Comparison of three generic questionnaires measuring quality of life in adolescents and adults with cystic fibrosis: The 36-item short form health survey, the quality of life profile for chronic diseases, and the questions on life satisfaction

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Abstract

Objective: To compare different generic instruments in measuring quality of life and to demonstrate dimensions of quality of life (QL) in patients with cystic fibrosis (CF). *Methods*: The short-form-36 health survey (SF-36), the quality of life profile for chronic diseases (PLC), and the questions on life satisfaction (FLZ^M) were simultaneously employed in a cross-sectional study with 70 adolescents and adults with CF. The different concepts of the measures were compared. Internal consistency (Cronbach's α), convergent and construct validity (correlation patterns, common factor analysis), and external validity (correlations with symptom and pulmonary function scores, with intensity of therapy; comparisons with healthy peers) of the three instruments were investigated. *Results*: Similar reliability, but different validity of the questionnaires are demonstrated. Seventy-three percent of the total variance across the three measures could be explained with a seven-factor-solution: (1) physical functioning (19.3% of total variance), (2) mental health (19.3%), (3) social integration (7.5%), (4) role function/pain (7.5%), (5) economic/material living conditions (7.5%), (6) partnership/family (6.7%) and (7) anxiety (5.2%). *Discussion*: The different validity of the instruments has to be considered in chosing a questionnaire appropriate to the purpose of measuring. Shortcomings of each instrument can be overcome by multimethod designs and by developing disease-specific scales.

Key words: Adolescents and adults, Cystic fibrosis, Generic questionnaires, Measurement effects, Quality of life

Introduction

Cystic fibrosis (CF) is the most frequent hereditary disease in the Caucasian race. It is not curable, but recent progress in medical treatment has prolonged life expectancy into adulthood. The median survival rate is about 32 years [1]. Due to this progress, quality of life (QL) has become a key parameter in evaluating therapy for adolescent and adult patients with CF. It is recommended to assess QL as an additional outcome parameter in therapy studies as well as in planning therapy individually.

Measuring QL in the case of CF is an emerging field of research. It is not clear what should be measured under the umbrella of the global construct QL. Studies focusing on QL in patients with CF have demonstrated uncomparable results and contradictory findings [2–5]. The well-accepted definition of QL as a multidimensional construct integrating physical, psychological, social and functional aspects of subjective health [6] is lacking a theoretic foundation. It is possible to measure QL by many different ways. According to the multi dimensionality of the construct, most of the instruments consist of multiple items or scales, which have to be composed to a QL-profile. If QL is studied in patient populations, the focus on subjective health is indicated by the term 'health-

related quality of life' (HRQL). HRQL is defined as 'physical, emotional, mental, social and behavioral components of well-being and functioning as perceived by the patient or by observers' [7]. Most authors prefer to obtain the patient's self-perception by self-reporting questionnaires. Some HRQL-instruments tend to assess more objective aspects of health (for example: 'How many blocks have you been able to walk?'), other instruments assess satisfaction with specific aspects of daily life (for example: 'How satisfied are you with your present mobility?'). The percentage of items targeting on physical, psychological, social or functional aspects of health and the time frame in question differs among the instruments.

Obviously there is no agreement on a homogenous way of measuring QL, neither generally nor in case of specific chronic diseases. It is not clear, which aspects of the construct have specific relevance for a CF-population. Therefore, it is necessary to compare different methods and discuss their specific properties and limitations. Most of the instruments that have been applied in the case of CF are generic ones. If comparisons between patients with different diseases or with healthy populations are intended, generic instruments are needed. Disease specific instruments for CF have been developed recently or are still under development [8–12].

To study measurement effects on QL-results in the case of CF and to evaluate psychometric properties of different generic questionnaires we have compared the results of three instruments in the same sample of adolescent and adult CF-patients in a cross-sectional design. Another purpose of our study was the extraction of secondary dimensions of QL, in order to define a disease-appropriate QL-pattern. We chose three generic questionnaires with a different scope of items and different ways of measuring. These instruments represent different approaches in measuring QL, although they all address the patient herself/himself with her/his subjective perception.

Methods

Sample

Seventy adolescents and adults with CF from five outpatient clinics in southern Germany partici-

pated in the study. The patients were between 16 and 38 years of age (mean 25.5 years). 54% of the participants were female, 47% lived in a partnership, 50% lived together with their parents. Twenty-seven percent had a common education of 9 years (German *Hauptschule*), 73% had a secondary education (more than 9 years) or were still in school. Most of the patients had been diagnosed in early childhood (median 2.5 years, range 0–33 years). The median forced expiratory volume in one second (FEV1, a measure of pulmonary function) was 56% of predicted (range 22–106%), the median body mass index (BMI) was 19.8 (13–26). Eighty-one percent of the patients were colonized with *Pseudomonas aeruginosa*. On average subjects received one to two courses of IV antibiotics per year. The mean daily time for doing home therapies was 1.5 hours and ranged between 0 and 4.5 hours.

In one of the five outpatient clinics (Ulm), 94.4% of the patients in the target group aged >15 years participated, therefore this subgroup (n = 34) can be considered as representative for the German CF-population which is mainly treated in specialized outpatient clinics. Although no significant differences appeared in sociodemographic and health statistics between the Ulm subgroup and the remaining sample, selection effects (for example the motivation to answer the questionnaires) might have distorted the QL-results in the total sample. Therefore we decided to use the Ulm subgroup for comparisons with healthy peers.

