

Quality of life assessment in geriatric surgery

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Abstract. An excessive number of studies on health-related quality of life (HRQOL) has rendered results often contradictory and difficult to interpret. HRQOL evaluation in the aged is even more difficult, due to intrinsic conceptual and methodological problems. Since no structured instruments are available for use in geriatric surgery, it would be necessary either to work out a new specific instrument or to adapt/adopt an already existing method. Properties and methodological steps for development and validation are set forth. The Functional Assessment for Cancer Therapy (FACT) scale was developed for patients with cancer and has been recently validated also in the elderly. The Multidimensional Assessment for Cancer in the Elderly (MACE) was originally developed for elderly cancer patients. Since both methods are irrespective of subjects undergoing surgery, its use requires further validation. The MACE gives a broad information spectrum, but in geriatric surgery it seems too complex. The FACT-G is a simple core item questionnaire which can be integrated by disease-specific items and seems more compliant. A disease-specific and treatment-specific application of FACT questionnaires by multicenter studies might be useful in evaluating surgical procedures in patients in whom significant advantages in survival cannot be expected, but QOL can still significantly improve.

Key words: Quality of life, elderly patients, geriatric surgery, geriatric assessment

Introduction

Although questions about the meaning of life (what is a life worth living and what should be a good life?) are as old as mankind, only since the late 1970s has the term “quality of life” been used in social sciences. Quality of life (QOL) has become a common endpoint in all fields of clinical research. In medical literature, the number of publications which address health-related quality of life (HRQOL) or instruments for HRQOL assessment has increased exponentially in the last three decades, so that an undefined magma of studies – a veritable Tower of Babel – is now available, the results of which are often contradictory or, at the very least, difficult to compare and to reproduce (1). The related problems are to a large ex-

tent conceptual and methodological, since the results depend on what is meant by quality of life and how it is measured.

HRQOL evaluation in the aged is even more uncertain, since elderliness is a differing experience for each subject, with a wide range of possibilities involving many dimensions of existence. In addition, the assessment is complicated by unresolved problems, such as heterogeneity of the population, frequency of illiteracy, poor compliance with the questionnaires, the influence of comorbidity, and the use of instruments unfit for the aged population (2). Nonetheless, the HRQOL assessment is fundamental in the aged, not only because comorbidity and disability, typical of elderly patients, are at high risk of developing treatment-related complications and represent a good pre-

dictor of mortality (3), but also because a treatment which is not expected to improve survival can be recommended if it demonstrates an improvement in QOL. For the surgeon, this is a crucial issue.

Quality of life of elderly people

The experience of being aged is emotionally variable from one subject to another. Whether or not elderliness will be an enjoyable stage of the vital cycle will depend on objective factors and on the subjective interpretation of this reality by the elderly subject. In other words, QOL depends on a subject's external variables (contingencies, environmental resources, health conditions) and, above all, on his/her internal variables (emotional attitude in facing the facts of life). QOL is increasingly acknowledged as strongly dependent on subjectivity and, when we consider HRQOL, there is a great variability as to how physical limitations, diseases and health expectations are faced. However, the external contingencies may vary enormously, and the presence of protecting factors such as economic resources, family network and support can attenuate the impact of negative events on his well-being. If we trace hypothetical internal (emotional) and external (contingencies) co-ordinates, QOL can be represented as the intersecting point between reality and perception of this reality.

Quality of life measurement

Structured and non-structured instruments can measure QOL. Structured instruments (questionnaires, tests, scales, indexes) use concepts, constructs and contents which are mainly an expression of professionals' and researchers' standards and definitions of QOL. Non-structured instruments consist of individual interviews which identify the components of QOL on the basis of a personal, subjective interpretation. In general terms, QOL can only be individually described and measured. However, this approach is vague and usually leads to difficulties in data collection and interpretation. When HRQOL is addressed, and disease-specific, age-specific or treatment-specific

conditions are considered, it is mandatory to approach the patients by a simple, standardised, objective, easily administered, measurable and reproducible method. Only structured instruments can fulfil these requirements.

