Symposium article

 Unsolved problems in evaluating the quality of life of cancer patients

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Summary

Background: The current means of evaluating the quality of life (QoL) of cancer patients, generally employ a multidimensional approach involving validated self-administered questionnaires. In measuring QoL, as well as in interpreting the results of an assessment, the patient, questionnaire, and setting of administration may all give rise to problems.

Design: Based on our experience and review of a large number of published papers, the most relevant problems in evaluating QoL of cancer patients are highlighted.

Results: The difficulties that patients have with the most frequently used psychometric questionnaires are demonstrated by the fact that more than 10% of patients who gave their consent to be enrolled in a longitudinal study measuring QoL did not fill out the first questionnaire. This percentage is higher among older patients having a low level of education, in patients with disseminated disease, and among those with a low performance status. Moreover, in longitudinal studies, there is a very high incidence of drop-outs, often correlated with the progression of disease, so that the results are sometimes inconsistent.

Conclusions: Quality of life, depending not only on the type and stage of disease, and the administered treatment, but also on patient characteristics, should be assessed only in a randomised clinical trial. In any case, the most relevant problem is connected to the selection bias due to drop-outs. Reasons for this should be sought in the apparent complexity of the questionnaire and inadequate information given to the patient. Simpler instruments, which can be filled out in a shorter period of time, and specific training by research nurses could help minimize this excessive phenomenon.

Key words: cancer patients, drop-outs, quality of life

Introduction

A great number of papers on the evaluation of quality of life (QoL) of cancer patients have been published during the last 20 years, but the major part of them were concerned with the reliability and validity of the measurement instruments. More than 600 QoL questionnaires have been validated; this could be due to both the complexity of the problem and the lack of a generally accepted theory.

Nevertheless, QoL can be considered the main objective in several clinical trials when therapies which give a similar survival rate are compared, or when the survival rate is expected to be different, but the best treatment is suspected to offer the worst QoL. Only a few studies on the rating of the QoL of cancer patients have been carried out.

Today, in evaluating QoL, there is general agreement on the following points:

- we need to measure the QoL of cancer patients and its variations, possibly in relation to the clinical evolution of the disease and to treatments administered to the patients;
- a multidimensional approach should be preferred, so as to correctly interpret the observed variations of QoL, i.e. if they depend on well-being, social role, physical performance, psychological distress, etc.;
- the evaluation must be performed by the patient; no other person can have an exact perception of the patient's QoL, as it depends on his/her feeling, intelligence, philosophy of life, perceptions, and so on;
- a valid tool is mandatory: every scale must be tested for reliability and validity.

Many problems arise both in measuring QoL and evaluating the results of an assessment of QoL in cancer patients. They involve the patient, questionnaire, setting of administration, and their interactions. The main aim of this paper is to describe them, so as to suggest some strategy to minimize their effect on such an important outcome.

Main problems connected with the patient

A questionnaire must be self-administered by the patient. In our experience, about 12% of cancer patients who gave their consent to be enrolled in a study on QoL did not fill out the basal questionnaire [1, 2], and in some papers, higher percentages are reported. Patients who refuse to fill out the QoL questionnaire cannot be considered to be randomly selected from the experimental population.
group. In fact, this percentage increases with age; more frequently, patients who refuse to fill out the questionnaire have a disseminated disease, a low performance status, and low levels of education [1].

Furthermore, in longitudinal studies, the percentage of patients who do not fill out the QoL questionnaire greatly increases during the follow-up, often with the progression of disease. For instance, a recent study [3] indicates that, in the sixth evaluation, about four months after the beginning of the trial, the percentages of responses were 36% and 42% (about 60% of patients were non-evaluated) in the two arms of treatment involved, respectively. Therefore, this selection bias is the main unsolved problem arising in measuring QoL of cancer patients.

Problems concerning the questionnaire

The use of psychometric questionnaires allows us to evaluate both the levels of each domain and their modifications during the follow-up. Generally, each domain is explored by one or more items, and the same questionnaire is used in repeated assessments during the follow-up.