Instruments

The short form 36 health survey (SF-36) was used in its German version [13]. This widespread multidimensional instrument measures HRQL in its functional, mainly physical and psychological, aspects in clinical and healthy populations. It allows comparisons to normative data of multiple German reference groups. The SF-36 produces eight scores on multi-item-scales: Physical functioning, physical role functioning, bodily pain, general health perception, vitality, social functioning, emotional role functioning and mental health. Most of the scales have been demonstrated as internally consistent in different patient and healthy populations (Cronbach's $\alpha > 0.70$).

The quality of life profile for chronic diseases (PLC) is a multidimensional German questionnaire focusing on psychosocial aspects of living with a chronic disease [14]. Forty items are grouped to six functional or symptom scales: Capacity, positive mood, negative mood, ability to relax and enjoy, sense of belonging to others, and contact ability. Each item is a question that has to be answered on a 5-point-rating scale (0–4). High internal consistency ($\alpha > 0.75$) and medium retest-reliablility (0.50–0.80) have been demonstrated for the scales in different clinical populations. According to the authors, the PLC should be complemented by disease specific symptom scales, which are not part of the instrument itself.

The questions on life satisfaction (FLZ^M) is a multidimensional questionnaire, which allows the respondent to weight her/his subjective importance in relation to her/his satisfaction with each of 16 dimensions [15, 16]. The questionnaire was administered in German. Eight general dimensions of life satisfaction are measured: Friends/acquaintances, leisure time/hobbies, general health, income/financial security, occupation/work, housing/living conditions, family life/children and partner relationship/sexuality. Eight dimensions are health-related: Physical condition/fitness, ability to relax, energy/zest for life, mobility, vision and hearing, freedom from anxiety, freedom from aches and pain, and independence from help/care. In the first step, the subjective importance of each dimension has to be rated by the respondent on scales between 0 (not at all important) and 4 (very important). In the second step, the present satisfaction on each of these dimensions has to be rated, again on 0–4 scales. The 16 scores are calculated by the formula *weighted satisfaction = importance rating × [(2 × satisfaction rating) − 3]*. Two sum scores can be computed by addition of the eight health-related and the eight general weighted scores and linear transformation to 0–100 scales. Internal consistency (Cronbach's α) of the two total scales has been demonstrated to be 0.82 and 0.89.

Table 1 reviews the general principles, construction, scoring procedures and range of scores assessed by the three instruments.

Additionally, the patients filled out disease-specific symptom lists for pulmonary symptoms (eight items), gastrointestinal symptoms (two items), and weight problems (one item). These symptom scales were taken from the German translation of the cystic fibrosis questionnaire CFQ [9]. The patients rated the severity or intensity of their symptoms on 4-point Likert-scales, ranging from 1 to 4. The scores on each of the three symptom scales were computed by addition of the raw scores with low scores indicating severe symptoms and high scores indicating absence of symptoms. The forced expiratory volume in one second (FEV1%) as an objective measure for present pulmonary function was taken from the patients' medical records. We chose the latest FEV1% available for each patient. Pulmonary function is usually tested several times a year as a routine procedure, independently from the health status. Therefore the maximum time frame between FEV1% and QL-measurement was about 3 months.

Procedure

Descriptive statistics indicating score distributions (mean, SD, percent of minimum and maximum scores, range) and reliability of the scales (Cronbach's α, item–scale correlations (ISC)) were computed for the total sample of 70 patients. To facilitate comparisons between the scales of different instruments, the PLC-scores and the weighted FLZ-scores were linearly transformed by the formula $[(x_i - x_{min}) : (x_{max} - x_{min})] \times 100$ to scales ranging from 0 to 100, with 100 points indicating optimal QL.

Spearman rank intercorrelations between the scales of the different instruments were computed to investigate convergence or specificity of the questionnaires. External validity was tested by Spearman correlations between the QL-scores and three disease-specific symptom scores (self-assessed by the patients), and with more objective measures as pulmonary function, BMI, daily time for home therapy, and number of recent IV courses.

Another procedure of testing validity of the three instruments consisted of comparisons between our study group and healthy peers. We used means and SDs of the subgroup with 34 patients nearly representing the total sample of one outpatient clinic. The sample was divided into two age groups (16–25 and 26–38 years) in order to relate the results of the study group to age-appropriate normative data. Means and SDs of German reference

Table 1. Comparison of general principles, construction, scoring procedures, and range of scores assessed by the three instruments

	SF-36	PLC	FLZ^M
Target population	General healthy population and general patient population	Patients with chronic diseases (not life threatening)	General healthy and patient population
Theory or context of the instrument development	– subjective health (medical outcome study) – behavioral and functional orientation – focus on physical and mental health	– health related QL (subjective health) – Integration of well-being and capacity – integration of physical, psychological and social domains	– subjective QL as dynamic construct – Overall and health related QL
Time period	Current: 15 items Past 4 weeks: 20 items Compared to last year: one item	Past 7 days	Past 4 weeks
Scales and items	Eight multi-item scales: – Six functional scales – Two symptom scales One change in health item	Six multi-item scales (one symptom scale, not included)	Two multi-item modules (importance × satisfaction) – Eight areas of life (general life satisfaction) – Eight dimensions of health satisfaction One general QL question
Scoring procedures	1. Linear transformation 2. Average of transformed scores. These scores are unweighted domain scores	Raw score calculation: Average of the items that contribute to the scale. These scores are unweighted domain scores	1. Weighted calculation of importance and satisfaction scores for each domain (wS = importance rating × [(2 × satisfaction rating) − 3]) 2. Linear transformation of the sum of weighted scores for each module so that sum scores range between 0–100. wS are aggregated weighted scores. 3. General QL item is linearly transformed to a 0–100 scale.
Ranges of scores	The score range is 0–100. High scores represent high QL (i.e. high functional status of absence of symptoms)	The score range is 0–4. High scores represent high QL (high functional status or absence of symptoms)	wS for each domain range between −12 and +20. Sum scores range between 0 and 100. High scores represent high satisfaction.

groups, which were published by the authors of the questionnaires [13, 15, 17], were utilized. *T*-tests for separate samples were computed.

