Quality of life in asthma and COPD: development of a disease-specific questionnaire

Maillé, A.R.

Citation for published version (APA):
Chapter 4

The Development of The ‘Quality of Life for Respiratory Illness Questionnaire (QoL-RIQ)’: A Disease-Specific Quality of Life Questionnaire for Patients with Mild to Moderate Chronic Non-Specific Lung Disease

A.R. Maillé¹, C.J.M. Koning¹, A.H. Zwinderman², L.N.A. Willems³, J.H. Dijkman³ and A.A. Kaptein¹

1. Medical Psychology, Department of Psychiatry, Leiden University Medical Centre
2. Department of Medical Statistics, Leiden University Medical Centre
3. University Hospital, Leiden University Medical Centre

The Development of the 'Quality of Life for Respiratory Illness Questionnaire'

Summary

Chronic Non-specific Lung Disease (CNSLD), encompasses asthma as well as chronic obstructive pulmonary disease (COPD). Recently there has been increasing awareness in the functional, psychological and social aspects of the health of patients; their quality of life (QoL). Quality of life research addressing CNSLD patients has been rather underdeveloped for quite a long period of time. The importance of quality of life is however increasingly recognised, and several research groups have started to study quality of life in CNSLD in more detail.

This paper describes the construction of a disease-specific quality of life instrument for patients with mild to moderately severe CNSLD. Items relating to several domains of quality of life were listed, and 171 CNSLD patients in general practice were asked how much of a problem each item had been (assessed on a seven point Likert-type scale). After applying an item selection procedure, a uni-dimensional quality of life questionnaire was constructed consisting of 55 items divided into seven domain subscales: breathing problems, physical problems, emotions, situations triggering or enhancing breathing problems, general activities, daily and domestic activities, and social activities, relationships and sexuality. Reliability estimates of the domain subscales of the constructed questionnaire varied from 0.68 to 0.89, and was 0.92 for the Quality of Life for Respiratory Illness Questionnaire (QoL-RIQ) - total scale.

A first impression of the construct validity of the questionnaire was gained by investigating the relationship between the quality of life domain subscales and several indicators of illness severity, as well as the relative contribution of illness severity variables, background characteristics and symptoms to quality of life, using regression analysis. Further research to validate the questionnaire to a greater extent (construct validity, test-retest reliability and responsiveness
to change) is currently taking place.

**Introduction**

Chronic non-specific lung disease (CNSLD) encompasses asthma, chronic bronchitis and emphysema. All three illnesses concern chronic ailments of the airways where the patient has, for a short or long time, suffered from shortness of breath. In general, asthmatic patients only have breathing problems only occasionally and/or over short periods of time, whereas for patients with chronic bronchitis or emphysema [chronic obstructive pulmonary disease – (COPD)] breathing problems are a constant factor.\(^1\)\(^2\) These chronic diseases have a prevalence of 10-20 %. Despite the introduction of new treatment modalities, CNSLD is responsible for a considerable and rising percentage of the morbidity and mortality rates in western countries.\(^3\)\(^4\)\(^5\)\(^6\)\(^7\) Not only is CNSLD a medical-biological problem, it also affects the perceived psychological and social health of patients.

In the past, various studies established that CNSLD has great consequences for the daily functioning of the patient. As well as symptoms such as breathing problems, coughing, allergic reactions etc., which arise directly from the disorder, fatigue, sleeping difficulties, and limitations in physical and daily activities have also been identified as consequences of CNSLD\(^8\)\(^9\)\(^10\)\(^11\). A variety of emotional problems result from CNSLD, such as fear, shame, helplessness, dependence and depression.\(^12\)\(^13\)\(^14\) Chronic non-specific lung disease can also have many effects on relationships and social contacts; social isolation and loneliness are often cited.\(^15\)\(^16\) Most of the studies mentioned above did not have the investigation of the quality of life of the patients as their main objective. They have therefore, frequently examined only parts of daily functioning.\(^17\)

In recent years, it has been increasingly recognised that the evaluation of health care should also include outcomes important to patients, such as quality of
As a result, there has been an increasing awareness of the functional, emotional and social aspects of the health of patients. This has come in addition to the usual regard for conventional relief-giving expedients that slow down the progress of illness or bring physical symptoms under control. Indeed, where decisions about the consequences of medical treatments and care of the chronically ill are concerned, the quality of life of the patient has become an important measure in health care.

