0.63,0.81) | 0.84         |
| EO3                           | 3.77±1.79       | 0.82 (0.75,0.88) | 0.90         |
| EO4                           | 3.96±1.63       | 0.70 (0.59,0.79) | 0.82         |
| IM1                           | 4.60±1.35       | 0.72 (0.62,0.80) | 0.84         |
| IM2                           | 3.75±1.71       | 0.70(0.59,0.79)  | 0.83         |

**Abbreviations:** SD, standard deviation; ICC, intraclass correlation, ThFAQLQ-AF; Thai version of Food Allergy Quality of Life Questionnaire – Adult Form; AADR, allergen avoidance and dietary restrictions; EI, emotional impact; RAE, Risk of accidental exposure; FAH, Food allergy related health; ThFAIM-AF, Thai version of Food Allergy Independent Measure - Adult Form; EO1, the chance of accidental exposure; EO2, the chance of severe reaction when accidentally exposed; EO3, the chance of dying when accidentally exposed; EO4, the chance of not acting effectively when accidentally exposed; IM1, number of foods to avoid; IM2, the impact of food allergy on social life.

**Convergent validity**

The convergent validity between the ThFAQLQ-AF and ThFAIM-AF was moderately correlated (ICC = 0.675, *p*-value < 0.001). (Table 3) The emotional impact domain in the total ThFAQLQ-AF was the most correlated with the total ThFAIM-AF. All domains in ThFAQLQ-AF were moderate to good correlation with all questions in ThFAIM-AF, except the allergen avoidance and dietary restrictions domain showed a weak significant correlation in three questions (EO3, IM1, IM2) and not significant in three questions (EO1, EO2, EO4) of ThFAIM-AF. (Table 4) Both questionnaires did not correlate with SF-36. (Table 3) The domain of allergen avoidance and dietary restrictions of ThFAQLQ-AF was the most correlated with general health perceptions, body pain, and social functioning of SF-36. The remaining domains and each ThFAIM-AF question were not correlated. (Table 5)

**Table 3. The convergent validity of the Thai version of FAQLQ-AF and FAIM-AF.**

| Questionnaire Compared   | Interclass correlation | <i>p</i> -value   |
|--------------------------|------------------------|-------------------|
| ThFAQLQ-AF and ThFAIM-AF | <b>0.675</b>           | <b>&lt; 0.001</b> |
| ThFAQLQ-AF and SF-36     | 0.004                  | 0.482             |
| ThFAIM-AF and SF-36      | 0.011                  | 0.454             |

**Abbreviations:** ThFAQLQ-AF; Thai version of the Food Allergy Quality of Life Questionnaire – Adult Form; ThFAIM-AF, Thai version of the Food Allergy Independent Measure – Adult Form; SF-36, The 36-Item Short Form Health Survey.

**Discriminant validity**

The summary of the discriminant ability of both translated questionnaires is shown in Table 6. The total ThFAQLQ-AF and ThFAIM-AF had the ability to discriminate participants who experienced cardiovascular symptoms and fruit allergy, respectively. The worst QoL was observed in participants who had cardiovascular symptoms. They had significantly higher scores in total ThFAQLQ-AF (4.69 ± 1.09 vs 4.26 ± 0.96, *p* = 0.038) and in the allergen avoidance and dietary restrictions domain (4.72 ± 1.09 vs 4.01 ± 0.95, *p* = 0.001). Participants diagnosed with fruit allergy also had a poorer QoL. They had significantly higher scores in total ThFAIM-AF (4.44 ± 1.25 vs 3.94 ± 1.17, *p* = 0.045) and in the question IM2 (4.11 ± 1.78 vs 3.20 ± 1.44, *p* = 0.007). Wheat-allergic participants scored significantly higher in allergen avoidance and dietary restrictions domain of ThFAQLQ-AF and question IM1. Reduced QoL was observed in participants who were allergic to more than one food. They had a significantly higher score of questions IM2 of ThFAIM-AF. The total SF-36 could not discriminate any factor in patients with food allergies.