To extract secondary dimensions across the three questionnaires, a common principal components factor analysis was computed, based on the correlation matrix of the 29 QL-scales. The cut-off for extraction of factors was defined at an eigen-value of >1. A varimax rotation was performed to increase discrimination between factors.

The statistics were performed by the program package SYSTAT 8.0®. It was decided, that missing values, which occurred in less than 1%, should be calculated by use of mean substitution.

Results

Score distributions and internal consistencies

Table 2 demonstrates descriptive statistics of the three instruments, based on the results of the total study group (n = 70). The SF-36 and the health-related items of the FLZ produce a lot of ceiling effects. This effect is extreme on the SF-36-scale emotional role functioning with 81.4% maximum scorers.

For all of the scales with the exception of the SF-36-scale emotional role functioning, an internal consistency of >0.70 is indicated by Cronbach's α. The ISC of the FLZ varied between 0.48 and 0.68 in the general life satisfaction module, and between 0.50 and 0.78 in the health-related satisfaction module.

Validity

Interscale correlations

Figure 1 demonstrates the convergence of the three instruments based on scale intercorrelations. Only coefficients >0.50 are considered (Spearman rank correlation coefficients between the scales of the different instruments can be studied in detail in the appendix).

Most of the common variance of the SF-36 and PLC is indicated by the number of correlation coefficients >0.50 for the scales SF-36-vitality and PLC-capacity. The SF-36-scales bodily pain and emotional role functioning are not well represented in the PLC; on the other hand the PLC-scale sense of belonging to others is not well represented in the SF-36.

Most of the common variance between the SF-36 and the FLZ is contained in the SF-36-scale vitality and the FLZ-sum score satisfaction with health. Again the SF-36-scale emotional role functioning seems to be the most specific one, whereas the general life satisfaction dimensions of the FLZ with the exception of the dimension leisure time/hobbies are not well represented in the SF-36.

PLC and FLZ have the least common variance. Only the FLZ-sum score satisfaction with health is represented in several PLC-scales. Some medium correlations between similar scales of the PLC and the FLZ (PLC-capacity and FLZ-physical condition/fitness $r = 0.51$, PLC-ability to relax and enjoy and FLZ-ability to relax $r = 0.51$) indicate more separate than common variance. The PLC-scales negative mood and contact ability are not well represented in the FLZ, and vice versa 14 of the 19 FLZ-scales considered have no correlation >0.50 with any of the PLC-scales.

Correlations with disease specific parameters

Table 3 shows correlations between the QL-instruments with three symptom scores (pulmonary, gastrointestinal and weight problems), with one objective measure for pulmonary function (FEV1%), and with two parameters indicating intensity of therapy (length of time for daily therapy, number of IV courses in the past year). QL-scales measuring physical functioning should correlate significantly with the symptom parameters and with FEV1%. Some medium correlations between QL-scores and symptom scores respectively FEV1% can be demonstrated. As expected, the highest correlations occur between pulmonary symptoms/function and physical-functioning scales. Gastrointestinal symptoms are significantly correlated with the SF-36-pain-scale (but not with the FLZ-pain-scale). No significant correlations between QL and BMI were found. Self-reported symptoms are significantly correlated with some psychosocial QL-scales as PLC-positive mood, PLC-ability to relax, PLC-contact ability and FLZ-independence from help and care. The intensity of therapy is negatively correlated with some scales measuring general health perception and physical functioning.

Comparisons with healthy peers

The comparisons with normative data of healthy peers for the adolescent group (16–25 years) are demonstrated in Figure 2. Only scales with significant mean differences between the CF-group and the healthy reference group are included in the figure. The SF-36 indicates a poorer QL of the adolescent patients on all dimensions with the exception of the scale emotional role functioning, compared to healthy adolescents, whereas the QL of our CF-group is on the same level compared with healthy peers in all of the six PLC-scales. The general life satisfaction as measured with the FLZ is significantly less on the dimensions leisure time/

Table 2. Features of score distributions (linear transformation to uniform scales ranging between 0 and 100) of the SF-36, PLC, and FLZ^M, internal consistency (Cronbach's α) of SF-36, PLC and FLZ-modules resp. ISC for FLZ-items with FLZ-sum score (n = 70)