The main problems arising from the choice of domains are: first, domains may not be independent of the country where the evaluation is carried out. The ways of life (i.e., the patient's family could play a different role in the management of the cancer patient), as well as the mean levels of education may be different in various countries. Moreover, different social and national health systems could cause the patient to assign a different importance to the same domains (i.e., economic conditions may be more or less important depending on whether the cost of disease is completely supported by the national health system or is totally or partially charged to the patient). Therefore, in some countries, domains different from those explored in a questionnaire produced and validated in another country may be the most important.

Second, in longitudinal studies, the questionnaire used in subsequent evaluations is always the same, for obvious reasons of comparability. In this way, it is implicitly assumed that the same domains continue to be the most important even when disease is in progression.

For instance, at early stage of disease, limitations in doing household jobs (an item which frequently explores the domain 'social role') could be perceived as important, but probably the concerns are different when the disease becomes disseminated. Therefore, in my opinion, repeated measurements of QoL using the same items to explore a domain may lead to a lack of responsiveness.

Finally, a technical problem arises when a score for each multi-item domain is assessed. Today, the most frequent procedure consists in calculating a simple mean, but also in this way a weight system is being used: all items are assumed to be equally important. The choice of another weight system could highlight the different importance of each item in exploring the same domain. The score of each multi-item domain can be deeply affected by the choice of the weight given to each item, but it is unclear what the preferred procedure should be to evaluate the weight.

Problems arising from the setting of administration of the questionnaire

Experimental studies on the influence of the setting and the administration of the QoL questionnaire on the results have not yet been undertaken. Answers could be affected by both the time and place in which the questionnaire is filled out. Perhaps, a patient waiting to receive chemotherapy might give answers different from those that he/she would give after hearing reassuring news about his/her disease.

Moreover, relatives or nurses sometimes assist the patient in filling out the questionnaire, and this is a source of possible bias because the questionnaire should always be self-administered.

Finally, often patients do not receive adequate information on the purpose and methodology of a QoL study, nor on the content of the items, and this could lead to errors or omitted responses.

Discussion

The quality of life of cancer patients depends not only on the type and stage of disease, and the administered treatment, but also – and strongly – on patient characteristics. This leads us to attribute sufficient reliability to any assessment of QoL performed in the context of a randomised clinical trial only; when we compare the scores obtained from different study groups using the same questionnaire, or from the same study group at different times, any conclusion should be cautiously interpreted.

Moreover, comparisons between scores of the same domain obtained using different questionnaires should be avoided. In fact, even when two questionnaires are filled out by the same patients, correlation between the scores referring to the same domain is generally low [4].

However, when results from a randomised clinical trial are analysed, a selection bias generally occurs, due to the presence of drop-outs, i.e., patients who, from a certain date, refuse to fill out the questionnaire. This phenomenon is frequently correlated with the progression of disease, so that the evaluation of QoL is obtained from patients who are in better conditions. Perhaps more simple questionnaires could minimize the dropping-out phenomenon; at least more time spent in giving information to the patient could reduce it. Research nurses should be prepared to participate in QoL studies, because the oncologists generally do not have enough
time to give detailed information to the patient and to manage the research efficiently.

The accuracy of the measurement of QoL can be increased if the questionnaire is validated in each country where it is used. First of all, the questionnaire has to be tested for reproducibility and its multi-items subscaled for internal consistency. Then, its validity has to be studied. Proof of its reliability and validity in one country may not be obtained in another country.

In conclusion, today, many unsolved problems affect the evaluation of the QoL of cancer patients; among these the greatest seems to be the high numbers of dropouts. Psychometric questionnaires allow us to analyse variations in the score of each domain, but the price paid for this is too high, the results of a longitudinal study being generally affected by a too severe selection bias. Instead, the use of simpler tools, filled out by the patient in a very short time, seems the best way to evaluate QoL. Obviously, these new instruments are to be tested for reliability and validity, also in comparison with validated psychometric questionnaires.

References


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