

Recommendations for the Assessment of Quality of Life in Dermatology*

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Key Words

Guidelines · Quality of Life

Summary

Quality of Life (QOL) should be considered in dermatological therapy studies as an additional target criterion with somatic and possibly economic parameters.

QOL is recorded in several dimensions. This is possible with simple and relatively methodologically reliable means by information from the patients obtained with a questionnaire.

Background and Objectives of the Guidelines

The assessment of medical therapeutic procedures was based for a long time almost exclusively on 'objective' clinical-somatic target criteria. The attempt to record subjective factors related to the patient's experience and behavior in a standardized and reliable form in order to make use of them in assessing the course of disease and therapeutic effects has been increasing over the past 10–15 years. These are collated in a broad sense under the term 'Quality of Life' (QOL).

Commentary: The first attempt to take 'QOL' into consideration in treatment were made in oncology (e.g. EORTC study group 'quality of life',

*The authors are members of a subcommission of the German Society of Dermatology (DDG) which develops guidelines for the assessment of quality of life and pharmaco-economic parameters in skin diseases. A guideline entitled 'Quality-Assuring Guidelines for the Evaluation of Quality of Life in Dermatological Studies' will be officially adopted, soon.

Validated questionnaires which reflect both general and disease-specific factors of QOL are desirable. If these are used in prospective studies, they must include adequate sensitivity to change over time.

Prior to using a questionnaire, its quality characteristics should be examined for validity, reliability, specificity and sensitivity using the criteria formulated below.

There are several validated QOL questionnaires in skin diseases, allergies, wound healing and venous diseases available in English, German and other language versions. Foreign language inventories require re-validation after translation.

Aaronson 1993). In this area, it must frequently be decided whether severe side effects and detriment to well-being (QOL) associated with therapeutic measures (such as chemotherapy) are to be accepted in order to extend with any degree of certainty the remission time or survival time. QOL has also frequently been applied in clinical studies of diseases in internal medicine [4].

In dermatology, it has apparently not been obvious that, beyond the somatic factors, the patient's subjective experience could be recorded. Meanwhile, however, it has been found useful to also ask whether treatment measures in skin diseases really lead to greater well-being of the patient in addition to the desired somatic efficacy.

In clinical studies, the costs of the treatment measures are increasingly frequently systematically examined and set in relation to the clinical efficacy and to altered QOL.

For the assessment, the following three parameters are noted: 1. clinical efficacy / side effects; 2. costs of the measures; 3. QOL, well-being and/or patient satisfaction.

Although QOL recording is largely accepted as necessary in clinical studies, there remain deficits in the methodological research of the way in which QOL can be most reliably recorded and in which query [20].

In addition to assessment of therapeutic courses, recording QOL in dermatology can improve knowledge of the psychosocial stress associated with skin diseases, for individual

patients it can provide the indication for necessary psychotherapeutic measures and with respect to health-politics, it can underline the necessity and costs of dermatological therapy even though no vital indication may be given.

The following recommendations summarize the current status of research in recording QOL in dermatology. Where necessary, general methodological aspects of QOL research are also discussed.

Hints about the meaningful use of QOL instruments in dermatological studies will be given on the basis of proven methodical studies.

The recommendations have been developed during a Guidelines Meeting and several telephone conferences between December 97 and March 1998, and the written versions were corrected twice by the Subcommittee members. A working paper by the Chairman, summarizing the status of research and the internationally published recommendations for recording QOL served as the basis for the guidelines. The working paper is based on scientific sources located by an updated online literature search in the data bases Medline (1996–1999), Psyn-dex (1996–1999) and Psychlit (1975–1999).

Definition and Measurement of Quality of Life

The term 'QOL' is understood in very different ways in everyday living and in research. For this reason, a precise definition of the term is needed for scientific purposes.