	Mean	SD	max (%)	min (%)	Range	α	ISC
SF–36							
Physical functioning	79.5	22.6	18.6	0	20–100	0.93	
Physical role functioning	67.5	37.7	47.1	14.3	0–100	0.84	
Pain	78.5	26.3	47.1	2.9	0–100	0.92	
General health	44.1	22.3	2.9	2.9	0–100	0.78	
Vitality	56.0	18.5	1.4	0	10–100	0.85	
Social functioning	80.7	23.0	47.1	1.4	0–100	0.88	
Emotional role functioning	90.5	22.8	81.4	2.9	0–100	0.69	
Mental health	71.4	16.2	2.9	0	32–100	0.81	
PLC							
Capacity	64.6	21.6	4.3	0	15.6–100	0.93	
Positive mood	58.4	18.0	2.9	0	20–100	0.85	
Negative mood	74.7	16.7	2.9	0	31.3–100	0.86	
Ability to relax and enjoy	71.1	15.8	2.9	0	28.1–100	0.85	
Sense of belonging to others	77.1	17.1	11.4	0	35–100	0.72	
Contact ability	68.1	18.6	2.9	0	8.3–100	0.85	
FLZ^M							
General life satisfaction	58.0	14.0	0	0	31.6–96.1	0.72	
Friends/acquaintances	67.1	23.5	17.1	1.4	0–100		0.54
Leisure time/hobbies	53.7	21.1	7.1	0	9.4–100		0.68
General health	53.5	27.0	11.4	7.1	0–100		0.60
Income/financial security	53.3	21.8	4.3	2.9	0–100		0.63
Occupation/work	55.7	22.7	7.1	0	9.4–100		0.53
Housing/living conditions	64.7	21.5	10.0	1.4	0–100		0.65
Family life/children	56.7	23.3	12.9	0	9.4–100		0.59
Partner relationship/sexuality	59.2	29.7	22.9	5.7	0–100		0.48
Satisfaction with health	64.7	14.0	1.4	0	32.4–100	0.77	
Physical condition/fitness	53.2	25.1	10.0	2.9	0–100		0.66
Ability to relax	51.8	16.4	1.4	0	9.4–100		0.50
Energy/zest for life	62.9	25.0	18.6	1.4	0–100		0.69
Mobility	71.4	22.7	27.1	1.4	0–100		0.70
Freedom of anxiety	62.4	21.4	11.4	1.4	0–100		0.55
Freedom from aches and pain	63.3	26.0	15.7	2.9	0–100		0.78
Independence from help/care	80.3	22.2	45.7	0	25–100		0.69
General QL	69.3	20.0	11.4	1.4	0–100		

hobbies, general health and partner relationship/sexuality. The adolescents' satisfaction with their health is lower compared with healthy peers on the FLZ-dimensions physical condition/fitness, ability to relax, energy, and freedom from aches and pain, whereas adolescents with CF are significantly more satisfied with their independence from help/care than their healthy peers.

The results for the age-group 26–38 years are demonstrated in Figure 3. Again our study group is scoring significantly lower on all of the SF-36-scales with the exception of emotional role functioning, compared with the reference group of healthy peers. The extent of the mean differences is highest on the scales physical function, physical

role functioning, general health perception, and social role functioning. Only on two of the six PLC-scales (capacity, contact ability) did the adult CF-patients score significantly lower than their healthy peers. There are no significant differences on the general life satisfaction dimensions of the FLZ with exception of the general health scale. On the four specific health-related FLZ-dimensions: Physical condition/fitness, ability to relax, energy and freedom from aches and pain, adults with CF are scoring significantly lower than their healthy peers.

Factor analysis
Our last step of data analysis consisted of a common factor analysis on the correlation matrix of
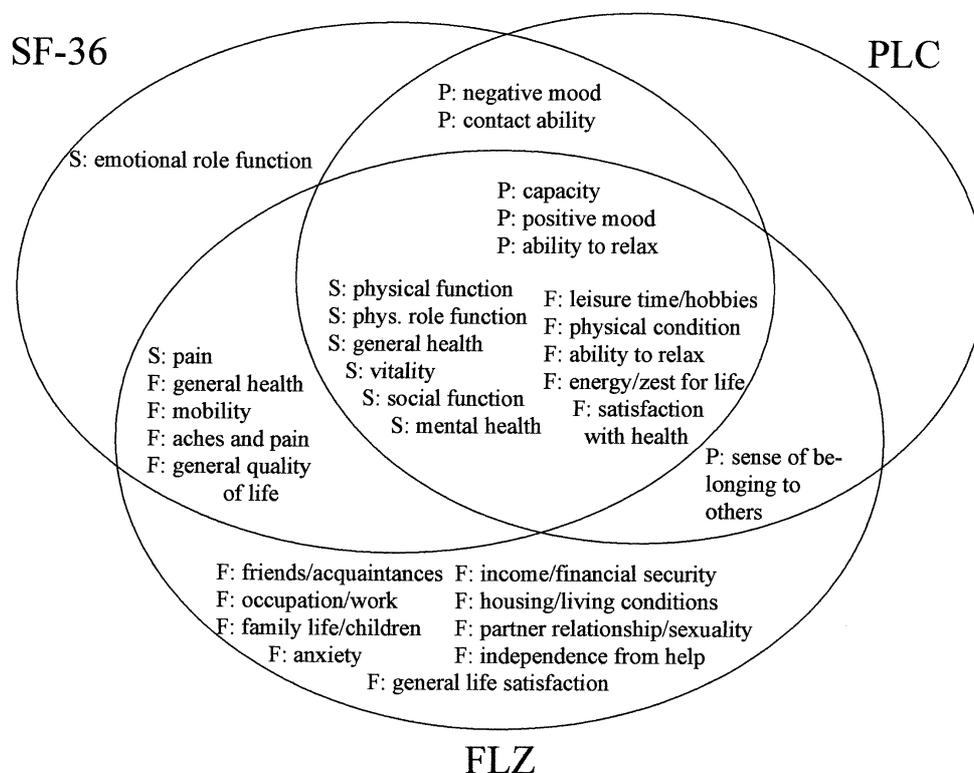
Figure 1. Convergence of SF-36, PLC and FLZ^M (scales appearing in the overlapping sectors indicate correlations $\geqslant 0.50$ with one or more scales of the complementary questionnaire, i.e. the scales in the middle section correlate with similar scales in both other instruments).

