Drug addiction maintenance treatment and quality of life measurements

Giedrius Vanagas, Žilvinas Padaiga, Emilis Subata[1]
Department of Preventive Medicine, Kaunas University of Medicine
[1]Psychiatry Clinic, Faculty of Medicine, Vilnius University

Summary. *Quality of life measurements are increasingly incorporated into trials of pharmaceuticals. This can be applied to a wide range of medical areas including drug-addiction maintenance treatment programs. Maintenance treatment has been demonstrated to be an effective treatment for opioid addiction but still lacks quality of life specific measures to measure the maintenance program effects and until now there have been only few attempts to assess the impact of opioid dependence and its treatment on the drug-addicted patients' quality of life.*

The aim of this article is to describe quality of life concept, measurement instruments, selection criteria and its applicability in the drug addiction maintenance studies.

Introduction

Maintenance treatment has been demonstrated to be an effective treatment for opioid addiction and reduce the incidence of HIV (1–4). Although methadone or other maintenance treatment has been successful (5), but it was associated with a wide range of problems (6–11) (up to 50% of methadone patients withdrew from treatment in the first 6 months (7, 12) and other).

Quality of life (QoL) evaluation represents an assessment of the impact of maintenance treatment on addicted patient's functioning and well-being.

There are three broad applications of these scales:
1. Descriptive studies – QoL of various populations is measured and compared;
2. Association studies – patient characteristics are associated with QoL;
3. Intervention studies – QoL is used as an outcome variable.

QoL concept reflect the subjective perception of a drug-addicted patient's well-being and functioning, pertaining to physical, emotional and social aspects as well as everyday life activities (13). QoL measurements are increasingly incorporated into trials of pharmaceuticals (14–17). This can be applied to a wide range of medical areas including drug-addiction maintenance programs (18–21) but until now there have been only few attempts to assess the impact of opioid dependence and its treatment on the drug-addicted patients' quality of life (22–24).

In general, we argue that individual and differences play an important role in moderating the manner in which they respond to life circumstances (25, 26). These differences then play out in turn in the quality of life that is experienced.

The aim of this article is to describe quality of life concept, measurement instruments, selection criteria and its applicability in the drug addiction maintenance treatment studies.

Quality of life

Many aspects of human suffering (or its absence) can be reliably measured. One of the approaches to this difficult yet invaluable task makes use of the concept of "quality of life". This concept, developed in the social sciences, was first applied in medical practice to determine if available cancer treatments could not only increase the survival time of patients but also improve their sense of well-being (27, 28). The concept of quality of life was later applied to drug addiction studies in terms of functioning, well-being, and life satisfaction (16, 18, 29).

According to D. L. Patrick and P. Erickson, life has two dimensions: quantity and quality. Quantity of life is expressed in terms of biomedical data, such as mortality rates or life expectancy. Quality of life refers to complex aspects of life that cannot be expressed by using only quantifiable indicators; it describes an ultimately subjective evaluation of life in general. It encompasses, though, not only the subjective sense of

Correspondence to G. Vanagas, Department of Preventive Medicine, Kaunas University of Medicine, Eivenių 4, 50009 Kaunas, Lithuania. E-mail: vanagas.g@kmu.lt

well-being but also objective indicators such as health status and external life situations (31). Data about quality of life can be used to estimate the impact of maintenance program using different treatment modalities (such as methadone with and without ancillary services) and to differentiate between two therapies with marginal differences in well-being, crimes, HIV or hepatitis incidence (5, 28).

