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Monitoring quality of life in outpatients with cystic fibrosis: Feasibility and longitudinal results ☆

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Abstract

Background: To investigate the feasibility of monitoring quality of life (QL) with cystic fibrosis (CF) in a clinical setting, to explore changes in subjective health and to describe the impact of multiple medical and psychosocial factors on the patients' QL.
Methods: 108 adolescent and adult outpatients (age 15–47years, FEV_1 20–125% of the predicted) answered the Questions on Life Satisfaction repeatedly parallel to each pulmonary function test (2–16 assessments per patient within 18 months). Multiple regression analysis determined the contribution of medical and psychosocial factors to the patients' QL.
Results: Good acceptance of the instrument was observed. The completion time was between 5 and 29 min per assessment (median 11 min). QL remained quite stable (r_{tt}=.69) with the previous QL score predicting most of the variance of the present score. Additionally, a longer interval between assessments, new colonization with *Pseudomonas aeruginosa*, infection exacerbations, partnership, vocation and living separately from parents significantly predicted QL at the second assessment. Pulmonary function varied independently of QL.
Conclusions: Medical factors such as pulmonary exacerbation and social living circumstances have an impact on the QL of patients with CF. Repeated QL assessments in clinical routine are feasible and useful to recognize the individual patient's adaptation to the disease.

Keywords: Adolescents and adults; Cystic fibrosis; Life satisfaction; Longitudinal assessment; Psychosocial aspects; Quality of life

1. Introduction

Although quality of life (QL) is considered increasingly important in chronic conditions, there is a lack of prospective longitudinal studies and clinical trials involving QL with cystic fibrosis (CF) [2–4]. Therefore, the knowledge of changes in patients' subjective health and its determinants is limited. So far, monitoring QL in clinical practice is mostly done routinely by the "How are you?" question. The use of standardized psychometric instruments is still limited, although several disease-specific instruments have been developed over the past ten years [5–9]. Lack of staff trained in applied psychometrics and limited practicability of these instruments may be responsible for the abstinence from structured routine assessment of QL in clinical practice.

With regard to its definition as a multi-dimensional measure integrating self-reported physical, emotional and social functioning and well-being [10], QL is a dynamic psychological construct, which describes the subjective health perception of the patients independently of objective health parameters [11]. QL scores reflect the impact of disease-related stressors and other life stressors in relation to the psychological adaptation of the individual [12]. Patients may maintain good QL in spite of being seriously ill, and other patients may report a bad QL although they have a mild manifestation of the disease [13,14].

There is an ongoing discussion on the best way of measuring QL in CF [9,15,28]. Some questionnaires such as the

Abbreviations: ANOVAR, repeated measures analysis of variance; BMI, body mass index; CF, cystic fibrosis; FEV_1, forced expiratory volume in one second; FLZ^M, Questions on Life Satisfaction; FLZ^M-CF, Questions on Life Satisfaction, disease-specific module for CF; QL, quality of life.

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disease-specific Cystic Fibrosis Questionnaire CFQ [8] or the generic SF-36 [6] assess primarily the patients' perceptions of their functional health. The Questions on Life Satisfaction (FLZ^M) have been proposed as a reliable and valid instrument to reflect the subjective perspective of the patient by considering the importance and satisfaction ratings by the individual for different life domains [7]. So far, the FLZ^M has been used in a study with CF patients evaluating the effectiveness of inpatient rehabilitation programmes [16], but the feasibility of the FLZ in an outpatient setting has not yet been demonstrated. Therefore a purpose of the present study is to demonstrate the feasibility of repeated QL assessments in clinical routine. Feasibility in clinical routine is dependent on the practicability of the instrument, for example by its shortness, its costs, and its easiness of data collection and analysis. We assessed feasibility by observing the acceptance of repeated assessments by patients and professionals, by the proportion of missing data, and by measuring the time needed to fill in the instrument.

Another area of interest is the identification of factors impacting on patients' QL with CF. Multiple factors have been analysed, but the findings are only partially consistent. The following aspects have been reported to correlate with QL in CF patients: socio-demographic factors such as age [17,18] and gender [9,18–21]; cultural background [22]; disease factors such as pulmonary function [5,7,14,17,20,21,23–25], infection [19,26,27], body mass index [5,20,28], or concurrent medical conditions [26]; treatment factors such as intra-venous [29] or inhalative therapy with antibiotic drugs [25,30], recombinant human DNase [17], hospital admission [17,27], heart and lung transplantation [21,31], daily time for therapy [32], and the number of different medications [26]; and psychosocial factors such as work status [33], coping with the disease [12], psychopathology, hope for the future and family functioning [34]. However, most of the findings are based on cross-sectional studies and cannot estimate determinants of changes in QL. Only few prospective longitudinal studies with QL as the primary variable have been done so far. Based on multiple regression analysis, Bradley et al. [29] reported that changes in exercise capacity and sputum output contributed significantly to changes in QL. With the same method, Johnson et al. [17] found that only previous scores of QL and the number of hospital admissions showed a substantial quantitative association with QL. In another longitudinal QL study, Kotwicki et al. [26] found that changes in QL were associated with changes in the number of respiratory infections, changes in the number of concurrent medical conditions, and changes in different medications. Vermeulen et al. [31] showed improvements in QL after heart lung transplantation, and in a study of the course of QL during pulmonary exacerbations Yi et al. [27] reported that hospitalization was associated with an improvement in psychosocial QL by the post-exacerbation assessment.

Most of the QL research with CF patients is based on cross-sectional clinical studies with selected samples of participants. It is not clear whether these results can be generalized to the average CF population. The only community-based longitudinal survey study by Sawyer et al. [35,36] followed up 123 children and adolescents with CF for two years and found a stagnation of QL as measured by the Child Health Questionnaire. However, to our knowledge a clinic-based naturalistic approach to measuring QL in CF has never been done. Therefore the purpose of the present study was to include a non-selective sample of typical patients attending outpatient CF clinics in Germany and follow them up by repeated QL assessments. In accordance with the previous findings in the literature, this study explores multiple determinants of QL with CF and investigates intra-individual changes of QL in a naturalistic design of outpatient treatment. The following explorative research questions are addressed:

1. How stable is quality of life with CF under naturalistic conditions of outpatient treatment? In which domains of QL is there a higher or lower extent of intra-individual change?
2. Which factors out of a broad range of psychosocial, socio-demographic, medical and treatment factors have a significant impact on QL with CF? Are changes in health condition as a decrease in pulmonary function or pulmonary exacerbations correlated with changes in QL, and to what extent is QL determined by different factors?

2. Methods

2.1. Study design

The study took place in four German outpatient CF centres. All patients with a minimum age of 15 years were asked to participate. Informed consent of adult patients and of legal guardians of adolescent patients, and informed assent of adolescents themselves were acquired according to the guidelines of the local medical committee. In a prospective longitudinal approach, QL was assessed repeatedly parallel to each pulmonary function test during the observational period of 18 months. Forced expiratory volume in one second as a percentage of the predicted value (FEV_1%), body mass index (BMI), infection parameters, antibiotic i.v. therapy within the four weeks prior to assessment, socio-demographic data and psychosocial living circumstances such as partnership status, vocation and housing were recorded at each QL assessment. The interval between the assessments depended on the standards of routine monitoring of pulmonary function (1–4 times per year), on the patients' compliance with these standards, or on specific clinical indications, for example in the case of pulmonary exacerbation. Therefore the interval between the assessments varied from 1 to 405 days with a median of 86 and a standard deviation of 66 days.

2.2. Participants

148 patients were enrolled in the study with a total of 460 assessments. All patients were Caucasians. 108 patients were