29×29 QL-scales. A seven-factor-solution resulted, representing 73% of the total variance. Table 4 shows the loadings of each scale/item on the seven factors after varimax rotation. All loadings $\geqslant 0.50$ or the highest loading in any of the seven factors are considered. The factors can be interpreted as follows (in parenthesis explanation of the percent of total variance):

– I. Physical functioning (19.31%): Condition, fitness, capacity, vitality, mobility, independence from help/care, general health perception, pain.
– II. Mental health/psychosocial functioning (19.30%): Ability to relax and enjoy, positive and negative mood, contact ability, mental health, sense of belonging to others, social role functioning, vitality, capacity.
– III. Social integration (7.52%): Friends/acquaintances, energy/zest for life, sense of belonging to others.

– IV. Role functioning/pain (7.54%): Physical and emotional role functioning, pain.
– V. Economic/material living conditions (7.5%): Income/financial security, housing/living conditions, occupation/work, leisure time/hobbies.
– VI. Partner/family relations (6.7%): Partner relationship/sexuality, family life/children.
– VII. Anxiety (5.15%): Freedom from anxiety.

Discussion

Three generic instruments (SF-36, PLC, FLZ^M) measuring HRQL or satisfaction with life were compared in this paper with regard to their performance in a sample of adolescent and adult patients with CF.

The qualitative comparison of the three questionnaires reveals different ways of measuring QL.

Table 3. QL measures and disease specific symptoms respectively intensity of therapy (Spearman rank correlations, only correlations ⩾0.40 are included, n = 70)

	Absence of pulmonary symtoms	Absence of gastro-intestinal symptoms	Absence of weight problems	Daily time for home therapy	Number of recent IV courses	Pulmonary function (FEV1%)*
SF-36						
Physical functioning	0.65			−0.42	−0.54	0.71
Physical role functioning	0.51					
Pain		0.57	0.44			
General health perception	0.53					0.58
Vitality	0.46					0.42
PLC						
Capacity	0.66			−0.42		0.50
Positive mood	0.44					
Ability to relax and enjoy	0.41		0.42			
Contact ability	0.44					
FLZ-health related						
Physical condition/ fitness	0.49			−0.45	−0.53	0.66
Mobility			0.46			
Freedom of aches and pain						0.47
Independence from help/care						0.42
Satisfaction with health (sum score)			0.42	−0.41		0.48

*Forced expiratory volume in one second in % of the predicted.

The SF-36 has been developed as a survey instrument [18], most of its items focus on physical and functional health. The PLC has been developed for the target population of patients with mild to severe, but not directly life-threatening chronic diseases. It integrates aspects of well-being and functioning, most of its items focus on psychosocial health. The FLZ^M differs considerably from the two other questionnaires. It has not been developed according to the principles of classical test theory, and it focuses the subjectivity of the respondent by offering ratings of subjective importance and satisfaction with each of eight general and eight health-related aspects of life. Weighting of satisfaction scores by subjective importance is the main principle of the FLZ. Another purpose of the FLZ is the integration of general life satisfaction and satisfaction with health in two modules. The time frame for answering the questions differs between the instruments from present time to 4 weeks. Therefore different sensitivity for short-term changes in QL can be expected.

The feature of score distributions and the high number of maximum (= optimal) scorings reveal that CF-patients score in the upper section of all but two of the SF-36-scales. It seems as if mild restrictions of health cannot be detected by the SF-36. The discriminative ability of the SF-36-scale emotional role functioning is questionable because of a ceiling effect. In the PLC, patients with CF score in the upper medium section of the scales. Variance between individuals is smaller in the PLC compared with the other questionnaires. Most of the FLZ-scores are distributed in the medium section of the scales. This phenomenon can be explained as an effect of the scoring procedure. Only a combination of both high subjective importance and high subjective satisfaction can lead to high scores. It has to be considered that the FLZ is conceptually sensitive for coping strategies
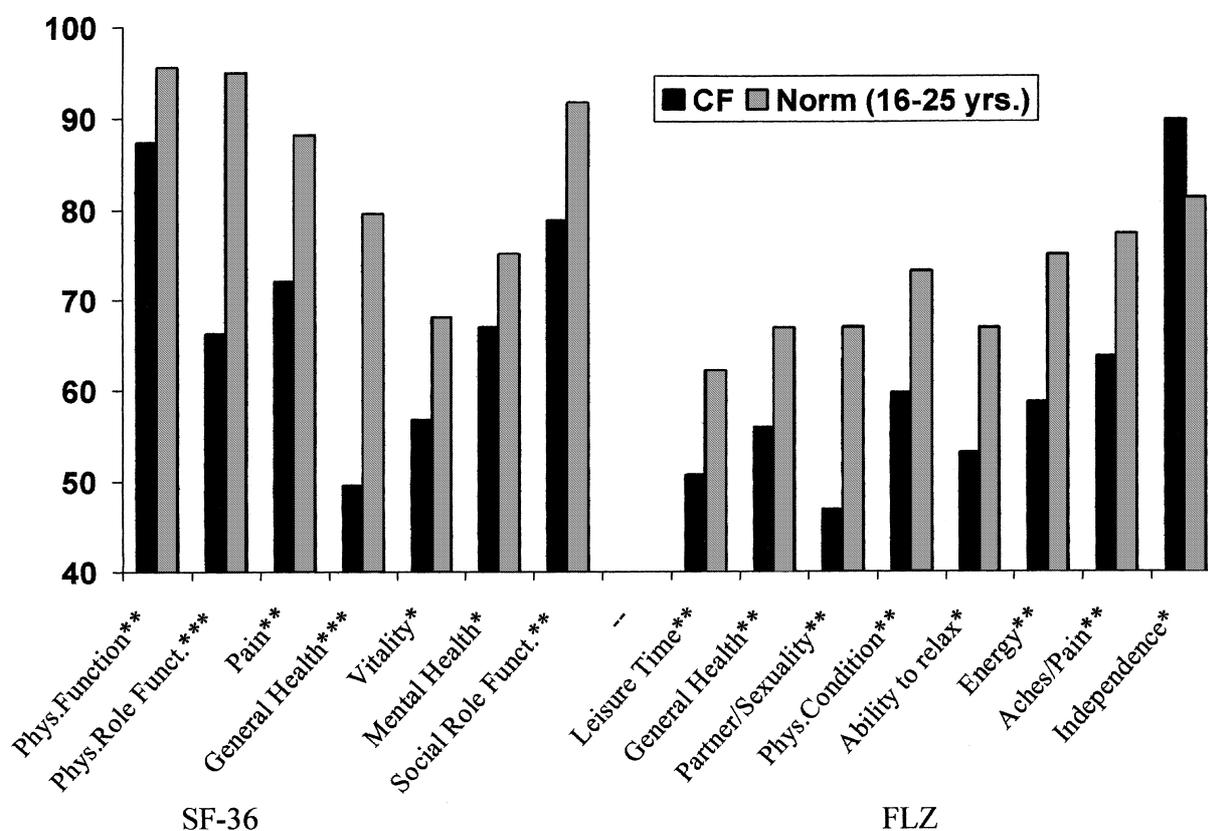
Figure 2. Differences between adolescents with CF and healthy peers (age range 16–25 years; n = 17; significant mean differences [*T*-test]: *p ⩽ 0.05, **p ⩽ 0.01, ***p ⩽ 0.001).