Table 4. Pearson's correlation coefficients for the Thai version of FAQLQ-AF and FAIM-AF.

|           |       | ThFAQLQ-AF                          |                                     |                                     |                                     |                                     |
|-----------|-------|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|
|           |       | Total                               | AADR                                | EI                                  | RAE                                 | FAH                                 |
| ThFAIM-AF | Total | <b>0.686</b><br>( <i>p</i> < 0.001) | <b>0.249</b><br>( <i>p</i> = 0.011) | <b>0.788</b><br>( <i>p</i> < 0.001) | <b>0.705</b><br>( <i>p</i> < 0.001) | <b>0.767</b><br>( <i>p</i> < 0.001) |
|           | EO1   | <b>0.448</b><br>( <i>p</i> < 0.001) | 0.123<br>( <i>p</i> = 0.215)        | <b>0.557</b><br>( <i>p</i> < 0.001) | <b>0.464</b><br>( <i>p</i> < 0.001) | <b>0.513</b><br>( <i>p</i> < 0.001) |
|           | EO2   | <b>0.522</b><br>( <i>p</i> < 0.001) | 0.175<br>( <i>p</i> = 0.076)        | <b>0.577</b><br>( <i>p</i> < 0.001) | <b>0.568</b><br>( <i>p</i> < 0.001) | <b>0.587</b><br>( <i>p</i> < 0.001) |
|           | EO3   | <b>0.554</b><br>( <i>p</i> < 0.001) | <b>0.234</b><br>( <i>p</i> = 0.017) | <b>0.626</b><br>( <i>p</i> < 0.001) | <b>0.552</b><br>( <i>p</i> < 0.001) | <b>0.590</b><br>( <i>p</i> < 0.001) |
|           | EO4   | <b>0.430</b><br>( <i>p</i> < 0.001) | 0.141<br>( <i>p</i> = 0.152)        | <b>0.501</b><br>( <i>p</i> < 0.001) | <b>0.412</b><br>( <i>p</i> < 0.001) | <b>0.577</b><br>( <i>p</i> < 0.001) |
|           | IM1   | <b>0.614</b><br>( <i>p</i> < 0.001) | <b>0.220</b><br>( <i>p</i> = 0.025) | <b>0.689</b><br>( <i>p</i> < 0.001) | <b>0.653</b><br>( <i>p</i> < 0.001) | <b>0.670</b><br>( <i>p</i> < 0.001) |
|           | IM2   | <b>0.642</b><br>( <i>p</i> < 0.001) | <b>0.262</b><br>( <i>p</i> = 0.007) | <b>0.737</b><br>( <i>p</i> < 0.001) | <b>0.654</b><br>( <i>p</i> < 0.001) | <b>0.654</b><br>( <i>p</i> < 0.001) |

Notes: Data present in a correlation coefficient (*p*-value)

Abbreviations: ThFAQLQ-AF, Thai version of Food Allergy Quality of life Questionnaire - Adult Form; AADR, Allergen avoidance and dietary restrictions; EI, Emotional impact; RAE, Risk of accidental exposure; FAH, Food allergy related health; ThFAIM-AF, Thai version of Food Allergy Independent Measure - Adult Form; EO1, the chance of accidental exposure; EO2, the chance of severe reaction when accidentally exposed; EO3, the chance of dying when accidentally exposed; EO4, the chance of not acting effectively when accidentally exposed; IM1, number of foods to avoid; IM2, the impact of food allergy on social life.

Table 5. Pearson's correlation coefficients for the SF-36 with the Thai version of FAQLQ-AF and FAIM-AF.