Subjective multidimensional definition of health-related quality of life was proposed by D. L. Patrick and P. Erickson (30): "the value assigned to the duration of life as modified by the social opportunities, perceptions, functional states, and impairments that are influenced by disease, injuries, treatments, or policies". N. K. Aaronson et al (32) suggested that the assessment of quality of life should comprise at least the following four domains: 1) physical functional status, 2) disease and treatment related physical symptoms, 3) psychological functioning, and 4) social functioning. Additional domains that are of particular relevance to specific demographic, cultural, or clinical populations may sometimes need to be included in the assessment to increase the latitude of analysed QoL dimensions covered (32). R. A. Cummins et al (33) reviewed 27 definitions of quality of life. Their review suggests that 85% of the definitions included emotional well-being, 70% health, 70% intimacy issues, and 56% work and activities related to productivity.

The aim of the QoL evaluation is to go beyond the presence and severity of symptoms of disease or side effects of treatment, examining how drug-addicted patients perceive and experience its effects in their daily lives (34–36). This information can be used by both clinicians and drug-addicted patients to make treatment decisions, there is nothing more relevant than basing this decision on the drug-addicted patient's own QoL assessment (19, 23, 36–39).

QoL is defined as the subjective assessment of the impact of disease and treatment across the physical, psychological, social and somatic domains of functioning and well-being (40). Some authors have suggested that a minimum of three domains – physical, psychological and social which are essential to any assessment of QoL (41); while others have indicated that physical and psychological domains alone are sufficient (42). Regardless of the specific assessment approach used, a comprehensive assessment of QoL, consistent with the accepted multidimensional definition of this construct is recommended because it offers a balanced evaluation of multiple areas of functioning and well-being.

Quality of life instruments

QoL measurements range from the broad level of community well-being to the evaluation of single individual in specific contexts. R. A. Cummins (43) found more than 100 instruments measuring and defining QoL in different ways. No doubt the various approaches to life quality derive at least in part from the fact that researchers differ in what they choose to emphasize as being important in determining people's QoL (44) but QoL still lacks specific measures for the maintenance program effects.

The instruments may be global, generic or specific. Deciding which to develop will be dependent on the aims, methodological concerns, and practical constraints of the investigation.

Global measures are those designed to measure quality of life in the most comprehensive or overall manner. This may be a single question that asks the person to rate his/her overall life quality.

Generic QoL measures have much in common with global measures and were designed primarily for descriptive purposes. In health care they try to delineate full impact of a disease or its symptoms on the patient's life. Generic measures summarize a spectrum of domains and dimensions of health that apply equally and broadly to diverse conditions or populations, and usually contain the domains of physical, mental, and social health and are applicable to a wide range of populations. They are not designed to identify important, disease specific dimensions, which are often essential for the measurement of the outcome of a particular disease, or for detecting important clinical changes. They can be used with both drug-addicted and healthy populations, have special merit in situations where comparisons across different treatments or between sick and healthy groups are required. The disadvantage is that they may not address topics of particular relevance for a drug addiction and lack in sensitivity to measure specific drug addiction related QoL condition.

Specific measures were developed to monitor the response to treatment or to detect small, meaningful changes in specific conditions to which generic measures may be insensitive (28). They can be divided as disease or population specific and dimension specific measures.

Disease or population specific measures contain domains and dimensions that are designed to be valid only for a specified condition or population (42, 45). Disease specific measures, therefore, maximize content validity and provide for greater sensitivity and

specificity; however they cannot be used to compare QoL across conditions or populations (including control groups from the general population) and may be less relevant for measuring the general QoL of the target population.

Dimension specific measures focus on a particular problem within a patient group such as pain, fatigue, physical functioning. These measures are useful for monitoring specific problems that are to be addressed by an intervention.

In many situations all types of QoL measures are of value and can be used in combination to facilitate the investigator's ability to compare between populations (generic) and identify specific areas of problems for different patient groups (disease or dimension specific).

Several validated generic and specific instruments can be regarded as adequate QoL measures for drug-addicted patients. It is suggested that future studies addressing QoL should employ a combination of generic and specific instruments to maximize validity of the data (Table).