such as cognitive restructuring. CF-patients could tend to decrease their subjective importance of domains with lower performance and protect themselves from harmful dissonances in their health perception. Strong effects of coping strategies on QL-scores have been demonstrated [3, 19]. In this context, it is interesting to notice the higher health-related life satisfaction of patients with CF compared with their general life satisfaction in the FLZ sum scores.

Internal consistency was demonstrated as sufficient (Cronbach's α > 0.70) for most of the QL-scales. Intercorrelations between the scales from different questionnaires indicate convergence of those scales which are expected to measure similar domains. Considering all possible inter-questionnaire scale intercorrelations, it is obvious that the three instruments are only partially overlapping. Each questionnaire covers a specific scope of the total construct QL and differentiates specific do-

mains. The SF-36-scale vitality is differentiated by five PLC-scales, respectively six FLZ-scales. The social dimension is poorly represented in the SF-36. The validity of the SF-36-scale social functioning is questionable, because this scale correlates higher with physical and psychological scales of the PLC and FLZ than with corresponding social scales. On the other hand, the SF-36 is able to differentiate the capacity-scale of the PLC and the physical functioning/fitness scale of the FLZ. As expected, the general life satisfaction domain of the FLZ is poorly represented in the SF-36 and in the PLC, which are both designed to measure health-related QL. Another FLZ-scale, freedom from anxiety, is not covered by the other two questionnaires. The PLC seems to be at least independent from the other two questionnaires. In summary, it could be demonstrated that the SF-36 is performing best in the physical domain, whereas the PLC is performing best in the psychosocial
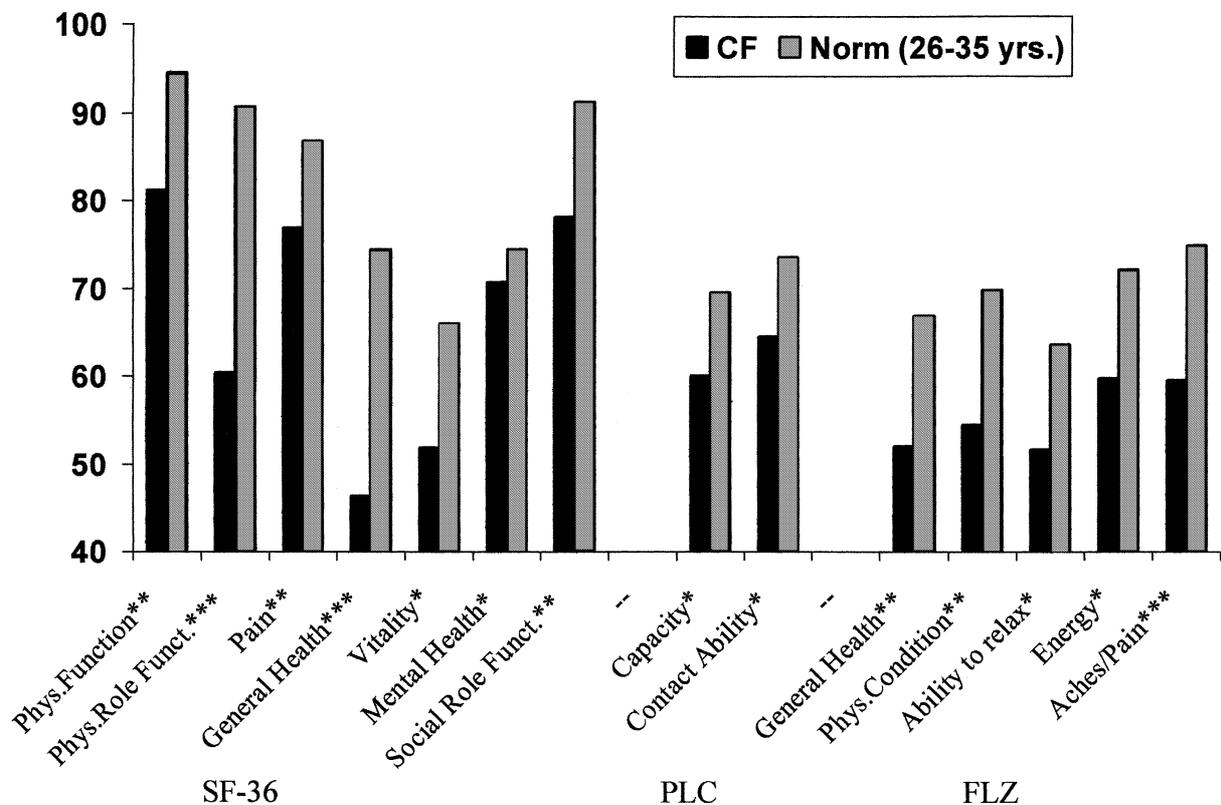
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Figure 3. Differences between adults with CF and healthy peers (age range 36–38 years; n = 17; significant mean differences [T-test]: $^*p \leqslant 0.05$, $^{**}p \leqslant 0.01$, $^{***}p \leqslant 0.001$).