There are so many structured scales and tests developed to measure HRQOL that there would be no need for any further methods. Unfortunately, no methods, up to now, have been specifically tailored to the specific requirements of elderly patients submitted to surgery. Thus, a study aimed at assessing the impact of a surgical treatment on quality of life in the aged would involve either the development of a new instrument or the adoption of an already-existing method, and/or its adaptation to the end points and research directions in progress.

The development, testing and validation of a new HRQOL measurement system is a major challenge, which usually takes several years to complete (4). The adaptation of an already-existing method may involve both the identification of more specific items and domains and all the processes for their validation (see below), with the risk of a disproportion between a ponderous task and the real advantages over the original method. The full adoption of an already-existing instrument, developed for conditions other than geriatric surgery, requires the greatest similarity between the two conditions, the one already studied and the one under study, and the validation of the new application.

In any case, the first step for working out, adopting or adapting HRQOL measuring instruments, consists of knowing their properties and development methods.

Types and properties of HRQOL measuring instruments

There are three main types of structured instruments: global, generic and targeted (or disease-specific). The global instruments (visual analogue scales, graded scales) are simple, and are easy to score and administer, but cannot identify specific areas of interest. The generic instruments (multi-item questionnaires) give an overall description of various aspects of health and well-being and permit comparison of diseases, but cannot reveal clinical changes or quantify specific dysfunctions such as abdominal pain, urgency or incon-

tinence. Targeted instruments reflect the most important problems of a specific population and are sensitive to changes with time or treatment, but are complex to administer and do not permit comparison between different diseases.

HRQOL is a wide, multidimensional concept, which originates from various domains, including physical, functional, social and emotional well-being. Although social and emotional well-being, as we have seen, are important dimensions in elderly patients, in geriatric surgery physical and functional well-being are fundamental points.

An HRQOL measurement in the elderly surgical patient should be as generic as possible to give, through a common core, an overall view of a population of elderly patients, but should also allow us to face the problems of specific diseases and the results of specific surgical treatments. The two approaches, generic and specific, may be combined through the so-called modular instruments, which are made up of a core module of common questions plus specific questions correlated with the disease and the treatment under study (5).

Steps and development of a new HRQOL evaluation instrument

The development of any generic or specific HRQOL measurement method requires some methodological steps, which can be summarised as follows (6):

1. *Item generation.* On the basis of previous experiences and expert opinion, all possible items regarding a condition have to be focused.
2. *Item reduction.* The number of items has to be reduced so as to be easily used, through an on frequency and/or importance selection process, preferably worked out statistically.
3. *Pretesting.* This step regards question wording, intelligibility and acceptability of each question.
4. *Psychometric testing* (7). This is the core of the methodological process, which expresses the properties of the instrument: validity (aptitude of a test to measure/discriminate what is in the initial hypothesis), reliability (stability in test-

retest, internal consistency, that is, correlation of items within the same domain or with the full questionnaire score), responsiveness (aptitude to detect clinical changes). Each property has its own statistical method of assessment.

5. *Cross cultural adaptation process* (8, 9). Translation of a measurement previously validated in another language (semantic, idiomatic, experiential and conceptual equivalence), which is not only a mere language but also a cultural translation.

Choice of an HRQOL evaluation instrument

Since no HRQOL assessment methods are specific for geriatric surgery, the ideal solution would be to work out a new method. This, however, would require too complex a methodological procedure. The adoption of an already existing method (from certain aspects, its adaptation would be even more difficult than the development of a new method) involves at least, as a minimal pre-condition, its application to a more limited area than overall geriatric surgery, which is too wide and indefinite. Owing to the magnitude of the problem, this area should be surgery for cancer. A second pre-requisite is the assumption – until it is in some way validated – that surgical therapy, for the present purposes, can be equalised to chemotherapy or radiotherapy.

