
Measuring Quality of Life in Epilepsy Surgery Patients

Samuel Wiebe and Paul A. Derry

ABSTRACT: Treatment of chronic conditions often entails trade-offs between benefits and risks or side effects. This is of particular importance in epilepsy. Consequently, assessment of effectiveness must incorporate this trade-off as perceived by the recipient of the intervention, ie., the patient. Measurement of health related quality of life (HRQOL) aims at capturing such patient-centred effects of therapy. Conceptual aspects of HRQOL are described and issues relevant to outcomes of epilepsy surgery are addressed. Finally, practical aspects of measurement in the context of epilepsy surgery are discussed.

RÉSUMÉ: Mesure de la qualité de vie chez les patients qui ont subi une chirurgie pour l'épilepsie. Le traitement de maladies chroniques implique souvent des compromis entre les bénéfices et les risques ou les effets secondaires. C'est particulièrement important dans le traitement de l'épilepsie. L'évaluation de l'efficacité du traitement doit donc incorporer ces compromis, tels que perçus par le patient. L'évaluation de la qualité de vie reliée à la santé a pour but de cerner de tels effets du traitement chez le patient. Nous décrivons les aspects conceptuels de la qualité de vie reliée à la santé et discutons des questions pertinentes aux résultats de la chirurgie de l'épilepsie. Finalement, les aspects pratiques de l'évaluation dans le contexte de la chirurgie de l'épilepsie sont discutés.

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The quality of one's life has multiple determinants, such as financial status, relationships, housing, recreation, health status, etc. Clinicians are concerned with health status as a determinant of QOL, or health-related quality of life. Conceptually, HRQOL can be defined as "a judgement of one's well-being based on consideration of physical, mental, social, and general health status."¹ Distinguishing between QOL and HRQOL is more important than a simple academic exercise. A recent appraisal of HRQOL measures used in clinical trials showed that instruments often failed to distinguish general QOL from HRQOL.² Clearly, an instrument that asks about global QOL without specific reference to health, will tell us nothing about the health-related component of the estimate.

The common element to any HRQOL definition should be its ability to capture the patients' subjective perception of whatever health area we are interested in measuring. As aptly put by Gill and Feinstein, "HRQOL is a uniquely personal perception denoting the way that individual patients feel about their health status".² The purpose is to review the available epilepsy-specific HRQOL instruments and the issues around its measurement in epilepsy surgery.

TRADITIONAL OUTCOME MEASURES IN EPILEPSY

Virtually all treatments in epilepsy embody trade-offs between seizure control and side effects. In refractory epilepsy, side effects may be severe and lifelong, since large amounts of

drugs must be taken for life. Epilepsy surgery attempts to render patients seizure-free with minimum or no use of antiepileptic drugs (AED). However, assessment of surgical benefit and morbidity must enter the equation. Do patients prefer fewer seizures with more side effects, or vice-versa? Can surgery significantly improve the risk benefit ratio as compared to AEDs? What is the patient's experience of various treatments? These questions are directly related to patient care and well-being and can only be addressed by assessing HRQOL.

Seizure frequency and severity:

For decades, treatment outcome in epilepsy was measured in terms of seizure frequency. Subsequently, mainly in the context of AED trials,³ it was recognized that not all seizure types have the same impact on affected patients. The two most popular instruments to determine seizure severity are the Liverpool Seizure Severity Scale⁴ and the National Hospital Scale (NHS).⁵ Their development and accumulated experience with their use is summarized in the section "Seizures as indicators of therapeutic control" in this supplement.

From the Department of Clinical Neurological Sciences, University of Western Ontario, London, ON Canada
Reprint requests to: Samuel Wiebe, London Health Sciences Centre, University Campus, 339 Windermere Rd., London, Ontario N6A5A5 Canada

PSYCHOSOCIAL MEASURES

Crucial to formulation of disease specific HRQOL instruments was the early recognition that epilepsy inflicts serious psychosocial damage on its victims. This section reviews the conceptual evolution leading to the current notion of HRQOL.

Initial efforts

As early as the mid 1900s, Lennox⁶ theorized on the consequences of epilepsy on the patient's life, family, interictal behaviour and vocation.