Methodological considerations

Domains. Measurement of drug-addicted patient's QoL is based on the assessment of the individual's perception of the impact of a series of medical and non-medical issues concerned with physical, mental (or emotional), and social functioning, concepts of global perception of function and well-being can also be addressed (42). Dimensions or items (questions) are components of a domain of health. For example the domain of physical functioning might include dimensions of self-care, activity and mobility; social functioning might include peer and family relationships. The domains (dimensions) of health that have been identified must reflect the perceptions and priorities of the individuals within the given population.

Validity. Validity is concerned with the degree to which a test or instrument measures what it is supposed to measure (42, 46) An instrument is only as valid as it measures the concept that it was designed to measure. Validity includes: face validity, content validity, criterion validity, concurrent validity, predictive validity and construct validity.

Construct validity. Construct validity is concerned with formulating and measuring theoretical constructs or hypotheses and identifying whether the instrument adequately reflects the stated hypotheses or theory (45, 47). If the predictions made on the basis of theory are not confirmed, then the problem could be with the validity of the measure or with the validity of theory. It can be examined using QoL questionnaires in two complementary evaluations. Low scores on a QoL scale of psychological well-being, for example, should predict high scores on a standard structured interview for depressive symptoms. This type of validity is generally divided into convergent and discriminative validity. Convergent validity requires correlation with related variables. Discriminative validity requires that the instrument should demonstrate that a measure does not correlate with other measures, which are unrelated and intended to be different (42, 48).

Content validity. Content validity provides data on whether the domains and dimensions defined by researchers adequately capture all the potential concepts and restrictions perceived to be relevant by and to the population being assessed (49). The number of items in each domain should also reflect its importance to the attribute. For example, potential aspects of physical functioning represented and do the chosen items correspond to what its constructors claim that they are measuring?

Face validity shows does the instrument look like it measures the concept? Face validity represents a simplified version of content validity and relates to how sensible a given measure/indicator is to an intelligent audience (50). If something is not sensible at face value or is ambiguous then face validity is unconvincing.

Criterion validity. The value of quality of life questionnaires in medical research rests squarely upon their validity, and physicians cannot interpret quality of life measures until the instruments were being assessed are adequately established. Validity can be examined in several ways, comparison with the best indicator available (criterion validity) is the preferred method (45, 47, 48). Criterion validity is the measure related to another measure of the same concept or phenomenon? In order to measure this, another equally valid instrument is needed and relates to the extent to which a measure of QoL produces the same results as an existing measure in a predictable manner (48).

Predictive validity and concurrent validity can also be tested. Predictive validity refers to the measures capacity to correlate with existing measures in predictable ways (45). In evaluating quality of life measures of functioning, self-reported physical abilities should correlate closely with behavioral performance that is defined objectively and measured directly. If a domain produces results that correlate with those obtained using the standard this demonstrates concurrent validity (47).

Table. **Instruments regarded as adequate quality of life measures for drug-addicted patients**