In the following, 'QOL' will be understood, as outlined by Bullinger [10, 13] and Schipper [34], as a construct which reflects the quality of the physical, emotional, social and role- or function-associated life situation of an individual. The degree of consensus between the desired and the actual life situation is also part of QOL.

Commentary: QOL, in the general scientific sense, is a multidimensional construct which cannot be directly recorded, but only portrayed in its parts (Bullinger). There are various opinions concerning the areas which belong to QOL. According to a basic WHO definition, QOL with reference to 'Health' consists of the physical, emotional and social well-being of an individual. Several authors stress that QOL comprises less the objective availability of material and immaterial things, but rather the degree to which the individual actually attains the desired state of physical, emotional and social well-being.

Although an 'objective' recording of QOL would be desirable, the definition makes it clear that 'QOL' in the sense of patient experience can only be recorded when a self-rating by the patient is included [35].

With respect to measuring QOL, there are also some basic methodological difficulties, since this is not a directly observable phenomenon and can only be quantified with reference to a model.

Differentiation must be made between a *general* and a *health-related QOL*. The latter includes all QOL areas of life which affect relevant dimensions of the individual's health.

Under '*health-related QOL*', further differentiation must be made between '*generic QOL*' and '*disease-specific QOL*'. The import of the former is that they may occur independent of the specific disease, while the latter focus on particular characteristics under a certain disease.

In spite of methodological difficulties in making QOL a measurable phenomenon, several instruments for recording the generic QOL have been found useful in the past years. These usually consist of standardized questionnaires which are completed either by the patient (*self-rating*) or by the examiner or family members (*outside rating*, '*proxy questioning*') The questionnaires are called 'inventories'.

Commentary: Common inventories for measuring health-related QOL are, for example: European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire [1], Nottingham Health Profile [25], SF-36 [11, 39], Fragebogen Alltagsleben (ALLTAG) [12]. Forms of LQ questionnaires with only a few individual items which are assigned to a scale are termed 'Indices' (e.g. Disability Index).

In addition to general questionnaires on QOL, numerous inventories have been developed which measure more specific, disease-related aspects of QOL. The advantage of the disease-specific instruments is usually more precise recording of stress which apply not only to sufferers of a certain diseases, but for sick individuals in general. The clinical courses are also usually better covered by disease-specific questionnaires ('sensitivity to change').

Status of Research in Quality of Life in Skin Diseases

Methodologically acceptable original articles on QOL in skin diseases are available on the diseases summarized in table 1.

Recommendations for Recording Quality of Life in Dermatological Studies

Basic studies show that, in spite of methodological limitations, QOL can be meaningfully recorded and that the course of disease can be reproducibly reflected.

It is recommended that the following information be kept in mind in the planning phase of a dermatological therapy study.

Selection of the Procedure

Standardized questionnaires for self-rating by the patient have proven useful in recording QOL due to their ease of use. Compared to interviews, they have the advantage of being quicker and permitting data recording and assessment independent of the interviewer.

Commentary: In addition to the greater time efficiency a methodological error is also avoided compared to interviews, namely influence of the examiner on the patient.

If the group of patients to be examined cannot perform a self-rating (for example in the case of small children), outsider ratings (so-called proxy ratings) can be used. These also require standardized measuring instruments. Special inventories are also necessary for older children [14].

Table 1. The articles on QOL in skin diseases published between 1966 and 1998

Area	Diseases
Chronic-inflammatory dermatoses	atopic exzema, psoriasis, chronic urticaria, acne vulgaris, M. Behcet, lupus erythematodes
Allergological diseases	intolerances to foods and medications, insect bite allergies, rhinitis allergica
Pathogen-related diseases	herpes labialis, onychomycoses, tinea corporis
Skin tumors	malignant melanoma, basalioma, spinocellular carcinoma, naevus flammeus and other genodermatoses
Vascular diseases, wound healing	chronic venous insufficiency, deep leg venous thrombosis, peripheral arterial occlusive disease, acute and chronic wounds

Commentary: Proxy-ratings are questions posed to persons close to the patient or to a patient's therapist, if the patient cannot give information him/herself [24]. They are usually required in studies on small children. Several authors set the lower age limit for a written self-rating at 8 years [14]. Younger children can, however, be brought to express themselves by using pictures ('Smilies') or in the interview form of the questionnaire.