Two decades later, Taylor⁷ proposed a revolutionary paradigm of epilepsy which still features in HRQOL models. It distinguishes between the disease (the biological manifestation), the illness (the experience of having the disorder), and the predicament (its effect on psychosocial status). Taylor's "illness" and "predicament" provide the conceptual framework for the subjective perception and impact of epilepsy in current HRQOL instruments.

For three decades, isolated psychological and functional instruments were used in a rather disorganized fashion, focusing on individual aspects of epilepsy such as driving, return to work, affective status, cognitive function, and personality profiles, without attempting a global assessment of HRQOL.

In 1980, using a psychometric approach, Dodrill⁸ developed the first comprehensive psychosocial measure specific for epilepsy patients, the 132-item, self-administered Washington Psychosocial Seizure Inventory (WPSI). The WPSI has a narrow scope,⁹ it may not discriminate among patients with mild and severe epilepsy¹⁰ and it does not detect small but clinically important changes in response to therapy.¹¹ Nonetheless, this instrument facilitated transcultural research and paved the way for developing comprehensive HRQOL models in epilepsy.

Interview-based assessment of patients' experiences

To capture the patient's experience of epilepsy-related disability, Chaplin et al¹² identified 14 areas of concern obtained by systematic patient interviews. Items reflect "the experience of patients with epilepsy, in their words, and unstructured by professional theory and models".¹³ The instrument has adequate cross sectional validity and test-retest reliability and is available in adult and children versions. However, experience with this tool is limited. For example, in a mailed survey, 89% of recently diagnosed patients had fear of seizures and 69% had fear of stigma in employment. That concerns were less severe than in patients with chronic epilepsy supports the negative impact of chronicity on psychosocial function in this group of patients.¹⁴

Current versus anticipated self-status or image

Using a repertory grid technique, Kendrick et al¹⁵ asked patients with severe epilepsy to list items of personal importance in each HRQOL domain, rate their severity, and rate their own HRQOL relative to other people. This produced a profile of the difference between perceived and desired health status whose validity, reliability and responsiveness appear adequate.¹⁵ Although experience with this instrument is scarce, it demonstrates that discrepancy between perceived self-image and self-status is a powerful predictor of psychosocial well-being in epilepsy.

HEALTH-RELATED QUALITY OF LIFE IN EPILEPSY

Clinicians usually ask patients questions such as "How are you doing?" These questions incorporate much more than a simple seizure count, they capture the patients' subjective perception of their seizures, treatment efficacy and side-effects.¹⁶ The importance of measuring patient-centred health status and well-being in epilepsy resulted in the development of epilepsy-specific HRQOL instruments and in a growing body of literature on this topic from 1990 onwards. In addition to generic HRQOL instruments such as the Sickness Impact Profile (SIP),¹⁷ Nottingham Health Profile (NHP)¹⁸ and Short Form-36 (SF-36),¹⁹ clinicians now have access to a plethora of epilepsy-specific HRQOL tools, such as the closely related QOLIE-89²⁰ and ESI-55,¹ and Liverpool Scales.⁴ Given this array of instruments, clinicians must decide which tool is best for their particular objective.

CHOOSING THE BEST INSTRUMENT TO MEASURE HRQOL

Choosing instruments to assess outcome should be carefully considered. Wrong choices may result in uninterpretable or irrelevant data and wasted efforts. Answering the following four questions should assist clinicians in choosing an appropriate HRQOL tool:

- 1) What is the scope of the intended HRQOL assessment? This can be limited to one or a few areas of interest or include all aspects of HRQOL.
- 2) What is the purpose of measuring HRQOL? Clinicians may wish to distinguish between patient groups at one point in time, to prognosticate outcome, or to measure the amount of change in response to an intervention.
- 3) How good are the available instruments? This refers to the instrument's content and measurement properties, i.e., validity, reliability and responsiveness.
- 4) What are the practical issues in using an instrument? It is important to know its size, whether it is self- or interviewer-administered, whether training is required, and whether epilepsy patients can complete it.

Scope of HRQOL instruments

Guyatt et al²¹ have proposed a taxonomy for HRQOL instruments based on their scope. Two main categories are recognized, generic and specific. Each has advantages and disadvantages.

Generic or general instruments

These cover all the recognized domains of HRQOL. The main advantages of generic tools are comprehensiveness, broad applicability (which allows comparisons across groups of patients and conditions), and knowledge about their measurement properties gained through extensive use in diverse populations. The major disadvantages are lack of focus on relevant aspects of specific conditions, and potentially an inferior ability to detect clinically important changes, although the latter remains to be proven.