|       |                            | ThFAQLQ-AF        |                                   |                   |                   |                   | ThFAIM-AF         |                    |                   |                   |                   |                   |                   |
|-------|----------------------------|-------------------|-----------------------------------|-------------------|-------------------|-------------------|-------------------|--------------------|-------------------|-------------------|-------------------|-------------------|-------------------|
|       |                            | Overall           | AADR                              | EI                | RAE               | FAH               | Overall           | EO1                | EO2               | EO3               | EO4               | IM1               | IM2               |
| SF-36 | Overall                    | 0.017<br>(0.863)  | -0.149<br>(0.131)                 | 0.135<br>(0.171)  | 0.067<br>(0.500)  | 0.038<br>(0.702)  | 0.038<br>(0.702)  | 0.017<br>(0.865)   | -0.030<br>(0.762) | -0.002<br>(0.984) | 0.035<br>(0.725)  | 0.031<br>(0.754)  | 0.122<br>(0.219)  |
|       | Physical functioning       | 0.036<br>(0.715)  | -0.068<br>(0.494)                 | 0.144<br>(0.145)  | 0.030<br>(0.760)  | 0.062<br>(0.530)  | 0.062<br>(0.530)  | -0.013<br>(0.896)  | -0.094<br>(0.343) | 0.086<br>(0.384)  | 0.082<br>(0.409)  | 0.044<br>(0.657)  | 0.164<br>(0.096)  |
|       | Role function-physical     | 0.080<br>(0.417)  | 0.172<br>(0.081)                  | -0.040<br>(0.687) | 0.067<br>(0.500)  | -0.032<br>(0.748) | -0.032<br>(0.748) | 0.011<br>(0.910)   | 0.085<br>(0.393)  | -0.091<br>(0.360) | -0.040<br>(0.684) | -0.028<br>(0.782) | -0.071<br>(0.476) |
|       | Body pain                  | -0.134<br>(0.175) | <b>-0.248</b><br>( <b>0.011</b> ) | -0.020<br>(0.844) | -0.072<br>(0.470) | -0.004<br>(0.969) | -0.004<br>(0.969) | 0.044<br>(0.658)   | -0.135<br>(0.173) | 0.061<br>(0.536)  | 0.002<br>(0.981)  | -0.033<br>(0.741) | 0.026<br>(0.793)  |
|       | General health perceptions | -0.072<br>(0.468) | <b>-0.305</b><br>( <b>0.002</b> ) | 0.071<br>(0.475)  | 0.030<br>(0.765)  | 0.088<br>(0.372)  | 0.088<br>(0.372)  | 0.096<br>(0.333)   | 0.046<br>(0.645)  | 0.102<br>(0.303)  | 0.062<br>(0.532)  | 0.035<br>(0.723)  | 0.065<br>(0.512)  |
|       | Social functioning         | -0.094<br>(0.341) | <b>-0.254</b><br>( <b>0.009</b> ) | -0.033<br>(0.740) | 0.003<br>(0.977)  | -0.025<br>(0.799) | -0.025<br>(0.799) | 0.012<br>(0.906)   | -0.047<br>(0.363) | 0.010<br>(0.917)  | -0.111<br>(0.263) | 0.001<br>(0.995)  | 0.017<br>(0.865)  |
|       | Vitality                   | -0.009<br>(0.927) | -0.095<br>(0.336)                 | 0.075<br>(0.447)  | 0.032<br>(0.748)  | -0.020<br>(0.840) | -0.020<br>(0.840) | 0.034<br>(0.734)   | -0.012<br>(0.901) | -0.063<br>(0.523) | -0.008<br>(0.937) | -0.033<br>(0.740) | -0.006<br>(0.953) |
|       | Role function-emotional    | 0.094<br>(0.343)  | 0.133<br>(0.178)                  | 0.045<br>(0.652)  | 0.042<br>(0.671)  | 0.017<br>(0.863)  | 0.017<br>(0.863)  | -0.073<br>(0.462)  | 0.074<br>(0.458)  | -0.061<br>(0.541) | 0.034<br>(0.730)  | 0.096<br>(0.331)  | 0.027<br>(0.788)  |
|       | Mental health              | -0.072<br>(0.466) | -0.126<br>(0.202)                 | -0.002<br>(0.983) | -0.029<br>(0.768) | -0.059<br>(0.554) | -0.059<br>(0.554) | < 0.001<br>(0.996) | -0.082<br>(0.408) | -0.086<br>(0.386) | -0.058<br>(0.558) | -0.081<br>(0.412) | 0.029<br>(0.770)  |

Notes: Data present in a correlation coefficient (*p*-value)

Abbreviations: ThFAQLQ-AF, Thai version of Food Allergy Quality of life Questionnaire - Adult Form; AADR, Allergen avoidance and dietary restrictions; EI, Emotional impact; RAE, Risk of accidental exposure; FAH, Food allergy related health; ThFAIM-AF, Thai version of Food Allergy Independent Measure - Adult Form; EO1, the chance of accidental exposure; EO2, the chance of severe reaction when accidentally exposed; EO3, the chance of dying when accidentally exposed; EO4, the chance of not acting effectively when accidentally exposed; IM1, number of foods to avoid; IM2, the impact of food allergy on social life; SF-36, The 36-Item Short Form Health Survey.