Basically, the methodological certainty of QOL recordings is greater in using multidimensional (containing several scales) than in unidimensional or only individual questions [15].

In therapy studies, it is not always practicable for organizational reasons to use extensive questionnaires. It is possible in such cases to use individual scales of the questionnaires, as long as these themselves are valid and as long as the authors of the questionnaires agree to this procedure. It should, however, be emphasized in the study protocol that QOL is measured only in certain aspects.

Only recording the individual questions without forming a scale is methodologically not enough to draw conclusions about QOL. Likewise, focusing only on symptom-related dimensions or QOL (such as physical complaints) cannot be considered a thorough recording of QOL.

In spite of the meanwhile large quantity of international research activity into QOL recording, many methodological questions, such as selection of the optimal QOL instrument, have not been definitively clarified.

Disease-Specific vs. Non-Specific Questionnaires

Preferably instruments should be considered which include disease-specific areas in addition to general QOL factors.

Commentary: Thus far, many studies of quality of life have been performed using general QOL questionnaires, e.g. Nottingham Health Profile [29] or SF-36 [5]. This has some disadvantages: Using a questionnaire which is not tailored to the disease could mean that some specific stresses associated with the disease are not recorded. General questionnaires are also often less sensitive to change, that is, they do not adequately register stress which actually does improve under therapy in venous disease. Most of the current recommendations even of health-economic and clinical-pharmacological societies thus contain references to combined use of both disease-specific and general QOL questionnaires [7, 38].

The advantage of disease-specific questionnaires is that their capacity for differentiation and sensitivity to change are often greater. The advantage of general questionnaires is the better comparability with other disease groups.

Validation and Sensitivity to Change

A questionnaire used in a therapy study should be validated. The following criteria belong to this:

Commentary:

Validation parameters:

Internal consistency: To guarantee high data quality, the scales of the questionnaires should be adequately represented by the items. For Cronbach's alpha, a minimum value of 0.70 is required internationally these days.

Retest reliability: The questionnaire should have brought the same results in repeated recordings. Repeats are most often performed at 1-week intervals, no clinical intervention should have occurred in the interval.

Convergent validity: In direct comparison with other already validated inventories, a check should be made on a larger patient collective to determine whether the QOL questionnaire actually does measure the QOL areas which it claims to measure.

Discriminant validity: The questionnaire should differentiate stage- or severity-dependent differences in QOL.

Sensitivity to change: Changes in QOL as a function of time as well as of therapeutic effect should be reflected.

1. Reliability
 - a) internal consistency
 - b) test-retest reliability
2. Validity
 - a) construct validity (e.g. factor analysis)
 - b) external validity
 - convergent validity
 - discriminant validity
3. Sensitivity
 - a) over time
 - b) as a therapy effect (responsiveness)

Feasibility of the Questionnaire

If the QOL questionnaire is used as part of a clinical study, it should not interrupt the study any more than necessary. The contents, graphic design, mode of questioning and instructions should also guarantee both comprehension and high acceptance on the part of the patients. The assessment of the questionnaire should be as simple as possible.

Commentary:

This requires:

- a) adequate length of the questionnaire to meet the requirement of high reliability of the inventory on the one hand and low stress for the patient on the other,
- b) self-explanatory questions as far as possible and little need for explanations by the interviewer,
- c) an optically favorable design for the patient to permit him/her to complete the questionnaire without assistance.

Formation of Scales and Computation of Scores

For reasons of reliability, especially in new development of procedures, it is in principle a good idea to cover partial areas of QOL with not only one but with several questions. Outliers and chance responses then have less weight.