domain. The FLZ is the most comprehensive of the three questionnaires investigated. It is covering the widest scope of physical, psychological and social domains, integrating HRQL and general life satisfaction.

The correlational statistics between QL, self-reported symptoms, objective pulmonary function, and intensity of therapy, demonstrate some external validity of the physical QL-scales. As expected, the correlations between pulmonary symptoms/FEV1% and those QL-scales measuring physical functioning are the most striking ones. The maximum level of these correlations are in the medium range (0.40–0.71) and indicate that the objective and the subjective perspectives on health are overlapping. About 50% of the variance of the pulmonary function (FEV1%) can be explained by the physical functioning score of the SF-36 and vice versa. All of the three questionnaires contain scales which correlate sig-

nificantly with symptom scores or pulmonary function parameters. On the other hand, it could be demonstrated, that several QL-measures especially in the psychosocial domains do not correlate with objective health.

The QL-scales differ in their ability to discriminate between CF-patients and healthy peers. Most of the significant mean differences are demonstrated as expected in physical functioning and general health scores. The extent of these mean differences is varying between the questionnaires. The mean differences between CF-patients and healthy peers are greater in SF-36 scores of physical functioning, whereas they seem to be smaller or even totally absent in the PLC-scores. The ability of the SF-36 to discriminate adults with CF from healthy peers has been reported before [20, 21]. Generally the SF-36 and the satisfaction with health module of the FLZ are able to demonstrate disease specific restrictions in quality of life,

Table 4. Common factor analysis (n = 70) across the scales of the SF-36, the PLC, and the FLZ^M (factor loadings > 0.50 or highest loading after varimax rotation are indicated)

Factor number	I	II	III	IV	V	VI	VII
% of common variance explained	19.31	19.30	7.52	7.54	7.48	6.68	5.15
SF-36 physical functioning	0.82						
FLZ physical condition/ fitness	0.81						
general health	0.80						
SF-36 general health perception	0.74						
FLZ mobility	0.65						
PLC capacity	0.64	0.58					
	0.61						
FLZ independence from help/care							
freedom from aches/pain	0.61						
SF-36 vitality	0.58	0.57					
PLC ability to relax and enjoy		0.86					
negative mood		0.79					
positive mood		0.77					
contact ability		0.74					
SF-36 mental health		0.70					
FLZ ability to relax		0.67					
PLC sense of belonging to others		0.51	0.50				
FLZ friends/acquaintances			0.83				
energy/zest for life			0.58				
SF-36 emotional role functioning				0.79			
physical role functioning				0.61			
pain				0.57			
FLZ income/financial security					0.74		
housing/living conditions					0.67		
occupation/work					0.57		
partner relationship/ sexuality						0.81	
family life/children						0.66	
freedom from anxiety							0.70
leisure time/hobbies					0.41		
SF-36 social functioning		0.48					

whereas the PLC measures primary psychosocial functioning of CF-patients on a comparable level than in a healthy population.

The results of the factor analysis in this study support the multidimensionality of the construct QL for a CF-population. About 40% of the total variance is represented by the two main factors, physical functioning and mental health/psychosocial functioning. The physical and emotional role functioning and bodily pain domains of the SF-36 could be summarized as specific factor with much common variance. According to the factor structure in our sample, it is suggested to differentiate the social dimension for CF-patients into an extra-family and an intra-family/partner-dimension. It should be discussed, if the patient's satisfaction with their socio-economical life circumstances has to be integrated in a comprehensive view of QL. A

specific independent dimension of HRQL in case of CF seems to be represented by the FLZ-anxiety-scale. The poor long term prognosis of CF and the fear of suffering in the terminal phase of the disease could be the basis for the relevance of this psychological factor, which is not well represented in the general mental health/psychosocial functioning factor.

Some limitations of our study have to be considered: We did not collect longitudinal data, and the time frame for measuring subjective health and objective pulmonary function has not been sufficiently standardized. Therefore, the sensitivity of the questionnaires for changes in the individual health status could not be investigated. Changes in the course of the disease, especially pulmonary exacerbations, seem to have a greater impact on QL than FEV1% or other more normative measures of disease severity [22]. Further studies should include more patients and longitudinal designs, for example pre-post lung transplantation or pre-post IV antibiotics.

