News

Quality of Life in Oncology: Report of the Psycho-oncology Study Group of the German Cancer Society and the Swiss Group for Epidemiologic and Clinical Cancer Research

From 10–12 May 1990 the first joint meeting of the study group of Psycho-oncology (PSO) within the German Cancer Society and the Swiss Group for Epidemiologic and Clinical Cancer Research (SAKK) took place under the heading "Quality of Life in Oncology". This meeting took the concept of quality of life as an explicit therapeutic variable in oncological medicine. The discussion focussed on clarification of the term itself, the context and its implications. Furthermore, issues of operationalisation and practical application in clinical trials were under discussion. Based on already available empirical data, relevant and clinically practicable methods of assessment have been reviewed. A volume with the complete contributions is in preparation.

Added to the conference was a closed meeting of the working group "Quality of Life in Oncology" together with the contributing experts. A consensus was passed on the use of quality of life-variables in comparative clinical trials. This consensus was passed based on the expertise of the contributors, but also on the engaging and well-informed discussion with the over 250 participants of the conference. Coming from all areas of oncology—cancer centres, hospitals with oncological specialisation, oncological working-groups, ambulant oncology teams, and including clinical psychologists, biostatisticians and psychotherapists, they formed a truly interdisciplinary and co-operative meeting, that focussed on quality of life from many different points of view.

It is the first time that all contributing sciences in the area of quality of life research agreed on a catalogue of fundamentals, which can serve as a guideline for future clinical research. This first interdisciplinary consensus is to be understood as a general guideline for conducting quality of life studies in the field of oncology in a sense of a master protocol. At present, no definitive recommendations can be given, nor which instruments for assessment are to be used. This will be the topic of the next consensus meeting, which will evaluate the clinical and psychometric properties of methods and instruments that are presently on trial in several studies.

Following is a quotation of the consensus, that may be regarded as the first step towards a practicable assessment of quality of life variables in clinical trials.

Consensus on the implementation of quality of life assessments in oncological clinical trials

Progress in medical oncology is not only measured by the duration of survival, but also by the quality of the survival time. Widely accepted, well conducted studies are the exception, since there has been little agreement up to now as to what constitutes quality of life or how it should be measured as a therapeutic variable in clinical research.

The following consensus is based on a multidimensional model, in which quality of life is viewed not as a single variable, but as a construct encompassing several domains. Dependent upon the specific research questions raised in various oncology studies, different components of the patient's quality of life need to be assessed. Clinical trials are necessary to improve upon the foundation of therapeutic decisions, but this will not substitute for the individual dialogue within the doctor–patient relationship.

The idea that we can measure quality of life *per se* is rejected.

1. *Research questions*

Beyond the traditional outcomes, such as survival time, remission periods and rates, and toxicity, normally used to judge the effectiveness of oncology treatments, is the question of the quality of survival. This is especially true for comparative studies of treatment effectiveness, where quality of life is viewed as an outcome of particular importance. There are meaningful quality of life research questions in the areas of long-term therapy with curative intention and in those whose primary purpose is palliation. For potentially curative treatment assessing quality of life is also important, even if there are no alternative treatments allowing comparison between patients receiving different therapeutic approaches. Information on quality of life obtained from descriptive studies is also desirable for depicting the sample and the course of the disease.

The global question that can be used as a guideline for study-specific questions is the following: to what extent do disease and treatment impact on quality of life in defined groups of patients?

It is essential that quality of life parameters are incorporated in the study during the planning stages. The most important criteria by which to judge quality of life studies in oncology protocols are the relevance of the research question, the psychometric/measurement properties of the instruments and the feasibility.

2. *Conceptualisation of the term "quality of life"*

Quality of life is understood as a multidimensional construct that includes the subjective evaluation of psychological, somatic and social experiences related to a defined time frame. This definition reflects the consensus in the literature as to what constitutes quality of life: (a) the somatic, (b) the psychological and (c) the social dimension.

These global dimensions can be subdivided into more specific domains. Included in the somatic dimension are functional status and general and specific symptoms—especially pain which may impose the most severe restrictions on daily living and therefore must be included as a criterion to judge the success of therapy. In the psychological dimension, domains such as anxiety, depression and subjective wellbeing are relevant. The social dimension incorporates domains such as family and social support, the doctor–patient relationship and financial burden, as well as the ability to work and general economic circumstances.