Commentary: In order to record various areas of QOL (e.g. physical well-being, social relationships), it is a good idea to conceive the questionnaire so that several questions represent one partial area. A part-score is calculated from the results of the individual questions in each area, if this is permitted by the psychometric tests. All scores together can result in a 'Total Score of QOL'. Forming a total score is, however, not recommended by all test authors, since the authors frequently assume differences in dimensions (subscales) and do not consider a total sum methodologically appropriate.

All individual questions which refer to a certain partial QOL area, taken together, form a scale. The scale value is calculated from the mean (score) or – less frequently – from the sum value of the individual questions.

Comparison Group

The (mean value) comparison with other random patient samples is essential for the interpretation of QOL results. These may be patient subgroups within the same study or also patients from other studies with the same or other diseases. It is thus desirable when reference can be made to a reliable data pool for the QOL questionnaire used.

Applicability to Pharmaco-Economical Cost-Benefit Analyses

If a cost-benefit analysis is to be made during a clinical study and the QOL used as the benefit value, one must be able to calculate a score applicable to this purpose from the QOL questionnaire [3].

Commentary: Constantly increasing healthcare costs draw public interest more and more to the question whether the benefits of a therapy are in a justifiable relationship to the costs. However, it is not enough to optimize therapy exclusively under price-result aspects. This would mean that maximum effect should be attained at minimum price. However, only a solution which takes the patient's well-being and his subjective needs into account is ethically justified. Recording QOL is thus also relevant for treatment-economics studies.

For this reason, procedures have been developed which determine how effective a therapy is in which changes in QOL at what price. This is termed the cost-benefit analysis of a therapy [37].

This analysis is only possible if an individual, clearly defined value for QOL under a given treatment can be recorded. This is frequently not permitted by the common psychometric QOL questionnaires, so specially-constructed procedures are usually used (e.g. HUI, EURO-QOL, QWB). In cost-benefit analysis, the QOL is found in the model 'QALYs' quality adjusted life years) [6, 16]. These analyses determine how many QOL-improved years can be attained with a given therapeutic procedure at what cost.

Available Dermatology-Specific QOL Inventories

Reference should be made to the available inventories prior to new construction of a questionnaire (a costly procedure which should only be undertaken with psychometric help). A questionnaire translated from another language should be re-validated prior to its use in order to rule out linguistic and cultural differences [8].

Commentary: Developing a new questionnaire on an exploratory basis in parallel to the use of a standardized procedure in a study is possible, but it requires several steps [15, 26]. Item definition (e.g. focus groups), formulation/linguistic pretest, use by at least 100 persons (patients), psychometric analyses of reliability and validity, repeat measurements after 1 week (without intervention) for retest-reliability, after intervention to sensitivity to change.

The following validated instruments are available for recording QOL in dermatology: Cardiff Acne Disability Index [30] Dermatology Life Quality Index [22], Dermatology-Specific Quality of Life Instrument [2], Eczema Disability Index [32], Freiburg Quality of Life Assessment [3], Lebensqualitätsfragebogen bei arterieller Verschlusskrankheit-86 [9], Marburger Hautfragebogen [36], Psoriasis Disability Index [21], Recurrent Genital Herpes Quality of Life Questionnaire [19], Rhinitis Quality of Life Questionnaire [26], Skindex [17, 18], and Tübinger Fragebogen zur Messung der LQ von CVI-Patienten [27]. For children: Children Dermatology Life Quality Index [23] and Pediatric Symptom Checklist [31].

Notes for Obtaining QOL Questionnaires

QOL questionnaires can usually be obtained from the author (general overviews, for example from Westhoff [40] and Bullinger [14]; on dermatology from Salek [32] and Finlay [23]). In some cases, there are copyrights governing use, including those of publishers (in Germany: Hogrefe-Verlag, Göttingen and Beltz-Test, Weinheim), so that the questionnaires must be obtained there and, where applicable, licence fees paid.

References

See German version of this article.