Generic instruments consist mainly of health profiles and utility indexes. Examples of health profiles include the well known SIP,¹⁷ the NHP,¹⁸ and the SF-36.¹⁹ In addition, single-item scales asking "How is your quality of life?" meet the criteria for a generic instrument.²² Utility measures provide a single number

describing the patients' valuation of their health status, ranging from 0 (death) to 1 (perfect health). Utility indexes are required for cost-utility analyses and for estimating quality adjusted life years (QALYs). The latter is a standard measure that incorporates quantity (time) and quality (HRQOL) of life, allowing for comparisons across conditions and interventions. QALYs are the current recommended standard for economic evaluations of medical interventions.²³ Commonly used utility methods are the Standard Gamble,²⁴ Time Trade Off,²⁵ Utilities Index,²⁶ Quality of Well Being Index²⁷ and EuroQOL.²⁸ For a complete treatment of utilities see Torrance.²⁹

Specific or targeted instruments

By focusing on a single condition, patient, symptom, population or function, these tools may be more responsive to change than generic tools. However, this may come at the expense of decreased comprehensiveness, and inability to compare between conditions or programmes. Their usefulness in AED trials³⁰ and epilepsy surgery has been proven.^{11,31} For instance, pain or mobility, commonly assessed by generic instruments, are of marginal importance to epilepsy patients. On the other hand, stigma and cognitive function, both important in epilepsy, are assessed by epilepsy-specific instruments. A combination of generic and specific instruments is probably a good compromise. This is accomplished in a closely related set of epilepsy-specific instruments, the QOLIE-89²⁰ (and its abbreviated versions the QOLIE-31³² and QOLIE-10³³) and ESI-55,¹ by adding epilepsy-specific items to a widely used generic instrument, the SF-36.¹⁹ In the Liverpool HRQOL model this is achieved by using a number of independent generic and epilepsy-specific scales as a battery.⁴

Purpose of HRQOL instruments

Not all HRQOL instruments serve all purposes. Thus, one must define the clinical question in order to choose the best instrument to answer it. In general HRQOL is measured for three reasons:³⁴

- 1) To distinguish between individuals or groups on an underlying dimension, eg., does HRQOL vary by type and

severity of epilepsy.³⁵ Instruments used for this purpose must have adequate discriminative properties.

- 2) To predict which patients will develop a specific outcome as compared to an available criterion standard, eg., the Karnofsky scale for cancer patients has important predictive usefulness. These tools must have proven predictive properties.
- 3) To measure change within patients over time, either as a result of natural history or clinical interventions, eg, is the amount of improvement in HRQOL after epilepsy surgery substantial or clinically relevant? Such instruments must show adequate responsiveness.¹¹

Ideally, an instrument should have demonstrated usefulness for all three functions. Formal research has shown that several of the generic tools have such versatility, eg., the SIP,¹⁷ the NHP¹⁸ and the SF-36.¹⁹ However, general statements such as "this is a validated instrument" are meaningless when choosing an instrument, unless information about validity, reliability and responsiveness is provided. Clinicians must keep in mind that ability to discriminate between patients groups does not guarantee ability to measure change over time.¹¹ In epilepsy surgery, as in any other intervention, clinicians are interested in measuring within-patient improvement over time. Therefore, instruments used to assess outcome must have proven responsiveness. Epilepsy-specific instruments with demonstrated responsiveness include the Liverpool battery of instruments,³⁶ ESI-55,¹¹ and QOLIE-89.³⁷

Instrument content and measurement properties

For a review of desirable measurement attributes of evaluative HRQOL instruments see McDowell,³⁸ Nunnally,³⁹ and Guyatt.⁴⁰ In general, in addition to content validity (are the items relevant, comprehensive, and unambiguous), the evaluative instrument must show evidence of responsiveness. The latter assesses the signal-to-noise ratio in evaluative instruments, the same way reliability does so in discriminative instruments. The signal refers to true within-subject change over time, and noise denotes within-subject differences

Table: The choice of HRQOL tool depends on the study objectives, clinical circumstances and instrument measurement properties.