Although the term ‘quality of life’ has not been unequivocally defined, it is generally assumed that a good approximation is provided by questionnaires which deal with at least the following areas of daily life: physical and functional status, psychological status and social functioning. With regard to assessing quality of life, a distinction is generally made between 'generic' and 'disease-specific' questionnaires. Generic instruments measure general characteristics and consequences of sickness, and have the advantage of being broadly applicable to people with different disorders. They also make mutual comparisons between individuals or groups with different illnesses possible. However, to take into account the characteristics problems and consequences for daily functioning of specific disorders, disease-specific questionnaires are being used with increasing frequency.

Quality-of-life research on CNSLD has been rather underdeveloped for a long period of time. This subject was considered to be one of the most important areas for future CNSLD research by Dutch medical and behavioural science experts in 1991. At that time, the only questionnaire that existed for research in this area was the Chronic Respiratory Disease Questionnaire of Guyatt et al., developed for patients with chronic bronchitis and emphysema. Prompted by developments in the area of quality of life in health care, and the need for the development of a questionnaire in the Dutch language for CNSLD patients, the present authors decided to develop a disease-specific questionnaire which included functional, psychological and social aspects of the
quality of life of CNSLD patients. In The Netherlands 80% of the diagnosed CNSLD patients are treated by general practitioners (GPs).\textsuperscript{24,25} CNSLD patients in a GP-setting are obviously more troubled in their daily activities than a healthy population;\textsuperscript{25} however, relatively little research has been done into the consequences of mild and moderately severe CNSLD on daily functioning.\textsuperscript{17} Therefore we decided to address patients with asthma and COPD from GP-settings.\textsuperscript{26,27}

In this article the first stage of this project is described; the construction of a disease-specific quality of life questionnaire for patients with asthma or COPD in general practice. The questionnaire itself is presented as well as some of its psychometric qualities.

**Methods**

*Item Selection*

The development of the questionnaire was guided by two principles: (i) the statement of Spilker\textsuperscript{19} that questionnaires on quality of life should in any case include the areas of physical and functional status, psychological status and social functioning, and (ii), the stages in development of quality of life questionnaires as described by Guyatt et al.\textsuperscript{28} Based on a study of the literature, other generic quality of life questionnaires, consultations with people providing medical care for CNSLD patients, and consultations with foreign experts in the area of quality of life and CNSLD (Guyatt and Juniper), a questionnaire was developed with a large number of items. This questionnaire was as broad and as comprehensive as possible, the aim being to reduce and modify it according to the responses from a large number of CNSLD patients. First, to check for completeness and clarity, the formulated items were put to 11 CNSLD patients in a semi-structured interview. From this, items were
supplemented and the questionnaire was modified. To achieve content validity, items were grouped into subscales on the basis of their apparent content. This resulted in a questionnaire containing 221 items on the following topics: breathing problems (14 items); other physical problems related to CNSLD (29 items); situations and/or substances that can trigger or enhance breathing problems (22 items); other problems related to (the treatment of) CNSLD, i.e. financial problems (16 items); emotions relating to breathing problems (47 items); general activities (19 items); daily and domestic activities (19 items); sports, hobbies and leisure pursuits (12 items); social activities (11 items); sexuality and relationships (8 items); profession and work (15 items); and schooling/training (nine items).

**Patient Selection**

For the benefit of the item-reduction phase, 14 GPs in the Western region of The Netherlands, in rural as well as urban settings, selected a total of 219 CNSLD patients in the age-group of 18-65 years. In all cases, the GP was the main provider of care. Patients with diabetes, rheumatic diseases, coronary disease, cancer, psychiatric disorders or other pulmonary disorders were excluded from the study. The protocol of the study was approved by the Ethical Committee of the Medical Faculty of the Leiden University Medical Centre, The Netherlands. The GP contacted the selected patients by letter. One-hundred and seventy-one patients (response rate: 78%) agreed to participate. These patients received the quality-of-life questionnaire, together with the MRC-ECCS-questionnaire for anamnestic data, and a questionnaire for demographic and further illness severity data. Questions regarding illness severity included: dyspnoea grade (MRCQ-score, part of the MRC-ECCS questionnaire); the number of attacks of shortness of breath of breathing problems in the 14 days preceding the investigation; the subjective severity of the breathing problems;
the number of visits from and to the GP in the 6 months preceding the investigation; and the number of days absent from work in the twelve months prior to answering the questionnaire. Assessment of lung function-parameters was not possible in this part of the study, for financial and logistic reasons. Based on data on anamnestic variables and symptoms (i.e. age at onset of illness, chronic cough, chronic wheeze, smoking history, MRCQ score, prescribed medication), patients were identified as 'most probably asthma', 'most probably COPD' or 'diagnosis unclear'.