Conclusions

Our study demonstrates comparable reliability, but different validity of the three generic instruments applied to an adolescent and adult CF-population. Before measuring QL in CF, it has to be decided which of the different QL-concepts is appropriate for the specific purpose of the investigator. It has to be decided how narrow or comprehensive HRQL should be measured. Validity of psychometric instruments can only partially be founded on convergence with objective health parameters and on discriminative ability against a healthy population. The results of our study confirm, that the patients' perception of their HRQL is not merely a function of their objective health status. In measuring QL, the patient herself/himself should refer to her/his subjective view on her/his life. In this context, the face validity of any instrument, which can be derived from the way of questioning, should be considered as important criterion for the quality of the measure.

QL is a useful construct to integrate the patient's view into clinical practice and into the evaluation of new therapy strategies. Regarding the measurement effects that have been demonstrated, further discussion of different approaches in measuring the QL of patients with CF is needed. The ongoing development of disease specific instruments and scales will increase the variety of methods. A multimethod assessment of QL, for example a combination of generic and disease-specific modules, can be proposed as the most comprehensive solution for patients with CF. If a short instrument is needed for economic and practical reasons, it should contain those domains which have empirically been described as secondary dimensions in our factor analysis.

Acknowledgement

Appendix

Spearman scale intercorrelations between SF-36, PLC and FLZ[M]
a) SF-36 and PLC

SF-36 and PLC	Physical function	Physical role-function	Bodily pain	Perceived general health	Vitality	Social function	Emotional role function	Mental health
Capacity	0.78	0.64	0.36	0.65	0.74	0.52	0.39	0.50
Pos. mood	0.48	0.47	0.32	0.49	0.70	0.54	0.18	0.53
Neg. mood	0.39	0.46	0.30	0.36	0.61	0.54	0.34	0.67
Relax/enjoy	0.41	0.43	0.36	0.34	0.66	0.55	0.29	0.63
Social integr.	0.00	0.12	0.16	0.09	0.39	0.40	0.11	0.41
Contact	0.47	0.46	0.22	0.37	0.68	0.46	0.23	0.48

b) SF-36 and FLZ^M

SF-36 and FLZ^M	Physical function	Physical role-function	Bodily pain	Perceived general health	Vitality	Social function	Emotional role function	Mental health
Friends	0.12	0.07	0.26	0.15	0.36	0.21	0.01	0.23
Leisure time	0.40	0.25	0.36	0.42	0.54	0.34	0.32	0.44
General health	0.57	0.48	0.36	0.68	0.55	0.45	0.07	0.36
Income	0.24	0.22	0.24	0.14	0.15	0.17	0.17	0.07
Occupation	0.07	0.18	0.14	0.09	0.10	0.10	0.09	0.09
Housing	0.19	0.10	0.23	0.18	0.21	0.27	0.21	0.28
Family life	0.00	0.04	0.15	0.06	0.04	0.27	0.09	0.14
Partner/sexuality	−0.04	0.01	0.13	0.03	0.12	0.30	0.18	0.34
Phys. condition	0.68	0.43	0.21	0.61	0.51	0.33	-0.02	0.21
Ability to relax	0.14	0.24	0.25	0.26	0.35	0.50	0.15	0.51
Energy	0.24	0.35	0.42	0.29	0.56	0.39	0.26	0.46
Mobility	0.52	0.52	0.41	0.37	0.53	0.31	0.11	0.17
Vision/hearing	0.08	−0.18	−0.06	−0.02	−0.05	0.02	−0.02	0.00
Anxiety	0.13	0.23	0.19	0.24	0.29	0.18	0.12	0.29
Aches and pain	0.44	0.37	0.56	0.40	0.51	0.48	0.15	0.22
Independence	0.48	0.29	0.38	0.35	0.42	0.33	−0.01	0.18
Perc. general QL	0.28	0.43	0.43	0.36	0.49	0.42	0.20	0.56
General life satisfaction	0.36	0.32	0.40	0.36	0.46	0.44	0.23	0.41
Satisfaction with health	0.56	0.50	0.50	0.50	0.66	0.53	0.16	0.41

c) PLC and FLZ^M

PLC and FLZ^M	Capacity	Positive mood	Negative mood	Ability to relax and enjoy	Social integration	Contact ability
Friends	0.17	0.16	0.21	0.18	0.40	0.25
Leisure time	0.50	0.34	0.40	0.41	0.38	0.39
General health	0.49	0.47	0.31	0.32	0.05	0.29
Income	0.20	0.05	0.08	0.12	0.13	−0.03
Occupation	0.00	−0.04	0.06	−0.14	0.05	−0.11
Housing	0.20	0.25	0.25	0.22	0.25	0.11
Family life	0.00	0.05	0.07	0.04	0.45	0.13
Partner/sexuality	0.07	0.00	0.08	0.17	0.39	0.17
Phys. condition	0.51	0.35	0.28	0.25	0.14	0.31
Ability to relax	0.30	0.48	0.46	0.51	0.42	0.35
Energy	0.33	0.37	0.48	0.43	0.52	0.37
Mobility	0.45	0.39	0.30	0.31	0.23	0.25
Vision/hearing	−0.04	0.00	−0.12	−0.12	0.03	0.01
Anxiety	0.26	0.39	0.39	0.38	0.32	0.28
Aches and pain	0.46	0.48	0.30	0.46	0.25	0.37
Independence	0.36	0.26	0.16	0.27	0.14	0.33
Perc. general QL	0.40	0.42	0.45	0.47	0.22	0.32
General life satisfaction	0.37	0.27	0.31	0.29	0.47	0.29
Satisfaction with health	0.56	0.56	0.48	0.52	0.40	0.48

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