Purpose	Candidate Instruments*
Obtain a general health status measure:	
Brief instruments	SF-36, HUI-3, EuroQol, NHP
Longer instruments	SIP
Compare epilepsy with other diseases	SF-36, SIP, NHP, HUI-3, EuroQol
Obtain QALYs (for cost-effectiveness studies)	HUI-3, EuroQol
Obtain epilepsy-specific health status measure:	
Brief instruments	Liverpool scales, QOLIE-31, QOLIE-10
Longer instruments	QOLIE-89, ESI-55
Measure change in health status due to interventions or to evolution of disease	QOLIE-89, ESI-55, SF-36, Liverpool scales
Measure seizure severity	Liverpool scales, NHS scale
Measure AED adverse events	Liverpool scales
Measure impact of epilepsy	Liverpool scales

*See text for abbreviations and descriptions

unrelated to true within-subject change. Responsiveness, therefore, refers to the instrument's ability to detect minimum clinically important differences in the condition of interest. Minimum clinically important difference may be defined as the change in health status perceived by the patient (or physician, depending on the viewpoint) to be of sufficient magnitude to require treatment, in the absence of unacceptable side effects.⁴¹ If responsiveness has not been established, at the very least there should be no ceiling or floor effects of the scores (score clustering at the extremes of the possible range), i.e., they must be potentially changeable.⁴⁰

Viewpoint of HRQOL measurement

The viewpoint in HRQOL studies refers to who interprets the patient's experience related to health. This is an important determinant in choosing a HRQOL instrument. The three major viewpoints frequently adopted in HRQOL assessment are the clinician's, the patient's, and less frequently society's, i.e., society attributes a certain value to a given health state.⁴² Clinicians are most interested in capturing the patient's subjective experience of a particular health state. Therefore, patient-centred measures are preferable.

A summary of recommended, validated HRQOL instruments is presented in the Table. These recommendations should be tempered by clinicians' preferences, as well as by the caveats described above regarding choice of instrument.

PRACTICAL ISSUES IN USING HRQOL INSTRUMENTS

Respondent burden

This refers to the time and effort required to complete one or a set of questionnaires. The problem is not inconsequential. Lengthy, difficult or ambiguous questionnaires are likely to be answered incompletely, carelessly or not at all. This results in unreliable data or in high rates of noncompliance. A similar problem may be encountered by administering questionnaires too frequently. The following are recommended:

- 1) Look for published evidence of respondent burden for candidate instruments, i.e., time it takes to complete, and reported response rates.
- 2) Read the questionnaire and assess its content, clarity and size.
- 3) Select a feasible number of instruments.
- 4) Plan frequency of administration carefully in order to avoid noncompliance (too frequent) or missing a lot of information (not frequently enough). A reasonable minimum may be baseline and one pre-established follow-up.
- 5) Pretest the instrument set before administering it widely. This extra bit of initial work is worth the effort.

Administering the instrument

The manner in which instruments are used is no less important than their measurement properties. Inappropriate use of a good tool will produce uninterpretable or biased results. Unwary clinicians often incur the following errors:

1) Modifying the questionnaire

It is difficult for clinicians to resist the temptation to add, delete, or reword a questionnaire to their specific liking, and then analyse and report results as per the original. This is a dangerous

practice. Unless the changed instrument is subjected to formal validation, one cannot be assumed that data obtained with it are equivalent to data obtained with the original version. Only two alternatives exist: a) Use the unmodified instruments, adding other tools to capture areas of interest as needed. b) Design and validate a new instrument, which is a labourious endeavour.

2) Using the wrong administration technique

Specific tools are designed for specific modes of administration. They may be strictly self- or interviewer-administered, and some can be used in either way. The developers' guidelines should be followed in this respect.

3) Administering instruments in an inconsistent fashion

Variations in mode and timing of administration introduces noise and bias. For instance, interviewer administration of selected patients may allow advertent or inadvertent coaxing by the interviewer (bias), or decrease precision of responses (noise). By the same token, all patients should receive the same amount of instruction. Similarly, variations in time of administration ignore the fact that HRQOL is not static, i.e., it changes with time.⁴³ If changes occur in a particular direction, e.g., worsening with time, results may be biased or diluted by including early measurements. For example, reports stating that "HRQOL was measured one to two years after surgery" should be cautiously interpreted.

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