Concerning the quality of life questionnaire, patients were asked to answer, on a seven-point Likert-type scale\textsuperscript{31} to what degree they had had trouble from the specified symptoms and/or complaints, or to what degree they were impeded by their disorder in carrying out specified activities. In this phase of developing the questionnaire, the authors wanted to identify the broad scope of possible consequences of CNSLD for the quality of life of patients. Therefore the respondents were asked to fill out the questionnaire, reflecting possible consequences of their disease in the 12 months prior to the investigation. For the items in the following categories it was possible to answer 'not applicable' for persons who did not pursue such an activity for reasons other than having too much trouble from breathing problems: general activities; daily and domestic activities; sport, hobbies and leisure pursuits; social activities; sexuality and relationships; profession and work; and schooling/training.

Upon completion, the questionnaire was returned by mail to the research group. The returned questionnaires were checked for completeness, and in the case of missing information, the patient was contacted by telephone.

\textit{Statistics}

Data were analysed using the SPSS-PC\textsuperscript{+} package.\textsuperscript{32} Items of the quality of life questionnaire were selected for the reduced version of the questionnaire as
follows:
1. Items with a ‘not-applicable’ answer-category included in the shortened quality of life - questionnaire, if less than 30% of the respondents answered ‘not applicable’.
2. The inter-item correlations were assessed. If an inter-item correlation was 0.8 or higher the two items were combined, since items which mutually correlate 0.8 or higher give little information or variability in the scale scores.\(^{33}\)
3. Furthermore, for every domain subscale, a factor analysis was performed. Items that loaded on the first two or three factors of each domain subscale were selected for inclusion in the final questionnaire, and again, to assure content-validity, were grouped into domain subscales on the basis of their content.

After item-reduction, Spearman rank (\(r_s\))\(^ {34}\) correlations between the quality of life domain subscales as well as between these domain subscales and demographic variables were assessed. Internal consistency of the quality of life domain subscales and their reliability was calculated.

As the ‘not applicable’ answers for the activities' domain subscales were recoded as missing the reliability of these domain subscale was determined using the split-half method, in which the items were inserted alternately. The reliability of the domain subscales without the ‘not applicable’ category was estimated with the Cronbach's \(\alpha\) coefficient.\(^ {35,36}\)

Spearman rank correlations between the domain subscales and demographic and illness characteristics were calculated. To study possible differences in QoL-scores between men and women as well as between asthma and COPD patients t-tests\(^ {34}\) were used.

Although it was not the ultimate purpose in this phase of the study, the authors
tried to get a first indication of the construct validity of the quality of life domain subscales. Therefore the correlation of the quality of life domain subscales and total score with some illness severity indicators as well as the relative importance of illness severity variables, background characteristics and symptoms in explaining quality of life, was studied using regression analysis. The illness severity indicators were: the MRCQ-score (dyspnoea grade); the number of attacks of shortness of breath or breathing problems in the 14 days preceding the investigation; the subjective severity of the breathing problems; the number of visits from and to the GP in the 6 months preceding the investigation, and the number of days absent from work in the 12 months prior to filling out the questionnaire.

Background characteristics were: gender, age, diagnosis (asthma vs COPD), duration of illness and history of smoking (ever smoked). Symptoms were chronic cough and chronic wheeze [MRC-ECCS$^{30}$].

LISREL analyses (LISREL -IV package)$^{37}$ were used to test the goodness of fit of the correlations between the quality of life domain subscales and the illness severity indicators.

Univariate regression analysis$^{34}$ was used to explain the relative contribution of the illness and background characteristics to total quality of life score.

**Results**

**Patients**

Of the 38 people (22%) that did not respond to the GP’s letter, only gender was known (44% male). Of the 171 mailed questionnaires, 155 were returned of which 9 were unsuitable, due to too many missing data. This reduced the number of suitable questionnaires to 146, which is 67% of the group of patients initially selected for potential participation in the study. Identification of diagnosis was
possible for 130 of these patients; 98 were labelled as ‘most probably having asthma’ and 32 were labelled as ‘most probably having COPD’. For 16 patients the diagnosis was unclear. Background information of the total group of 146 patients and of the asthma and COPD patients separately, is presented in Table 4.1.