The most used HRQOL instruments in cancer research are:

1. The European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire Core 30 Items (QLQ-C30) (10).
2. The Functional Assessment of Cancer Therapy – general version (FACT-G) – 27 items (11).
3. The Rotterdam Symptom Checklist (RSCL) – 39 items (12).
4. The Symptom Distress Scale (SDS) – 13 items (13).

All these systems are independent of age, although one of the above four methods – the only one, to the best of our knowledge – has recently been valida-

ted in elderly patients: the FACT-G (14). The FACT-G is a 27-item list of general core questions, divided into four domains: physical, social/family, emotional and functional well-being, appropriate for any form of cancer. Additional concerns are given for cancer-specific measurements; for example: FACT-Ga (gastric cancer), FACT-C (colorectal cancer); FACT-Leu (leukaemia). Sixteen cancer-specific questionnaires are now available and, in 1998, the FACT questionnaires were translated into 30 languages.

A multidimensional scale specifically developed for elderly cancer patients, the MACE (Multidimensional Assessment for Cancer in the Elderly) is also available, again irrespective of surgical treatment (15). It was worked out and validated by the Italian Group for Geriatric Oncology (GIOGer) (15, 16) with the aim of avoiding arbitrary decisions as to patient selection, favouring uniform treatment monitoring and allowing for better comparison of oncologic results. Like all Comprehensive Geriatric Assessment (CGA) scales, its structure is very complex, much more so than the FACT, since it includes various domains, partly selected from studies in which they have been psychometrically rated and validated in the elderly population (17-22): demographics, socio-economic status, neoplasm characteristics, comorbidity, major symptoms, use of health services, cognitive status, depression, balance, physical performance and disability. The administration of a CGA can take up to one hour and a half and is usually carried out by a trained professional, although a self-administration methodology has recently been reported (23).

Although the CGA instruments give a broad spectrum of information and originated specifically for elderly subjects, for whom a simple performance status evaluation does not appear to be reliable, owing to comorbidity interference (24), their use is probably too complex, consuming and distracting from the main end-points of geriatric surgery. In general terms, the fact that most patients with solid tumours have to undergo surgery suggests that HRQOL instruments which have been developed for elderly patients with cancer might be valid and reliable also in geriatric surgery. The availability of a simple general scale like the FACT-G, the possibility to integrate the core questionnaire with disease-specific items (modular instru-

ments) and its recent validation in elderly subjects are encouraging factors.

Conclusions and prospects

Traditional "hard" endpoints, such as survival and disease-free survival, are sometimes unfit for describing the effectiveness and efficacy of a treatment. In some situations, such as in geriatric surgery, "how" might be more important than "how long" a subject lives. Soft data, such as HRQOL, are therefore useful and suitable, and surgeons themselves, who generally beware of evanescent evaluation tools, should accept the HRQOL as a sensitive marker of correct therapeutic decision-making in the elderly.

The FACT-G scale, together with its disease-specific additional items, was developed as an instrument to assess HRQOL in cancer patients, and has also been validated in older patients. Its further validation in a subset of patients undergoing surgery is a process involving, in addition to the fulfilment of all general methodological requirements, a specific reappraisal regarding fields and methods of application. In geriatric surgery, for example, the administration of FACT questionnaires before surgery, one month after surgery and, hypothetically, six months later, might be a way to evaluate the impact of a particular surgical procedure on QOL, irrespectively of the oncologic outcome. Such an evaluation might be disease-specific, but also procedure-specific or, at least, specific for the curative or palliative character of the surgical procedure. In other words, specificity is to be intended as the possibility not only to have questionnaires specific for each particular condition (disease-specific measurement), but also to administer the same questionnaire to subsets of patients differing as to therapeutic choices (treatment-specific application). Hence the necessity to have wide series of patients available, involving the setting up of multicenter longitudinal studies.

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