**Table 6. Discriminant validity of the Thai version of FAQLQ-AF and FAIM-AF.**

| Factors   | ThFAQLQ-AF  | ThFAIM-AF  |
|---|---|--|
| Sex   | NS  | NS   |
| Age   | NS  | NS   |
| Anaphylaxis in the previous year                                | NS  | NS   |
| Presence of cutaneous symptoms                                  | NS  | NS   |
| Presence of respiratory symptoms                                | NS  | NS   |
| Presence of gastrointestinal symptoms                           | NS  | NS   |
| Presence of cardiovascular symptoms<br>(Present vs Not present) | <b>Total FAQLQ-AF</b><br>4.69 ± 1.09 vs 4.26 ± 0.96, <i>p</i> = 0.038<br><b>AADR domain</b><br>4.72 ± 1.09 vs 4.01 ± 0.95, <i>p</i> = 0.001 | NS   |
| > 1 food culprit<br>(The number of food culprit = 1 vs > 1)     | NS  | <b>IM2</b><br>3.39 ± 1.60 vs 4.09 ± 1.75, <i>p</i> = 0.035   |
| Wheat allergy<br>(Wheat allergy vs No wheat allergy)            | <b>AADR domain</b><br>4.75 ± 1.13 vs 4.19 ± 1.02, <i>p</i> = 0.034  | <b>IM1</b><br>4.00 ± 1.34 vs 4.74 ± 1.32, <i>p</i> = 0.027   |
| Fruit allergy<br>(Fruits allergy vs No fruit allergy)           | NS  | <b>Total FAIM-AF</b><br>4.44 ± 1.25 vs 3.94 ± 1.17, <i>p</i> = 0.045<br><b>IM2</b><br>4.11 ± 1.78 vs 3.20 ± 1.44, <i>p</i> = 0.007 |
| Shellfish allergy   | NS  | NS   |
| > 1 atopic diseases   | NS  | NS   |
| Confirm diagnosis with oral food challenge                      | NS  | NS   |

**Abbreviations:** ThFAQLQ-AF, Thai version of the Food Allergy Quality of life Questionnaire - Adult Form; AADR, Allergen avoidance and dietary restrictions; ThFAIM-AF, Thai version of the Food Allergy Independent Measure - Adult Form; IM1, number of foods to avoid; IM2, impact of food allergy on social life; NS: not significant either a total score of ThFAQLQ-AF/ThFAIM-AF or individual domains.

## Discussion

The FAQLQ-AF and FAIM-AF were successfully translated into Thai language, cultural adaptation, and had good-excellent reliability and validity. These are the first specific questionnaires for Thai adults with food allergies (age 18 years). The result of test-retest reliability and internal consistency of the ThFAQLQ-AF and ThFAIM-AF was similar to the original,<sup>11,12</sup> and previous studies in Spanish.<sup>18</sup> This supports the utilization and accuracy of both questionnaires as tools for measuring QoL in food-allergic adults, which do not depend on the country.

The SF-36 was the self-answered questionnaire measuring general health-related QoL. The food allergy was episodic in nature, having specific triggers and treatment. This type of burden was poorly measured by generic questionnaires.<sup>19</sup> Our study showed that SF-36 was not correlated with the food allergy-specific questionnaires and had no ability to discriminate any factors of food allergy. Some impacts of food allergy were not stated in SF-36, such as the problem of reading food product labels, selecting foods, or worrying about death due to food allergy. Moreover, SF-36 had more questions than ThFAQLQ-AF and ThFAIM-AF. It was time-saving that may be suitable to use in clinical practice.