<table>
<thead>
<tr>
<th>Background Characteristics</th>
<th>Total (n=146)</th>
<th>Asthma (n=98)</th>
<th>COPD* (n=32)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years (sd)</td>
<td>40.6 (12.2)</td>
<td>34.8 (10.0)</td>
<td>53.5 (6.3)**</td>
</tr>
<tr>
<td>Percentage male (%)</td>
<td>40.4</td>
<td>35.7</td>
<td>56.2</td>
</tr>
<tr>
<td>Duration of illness in years (sd)</td>
<td>14.1 (13.3)</td>
<td>15.0 (13.4)</td>
<td>10.7(12.5)</td>
</tr>
<tr>
<td>(Ex)smokers (%)</td>
<td>65.1</td>
<td>53.1</td>
<td>90.6 ***</td>
</tr>
<tr>
<td>Visits to GP last 12 Months (sd)</td>
<td>3.7 (4.6)</td>
<td>3.2 (3.2)</td>
<td>6.1 (7.9)**</td>
</tr>
<tr>
<td>Visits to pulmonary physician last 12 months (sd)</td>
<td>0.3 (.7)</td>
<td>0.3 (.6)</td>
<td>0.6 (.8)*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Current medication</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Any pulmonary medicine (%)</td>
<td>95.2</td>
<td>96.2</td>
<td>96.9</td>
</tr>
<tr>
<td>Inhalation steroids (%)</td>
<td>51.4</td>
<td>48.9</td>
<td>62.5 ***</td>
</tr>
<tr>
<td>B2-agonists (%)</td>
<td>46.6</td>
<td>41.8</td>
<td>75.0 ***</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Symptoms</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic cough (%)</td>
<td>29.5</td>
<td>19.4</td>
<td>59.4 ***</td>
</tr>
<tr>
<td>Ever wheezing (%)</td>
<td>26.7</td>
<td>26.5</td>
<td>37.5</td>
</tr>
<tr>
<td>Degree of dyspnoea (MRCQ: 1 - 5 (sd)</td>
<td>2.5 (1.4)</td>
<td>2.3 (1.3)</td>
<td>3.4 (1.5)***</td>
</tr>
<tr>
<td>Degree of dyspnoea &gt; 2(%)</td>
<td>33.8</td>
<td>23.5</td>
<td>65.6 ***</td>
</tr>
</tbody>
</table>

*note that of n = 16 the diagnosis asthma or COPD was unclear. p ≤ 0.05; ** p < 0.01; *** p<0.000

The mean age of the patient group was almost 41 years; COPD patients were significantly older that asthma patients. Forty percent of the study population
were male; the COPD group consisted of significantly more males than the asthma group. Almost all the patients (95%) in the study used pulmonary medication, and about half the patients used inhalation steroids. β2-agonists were used by slightly less than half the patients (47%); this medication was prescribed to significantly more COPD patients than asthmatic patients (75% vs. 42%).

Symptoms of chronic cough and wheeze were apparent in more than 25% of the total patient group; significant more COPD patients than asthma patients (60% vs. 19%) reported complaints of chronic cough. The degree of dyspnoea was also significantly higher in COPD patients than in asthma patients (3.4 vs. 2.3); the mean degree of dyspnoea for the total patient group was 2.5, reflecting a mild to moderate degree of dyspnoea. One-third of the patient group reported a degree of dyspnoea higher than two. In the group of COPD patients two-thirds of the patients had a degree of dyspnoea higher than two, whereas in the group of asthma patients less than one-quarter of the patients had this grade of dyspnoea.

**Item reduction**

The first two steps of the selection procedure described above (not more than 30% scores of ‘non-applicability’ for items with this answer category, and inter-item correlations of 0.80 or more) resulted in a substantial reduction in items, (a 44 item reduction in Step 1; 18 items transformed into nine in Step 2). The domain subscales ‘schooling/training’ and ‘other problems related to the treatment of the disease’ were applicable to only a minority of the respondents. From the subscale ‘profession and work’ only some general statements (i.e. being able to do one’s daily activities) were applicable to the majority of the respondents. The domain subscales ‘general activities’ and ‘domestic and daily activities’ were put together, as well as the domain subscales ‘social activities’
and 'relationships and sexuality'. The third step, factor-analysis per domain subscale, selecting the items loading on the first two or three factors resulted in a further reduction of the number of items. With this three-step selection procedure the questionnaire was reduced from 221 to 55 items, with seven domain subscales (see Appendix at the end of this chapter).

Spearman-rank correlations between the domain subscales are presented in Table 4.2. The quality of life domain subscales correlated with correlation coefficients \( r_s \) ranging from 0.39 to 0.68. The correlations between the domain subscales on the one hand and the QoL-RIQ - total score ranged from 0.69 to 0.84. All correlations were significant at \( p < 0.000 \).