Beyond these global dimensions, there are other areas that could be included in quality of life: sexuality, culture-specific phenomena and spirituality are examples. According to the specific questions of a trial there may be further differentiations of or additions to the aforementioned areas. So-called "modular" approaches (disease- and/or treatment-specific) may complete the more general dimensions of quality of life research.

A systematic assessment of the individual and his or her lifespan experiences cannot be the aim of oncological comparative studies. Rather, the study-specific dimensions of quality of life in relation to its more global concepts should be determined.

3. *Methods of assessment*

As a basic criterion for selecting methods of assessment, it is necessary that the proxy or expert (physician/evaluator) rating

and the patient's self-rating are viewed as being equally important and used as complementary methods. When selecting or developing instruments, the individual rating of the different dimensions must be taken into account as well as the time frame of the evaluation protocol. The selected method of assessment is generally one of the following: questionnaire, interview or diary.

When selecting tests to be completed by experts or patients, it is important that the psychometric properties, the validity and the reliability, are known. A critical problem in assessing quality of life is the responsiveness of the measure and its ability to respond to changes over time. Global measures may lack the ability to detect small but important clinical changes in specific patient samples. Therefore it is highly recommended to use an instrument with documented psychometric properties and one which is known to apply to the specific research question and to encourage the development of specific oncological quality of life instruments through interdisciplinary co-operation.

The basic sociodemographic characteristics should be assessed in a standardised way for descriptive or comparative purposes.

4. *Study design*

The objective of assessing the influence of therapy on quality of life can only be achieved by longitudinal studies. Patients should be assessed prior to beginning treatment if responses are to be monitored over time. Given the present state of knowledge, cross-sectional studies, as pilot studies, may be desirable and useful.

The initial evaluation point and the intervals between assessments are to be planned *a priori*, according to the specific questions of the study. It it important to differentiate between short, medium and long-term effects and side-effects of a given therapy. Therefore the assessment protocol should have a meaningful relation to the therapeutic intervention and its outcomes (responsiveness of the tumour, toxicity and other side-effects). Other essential measures of supportive care should be described.

5. *Data collection*

The first step of data collection is to obtain informed consent from the subject after the objectives and procedures have been explained. Further, the primary physician, if he or she is not conducting the study, must be involved in the consent process. The routines of data collection (time, location, and who does it) must be clearly defined. Reasons for missing data and protocol deviances should be well documented. Generally it is recommended that data collection takes place during active treatment and follow-up.

6. *Data analysis and interpretation*

It is essential that a biostatistician/methodologist be involved in the planning and execution of the study and not only consulted when the data are ready for analysis. The assessment of quality of life must be an integral part of the whole study protocol. Appropriate statistical procedures must be selected and employed according to the purpose and design of the study and the available data.

The assessment of changes in quality of life parameters should be analysed both in terms of individual patient responses and between groups. According to existing information, extensive intra- and interindividual variance is to be anticipated and must be taken into account when making group comparisons.

Quality of life data are to be analysed and interpreted within the context of medical data and statistically significant differences are to be examined in relation to clinical relevance. Missing or incomplete data must be described and accounted for when performing the analyses and interpreting the results.

7. *Conclusion*

Research in quality of life in oncology has become a top priority. The examination of relevant clinical questions and the development of appropriate methods can only be done in a meaningful way if participating individuals work in the spirit of interdisciplinary co-operation.

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ECL Fundraising Survey 1989

The Association of European Cancer Leagues (ECL) has updated its European Fundraising Survey. The 1989 survey describes the development of the fundraising activities within 18 cancer leagues from 17 European countries, including additionally the American and the Canadian Cancer Societies.

In 1989, the ECL members raised a total of US$432.7 million. The American Cancer Society raised US$358.1 million, and the Canadian Cancer Society raised US$65.4 million. The funds raised per inhabitant were US$1.2, 1.4 and 2.5 respectively.

The survey uncovers rather extreme differences between the ECL countries, from US$0.2 to 10.4 per inhabitant (Figs 1 and 2); and the development from 1985 to 1989 (Fig. 3)—although indicating a steady overall growth in funds raised—also shows that the growth is very unevenly distributed. This is illustrated by the growth span described by the three fastest and slowest growing societies respectively.

To some extent, the differences described in the survey is of course explained by the different socioeconomic structures of the ECL countries. Also, some countries have cancer leagues which were not covered in the survey. Still, however, the differences are surprisingly large between countries where the basis for fundraising should be very much the same. This then can only be explained by the national cancer leagues' different approaches to fundraising, that is, by the differences in the principles and practices applied in building professional fundraising organisations within each league.