In Thai and Spanish FAQLQ-AF validation studies, the domain most affected was food allergy-related health.<sup>18</sup> In contrast, the allergen avoidance and dietary restrictions domain was the domain most affected in the Swedish and original study.<sup>11,20</sup> The difference with among these studies were the different types of food. In the Swedish and original studies, most participants were allergic to peanuts/tree nuts. The participants in Spanish and our study were allergic to fruits. The other factor that may be affected is the characteristics of the validated population. A Danish study used FAQLQ-AF to compare the impact of food allergies between age groups.<sup>21</sup> Twenty-nine adults with severe reactions (Sampson's score at least grade 3) and mainly allergic to peanuts and tree nuts were included. The domain most affected in this study was emotional impact.<sup>21</sup> The affected domain of food-allergic adults measured by FAQLQ-AF was varied and may depend on a region or type of food allergen. The QoL with different food allergens and ethnicity should be further investigated.

The convergent validity and correlation between ThFAQLQ-AF vs. ThFAIM-AF and ThFAQLQ-AF or ThFAIM-AF vs. SF-36 were similar to previous studies.<sup>11,18</sup>

As expected, the specific questionnaires performed better in capturing the impact on QoL in the food-allergic patient than the questionnaire that aimed to evaluate general health status. However, the allergen avoidance and dietary restrictions domain in ThFAQLQ-AF was significantly correlated with general health and social functioning in SF-36. The allergen avoidance and dietary restrictions domain consisted of 11 questions about troublesome behavior that you may have due to your food allergy, such as eating fewer products, having limited products to buy, and being less able to eat out. These actions may affect general health, such as malnutrition in patients who need to avoid multiple foods and limited social participation.

The total ThFAQLQ-AF score could discriminate against patients with severe symptoms identified by the presence of cardiovascular symptoms. This finding is similar to the original and Spanish studies.<sup>11,18</sup> However, participants who experienced anaphylaxis in the previous year did not show significantly different on all questionnaires. It may be because of the most affected systems of anaphylaxis patients in this study were cutaneous and respiratory, not cardiovascular symptoms.

Our study showed that fruit-allergic patients had lower QoL than those who were not allergic to fruits, measured by total ThFAIM-AF and question IM2 (higher score). Since the objective of FAIM-AF generation was to evaluate FAQLQ-AF's constructive validity, no previous studies have explored the discrimination ability of FAIM-AF. The population survey in the United States used FAIM-AF to evaluate the impact of food allergy on patient QoL.<sup>22</sup> A significantly higher total score of FAIM-AF was associated with wheat allergy, soy allergy, milk allergy, history of a severe reaction, history of the epinephrine autoinjector used, emergency visits required for reactions, and multiple food allergies.<sup>22</sup> However, there was no reported fruit allergy in this study.

Compared to non-wheat allergy in our study (primarily fruits allergy), patients with wheat allergy had a significantly higher score in the allergen avoidance and dietary restriction domain in ThFAQLQ-AF but a lower score for question IM1 in ThFAIM-AF. Both are representative of food allergy avoidance, but the allergen avoidance and dietary restrictions domain was more specific and covered more aspects than IM1. The different issue in wheat and non-wheat allergies in Thailand is patient education. Evidence shows that educating patients, such as providing a handbook on allergen avoidance, can improve their QoL.<sup>19</sup> The food labeling and recommendations for avoiding in wheat allergy were more established than fruit allergy, especially tropical fruits. The wheat-allergic patient may have a lower impact on a general question about avoidance because they were educated on what to avoid. The fruit-allergic patient had more impact on social life, demonstrated by the significantly higher score in question IM2.

The strengths of this study are the first Thai version of questionnaires evaluating adult food-allergic patients with confirming reliability and validity, demonstrating their characteristics and quality of life, with a significant sample size. The limitation of this study was the dominant proportion of fruit-allergic patients. Previous studies in adults showed that shellfish allergy or peanuts/tree nuts allergy was the most common.<sup>6,23,24</sup> This may impact the quality of life differently. However, the QoL result is not the primary purpose of this study. All patients in our study have clinical symptoms of an IgE-mediated reaction. The adaptation of both questionnaires to non-IgE mediated food reactions should be cautious and needs further investigation.

In conclusion, this is the first specific questionnaire in the Thai language to evaluate adult food allergies. The ThFAQLQ-AF and ThFAIM-AF were successfully developed and had good-excellent reliability and validity. Both questionnaires are short, easy to use, and more suitable for evaluating specific aspects related to food allergy than the general QoL questionnaires.

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## Conflict of interest declaration

No conflict of interest to declare.

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