<table>
<thead>
<tr>
<th>Quality of Life in Respiratory Illness Questionnaire</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Breathing Problems</td>
<td>1.0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B. Physical Problems</td>
<td>.68</td>
<td>1.0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C. Emotions</td>
<td>.55</td>
<td>.63</td>
<td>1.0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>D. Situations Triggering or Enhancing Breathing Problems</td>
<td>.44</td>
<td>.55</td>
<td>.49</td>
<td>1.0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E. General Activities</td>
<td>.40</td>
<td>.55</td>
<td>.49</td>
<td>.39</td>
<td>1.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F. Daily and Domestic Activities</td>
<td>.51</td>
<td>.67</td>
<td>.54</td>
<td>.49</td>
<td>.64</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>G. Social Activities, Relationships and Sexuality</td>
<td>.39</td>
<td>.48</td>
<td>.56</td>
<td>.51</td>
<td>.48</td>
<td>.60</td>
<td>1.0</td>
</tr>
<tr>
<td>H. QOL-RIQ - total score</td>
<td>.71</td>
<td>.84</td>
<td>.76</td>
<td>.74</td>
<td>.69</td>
<td>.81</td>
<td>.70</td>
</tr>
</tbody>
</table>

All correlations significant at \( p < 0.000 \)

From Maximum Likelihood factor analysis on the 55-items of these seven domain subscales, only one factor with an eigenvalue greater than 1 appeared. This factor explained 55% of the variance \( (\chi^2 = 26, \text{df}=14, p<0.05) \). So, the seven
quality of life domain subscales share a general quality of life factor. The Spearman-rank correlation between the QoL-RIQ total score and age was 0.09 (p=0.33). The correlations between the domain subscales and age ranged from -0.10 to 0.26 and were significant for ‘general activities’ (r_s=0.18; p=0.04) and for ‘daily and domestic activities’ (r_s=0.26; p=0.001), reflecting more problems on this aspects of daily life for elderly patients.

There was no difference in the QoL-RIQ total score between asthmatic and COPD patients. However, COPD patients indicated significantly more problems in the domain subscale ‘daily and domestic activities’ {asthma: 2.4 [mean(M)], 1.1 [standard deviation (sd)], 2.1 [median (Md)]; COPD: 2.9 (M), 1.3 (sd), Md 2.6; t=-2.47 p=0.02}. This might be explained partly by the intercorrelation between the diagnosis 'COPD' and age. Univariate regression analysis with the ranked score of ‘daily and domestic activities’ as dependent and age and diagnosis as independents shows that ‘age’ explains 6.9% of the variance (p=0.002) in this activity domain, whereas ‘diagnosis’ explains 4.6% (p=0.2). There were no differences between the scores for men and women, except in the category ‘situations and/or substances which trigger or enhance breathing problems’. Here, women scored higher than men [women: 3.45 (M), 1.31 (sd.); men: 3.00 (M), 1.23 (sd.); t=-2.09, p=0.04].

Reliability

Split-half reliabilities as well as Cronbach’s alpha’s of the domain subscales and the QoL-RIQ - total scale are depicted in Table 4.3. Split-half reliabilities were calculated for all domain subscales and the QoL-RIQ total scale, inserting the items alternately. They vary from 0.68 to 0.89 for domain subscales; the split-half reliability for the QoL-RIQ-total scale is 0.92. Cronbach’s α coefficients could only be calculated for the three domain subscales without the 'not applicable' answer category, and vary form 0.84 to 0.88.
Table 4.3  Domain subscales, number of items, and reliability per subscale

<table>
<thead>
<tr>
<th>Subscale</th>
<th>Number of items</th>
<th>Split-half reliability</th>
<th>Cronbach's alpha</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breathing Problems</td>
<td>9</td>
<td>.85</td>
<td>.85</td>
</tr>
<tr>
<td>Physical Problems</td>
<td>9</td>
<td>.85</td>
<td>.84</td>
</tr>
<tr>
<td>Emotions</td>
<td>9</td>
<td>.84</td>
<td>.88</td>
</tr>
<tr>
<td>Situations Triggering or Enhancing Breathing Problems</td>
<td>7</td>
<td>.68</td>
<td>-</td>
</tr>
<tr>
<td>Daily and Domestic Activities</td>
<td>10</td>
<td>.86</td>
<td>-</td>
</tr>
<tr>
<td>Social Activities, Relationships and Sexuality</td>
<td>7</td>
<td>.89</td>
<td>-</td>
</tr>
<tr>
<td>General Activities</td>
<td>4</td>
<td>.75</td>
<td>-</td>
</tr>
<tr>
<td>QOL-RIQ - total score</td>
<td>55</td>
<td>.92</td>
<td>-</td>
</tr>
</tbody>
</table>

*items inserted alternately

**Construct validity: preliminary results**

Although construct validity of the questionnaire is currently being studied in a separate part of this project, it was attempted to get a first indication of this important requirement of newly developed questionnaires.

The correlations of the seven quality of life domain subscales with the illness severity indicators were determined using Spearman-rank coefficients. The correlation coefficient between all quality of life domain subscales and the combination of illness severity indicators was calculated, and the relative contribution of several illness severity variables, background characteristics and symptoms to the QoL-RIQ total score was studied.

The correlations between the illness severity indicators and the domain
subscales ranged from $r = 0.23$ to $r = 0.48$ (see Table 4.4). The lowest correlation was between 'frequency of attacks' and the subscale-domain 'social activities, relationships and sexuality' whereas the highest correlations were between 'visits to the GP' and the subscale domains 'breathing problems' and 'daily and domestic activities'. The QoL-RIQ total score correlated with the illness severity indicators, with $r$ ranging from 0.45 to 0.49. The MRCQ score as well as the subjective severity of the breathing problems, had the highest correlation with the quality of life score. All correlations were significant, most of them at the $p < 0.000$ level.

**Table 4.4** Spearman Rank correlations ($r$) of the quality of life domain subscales.

<table>
<thead>
<tr>
<th>Illness severity indicators</th>
<th>Degree of dyspnoea MRCQ</th>
<th>Frequency of attacks</th>
<th>Subjective severity</th>
<th>Visits to GP</th>
<th>Absence from work</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality of life domain subscales</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breathing Problems</td>
<td>0.34</td>
<td>0.32</td>
<td>0.34</td>
<td>0.48</td>
<td>0.40</td>
</tr>
<tr>
<td>Physical Problems</td>
<td>0.41</td>
<td>0.39</td>
<td>0.41</td>
<td>0.40</td>
<td>0.41</td>
</tr>
<tr>
<td>Emotions</td>
<td>0.33</td>
<td>0.30</td>
<td>0.33</td>
<td>0.34</td>
<td>0.40</td>
</tr>
<tr>
<td>Situations Triggering or Enhancing Breathing Problems</td>
<td>0.41</td>
<td>0.33</td>
<td>0.41</td>
<td>0.27*</td>
<td>0.32*</td>
</tr>
<tr>
<td>General Activities</td>
<td>0.40</td>
<td>0.31</td>
<td>0.40</td>
<td>0.26*</td>
<td>0.31*</td>
</tr>
<tr>
<td>Daily and Domestic Activities</td>
<td>0.40</td>
<td>0.35</td>
<td>0.40</td>
<td>0.48</td>
<td>0.29*</td>
</tr>
<tr>
<td>Social Activities, Relationships and Sexuality</td>
<td>0.30</td>
<td>0.23*</td>
<td>0.30</td>
<td>0.43</td>
<td>0.31*</td>
</tr>
<tr>
<td>QoL-RIQ total-score</td>
<td>0.49</td>
<td>0.45</td>
<td>0.49</td>
<td>0.47</td>
<td>0.46</td>
</tr>
</tbody>
</table>

* *significant at $p < 0.01$; all other correlations significant at $p < 0.0001$

A canonical correlation coefficient of 0.65 was found between the combination of all quality of life domain subscales (the general quality of life), and the combination of all illness severity indicators. The correlation between the
quality of life domain subscales and the illness severity indicators was also estimated with a structural equality model (Figure 4.1). The correlation between the combined component of the quality of life domain subscales and that of the illness severity indicators is 0.92. This is the correlation between the combined set of the QoL-RIQ domain subscales and the combined set of illness severity indicators, but attenuated for the unreliability of all seven quality of life domain subscales and the illness severity indicators.

Next, to get an idea of the relative contribution of several variables to quality of life univariate regression analysis was used with the QoL-RIQ total score as dependent variable. Data on illness severity, background characteristics and symptoms were used as independent variables. The results of this analysis are presented in Table 4.5. The independent variables are grouped in these three categories, and listed in order of relative contribution to the total quality of life
score. From Table 4.5 it can be concluded that illness severity variables, and especially the more subjective variable 'severity of breathing problems', explain the highest proportion of the variance in the quality of life score (with p<0.000); subjective severity of breathing problems explains about 25% of the variance in quality of life.

Table 4.5  Univariate Regression analysis with ranked QoL-RIQ total score as dependent

<table>
<thead>
<tr>
<th>Independent variables</th>
<th>QoL-RIQ total score</th>
<th>explained variance (%)</th>
<th>significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>illness severity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- subjective severity of attacks</td>
<td>25.3</td>
<td>.000</td>
<td></td>
</tr>
<tr>
<td>- grade of dyspnoea (MRCQ-score)</td>
<td>17.5</td>
<td>.000</td>
<td></td>
</tr>
<tr>
<td>- absence from work</td>
<td>16.5</td>
<td>.000</td>
<td></td>
</tr>
<tr>
<td>- frequency of attacks</td>
<td>12.8</td>
<td>.000</td>
<td></td>
</tr>
<tr>
<td>- visits to GP</td>
<td>10.3</td>
<td>.000</td>
<td></td>
</tr>
<tr>
<td>background-characteristics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- gender</td>
<td>1.7</td>
<td>ns</td>
<td></td>
</tr>
<tr>
<td>- diagnose (asthma vs. COPD)</td>
<td>1.3</td>
<td>ns</td>
<td></td>
</tr>
<tr>
<td>- age</td>
<td>0.9</td>
<td>ns</td>
<td></td>
</tr>
<tr>
<td>symptoms*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- chronic wheeze</td>
<td>9.8</td>
<td>.000</td>
<td></td>
</tr>
<tr>
<td>- chronic cough</td>
<td>7.9</td>
<td>.001</td>
<td></td>
</tr>
<tr>
<td>- ever smoked</td>
<td>0.9</td>
<td>ns</td>
<td></td>
</tr>
<tr>
<td>- duration of illness</td>
<td>0.5</td>
<td>ns</td>
<td></td>
</tr>
</tbody>
</table>

* diagnosis is based on part of these symptoms

The contribution of the MRCQ score is also quite substantial; 17.5% of variance in quality of life score is explained by grade of dyspnoea. The contribution of the other illness severity variables is somewhat less proportional -absence from work, 17%; frequency of attacks, c. 13%; visits to GP, c. 10% - but still higher than the contribution of background characteristics and symptoms. The influence of background characteristics like age, gender and
diagnosis is negligible (ranging form 0.9 to 1.7%, not significant). Of the 'symptoms', chronic wheeze and chronic cough explain almost 10 and 8%, respectively, of the quality of life score. Smoking history as well as duration of illness do not contribute to the QoL-RIQ total score.

**Discussion and conclusions**

Through this investigation, a disease-specific quality of life questionnaire for mild to moderately severe asthma or COPD patients (the QoL-RIQ) has been developed, which contains 55 items, in seven areas of daily life. The internal reliability of the total questionnaire as well as of its domain subscales is quite satisfactory. The seven domain subscales address a broad scope of aspects of daily functioning which can be limited due to chronic respiratory illness. They also represent the three areas of daily life that should always be included in quality of life questionnaires: physical and functional status, psychological status and social functioning. The QoL-RIQ total score was not correlated with age, nor was there a difference between asthma or COPD patients. This indicates that the questionnaire can be used for both these patient groups, as well as for different age groups. Prudence is called for in some domain subscale scores; in particular the 'daily and domestic activities' seems to reflect more problems concerning elderly than younger patients. The domain subscale 'situations triggering or enhancing breathing problems' seems to reflect more problems in women than in men. This will be studied in more extent in the next phase of the project. The preliminary results on the construct-validity show significant correlations between quality of life and several illness severity variables. Most of these illness severity data are rather subjective, reflecting patients' experiences. A more objective illness severity variable is the MRCQ score, reflecting the degree of dyspnoea, based on activities patients are able or unable to perform.
Both the MRCQ score and the subjective severity of breathing problems showed the strongest correlation with the QoL-RIQ total score. Results of regression analysis also showed the importance of these two variables in contributing to the QoL-RIQ-total score. The more or less subjective illness severity variables were the most profound predictors of the quality of life score. Symptoms such as chronic cough and wheeze explained only small parts of the total quality of life score. Background characteristics (age, gender, diagnosis, smoking history, duration of illness) did not contribute significantly to the quality of life score. It appears that the illness severity indicators used, mainly reflect the subjective experiences of the severity of the illness. However, it has to be noted that this needs to be studied in more detail in the second phase of the study, in which the validity of the questionnaire will be tested.

Quality-of-life research in asthma and COPD patients has been a somewhat underdeveloped area for a long period of time. Recently, however, several research groups have started to study this topic in more detail. As a result, several disease-specific questionnaires assessing quality of life have been developed, most of them in the nineties, and have already been reviewed in detail.17,23,38,39

Currently six questionnaires are available in English which measure the disease-specific quality of life in asthma or COPD patients.8,33,40,41,42,43,44,45,46 Basically, it may be concluded that definitions of quality of life are mostly lacking, which seems to be a consequence of the absence of a straightforward theory of quality of life.17,23,39 Due to this some questionnaires contain only a limited number of areas of daily life which can be influenced by the disorder.8,45 The ‘Living with Asthma Questionnaire’40,41 and the ‘Asthma Quality-of-Life Questionnaire’46 are two measures which illuminate the physical and functional state as well as the psychological and social functioning of the patient. The ‘Life Activities Questionnaire for Adult Asthma’ (LAQAA)44 is not defined by the authors as a quality of life scale in itself, but can be used as a component of a battery of
quality-of-life instruments. However, it concerns activities in seven categories of daily life, which can be restricted or changed due to asthma. It seems that most of these questionnaires are meant for moderate to severe asthmatic and/or COPD patients. In developing the ‘Living With Asthma Questionnaire’, Hyland addressed patients in general practice settings, probably reflecting mild to moderate illness severity. The questionnaire seems to be focusing on asthmatic patients only.

The construction of domain subscales in the QoL-RIQ, is in accordance with the way most quality of life questionnaires are constructed, to achieve content validity. The fact that different questionnaires have different kinds and different numbers of subscales is a reflection of the different concepts of quality of life that authors have.

The uni-dimensionality of the Qol-RIQ reflects the general underlying quality of life factor which is shared by the domain subscales. This is in accordance with the results of Hyland, who also developed a uni-dimensional quality of life questionnaire for asthma patients, which consisted of 11 domain subscales.

It has to be mentioned that the quality of life questionnaire and the illness severity questions reflected different periods of time: in this scale-construction phase the quality of life questions covered a period of twelve months, whereas questions on illness severity covered periods of two weeks, three months, or twelve months. Caution is called for when drawing conclusions based on these results.

In general, lung function parameters are regarded as the most objective instruments to assess illness severity in asthma and COPD patients. In literature, some studies do show correlations between quality of life and physiological measures; however, others do not at all. If present, the correlations are, in general, not strong. It seems that relationships between quality of life in respiratory illness and spirometry are stronger when the quality of life questionnaire mainly (or sometimes only) assesses the physical component of
daily functioning. In general, lung function-parameters do not influence quality of life, indicating that this is something different than a straightforward reflection of 'objective' disease severity.

The questionnaire developed in this study is, in its present form, meant for asthmatic patients as well as people with COPD in general practice, reflecting mild to moderate disease severity. It covers a broad range of aspects from daily life, which is necessary for a quality of life questionnaire. Apart from research purposes, it may be used in clinical practice for diagnosis and for examination. At the moment, the validity of the developed questionnaire is being examined further, including the responsiveness to change and the test-retest reliability. The relationship of quality of life with individuals' characteristics and illness severity -including spirometry- is also being studied, and its reliability and applicability in outpatient and rehabilitation populations is being tested.

Acknowledgements

This study was supported by the Dutch Asthma Foundation (nr. 90.37). The authors wish to thank Glaxo Welcome b.v., The Netherlands, and M. Moyses for their help in translating the manuscript into English.

References

5. Gregg I. The importance of asthma to the general practitioner. The Practitioner 1987; 231: 471-477.


APPENDIX: Items of the Quality of Life for Respiratory Illness Questionnaire (QOL-RIQ)

Breathing problems
- difficulty breathing in
- wheezing
- heavy breathing
- chest tightness or shortness of breath
- an itchy throat
- the need to clear your throat frequently
- coughing
- recurrent colds
- a stuffed up nose

Situation that might trigger or enhance breathing problems
- being in air conditioned buildings
- being outside on cold days
- being outside on foggy days
- being outside on humid days
- being outside during the pollen season
- due to domestic animals or pets
- by flowers, trees, plants

Physical problems related to chest problems
- sleeping limbs
- pins and needles
- feeling your heart is racing
- tiredness
- exhaustion
- waking up in the morning with breathing symptoms
- the need to rest frequently during the day
- waking up in the night or early in the morning because of breathing problems
- poor appetite

Daily activities
- going upstairs
- running a short distance
- cycling
- lifting a heavy object
- going to the toilet
- taking a bath/shower and/or getting dressed
- washing yourself
- polishing
- looking after the family
- shopping

Emotions related to chest problems
- worried about my breathing problems
- puzzled about my breathing problems
- concerned about the future consequences of my breathing problems
- down in the dumps, depressed
- restless, nervous
- short-tempered, impatient with others
- moody
- feeling dependent upon others
- upset by too much sympathy of others

Social activities, relationships and sexuality
- going out for a day-trip
- going to (birthday) parties
- visiting friends and relatives
- having difficulties with cuddling and kissing
- having no sexual desire due to chest problems
- having difficulties with sexual intercourse due to chest problems
- being too tired to have sexual intercourse due to chest problems

Problems with general activities
- being unable to do one’s daily activities
- problems with 'getting started' in the morning because of chest problems
- less pleasure in one's daily activities due to chest problems
- problems with doing hobby’s