Instrument	Type	Scaling	Measures
Quality of Life Visual Analogue Scale	Global	0–100	Global satisfaction and well-being
Munich List of Life Dimensions	Global	0–10	Satisfaction and importance
WHOQoL	Generic	5-point scale	Physical, psychological health and well-being, social relations, environment, getting new knowledge
Euroqol EQ-5D	Generic	3-point scale 0–100	Mobility, self-care, usual activities, pain/discomfort, anxiety/depression + visual analogue scale
Lancashire Quality of Life Profile	Generic	Yes, No	Work, leisure, religion, finance, living situation, legal and safety, family relations, social relations, and health. It also incorporates global life satisfaction, visual-analogue scale
Sickness Impact Profile (SIP)	Generic	Yes, No	Physical (ambulation, mobility, body care), psychosocial (social interaction, communication, alertness, emotional behavior), other (sleep/rest, eating, work, home management, recreation)
Nottingham Health Profile	Generic	0–100	Energy level, pain, emotional reaction, sleep, social isolation, physical abilities
Short Form-36	Generic	0–100	Physical functioning, role-physical, bodily pain, mental health, role-emotional, social functioning, vitality, and general health perceptions
Quality of Life Questionnaire	Generic	7-point scale	Living situation, finances, leisure, family, social life, health, access to medical care
Quality of Well-being Scale	Generic	0–1	Symptom/complex, mobility, physical activity, and social activity
Opioid Withdrawal Scale	Specific, addiction	0–4	Addiction related symptoms
Zung Self-Rating Depression Scale	Specific (depression)	4-point scale	Depression
Beck Depression Scale	Specific (depression)	0–3	Mood, sense of failure, crying spells, body image and other feelings associated with depression
Mental Health Inventory	Specific (psychology)	1–6	Anxiety, depression, loss of behavioral/emotional control, positive affect, interpersonal ties
Multidimensional Pain Inventory	Specific (pain)	0–6	Pain severity, behavioral responses of others to displays of pain as punishing, activities check-list
Quality of Life Index for Mental Health	Specific (mental health)	Individually weighted	Life satisfaction, occupational activities, psychological well-being, physical health, social relations, economics, activities of daily living, symptoms, and goal attainment

Statistical methods can also be used to provide evidence on validity, such as factor analysis or principal component analysis. These methods can identify items, which correlate and can provide a statistical basis for the identification of dimensions. If the hypotheses are proved and questionnaire scores correlate with self-report data from established instruments measuring similar things and with the same construct assessed with different methods then validity is seen to be sound. Instrument can be applied to different populations, which are known to differ in terms of the concept being measured (45, 47).

Accuracy and reliability. Quality of life assessments of mental functioning generally include questions on memory. Self reported information in this area raises particular concern because neurological or psychological dysfunction can limit a patient's ability to report accurately (47, 51). In other words, we seek accurate information on cognitive abilities when dysfunction in this area might make the patient's judgments unreliable. Drug abuse and other forms of psychopathology can present a problem in this regard (47).

The reliability of a measure is the extent to which it consistently yields the same results in repeated applications on an unchanged population or phenomenon, in a reproducible manner (36). The key components of reliability are test-retest reliability where respondents give consistent responses when is measured at two different points in time (where there is no change in health status), intra-rater agreement where respondents give the same scores of the same subjects on different occasions, inter-rater agreement where the same scores achieved by different raters on the same occasions (45).

Sensitivity of an instrument is crucial for evaluative purposes. Sensitivity or responsiveness refers to the ability of a measure to detect hypothesized changes such as treatment effects over time. Sensitivity to change can be explored either through experimental or longitudinal designs.

Administration. When considering the mode of administration of a quality of life measure a number of issues need to be addressed, as a balance of maximizing compliance and reducing costs often needs to be made. Three standard formats are generally used in QoL measurements of drug-abused persons:

Face to face interviews can be used when is limitation in ability to concentrate on the questionnaire or understanding of some of the questions may require assistance. This is costly but compliance is high. It is of course essential to minimize interpretation of the questions by the interviewers and inter-rater reliability should be assessed (45). Wherever possible the interviewers should be independent of the investigators.

Telephone interview is less costly than face-to-face interview administration but achieves a lower compliance rate than face-to-face interview.

Self-report questionnaires. Although quality-of-life data can be collected in interviews or through patient diaries, most studies now employ self-report questionnaires, the most cost-effective method for obtaining patient-related information. Response rates tend to be lower than with other approaches but administration costs are minimized and questionnaires can be mailed from the investigating center (45). However validity issues in case of anonymity may be raised, particularly when used with drug-abused person.

Factors affecting quality of life scores in drug abuse

The assignment of QoL values to different health problems can be viewed as a classic problem of measurement involving the construction of a scale with a continuous unit of measurement. It is not surprisingly that people attach different QoL values to different health states. Preference information about health is usually obtained by asking respondents to assign values or ratings to imagined specific health states. Several standard scaling methodologies for determining these preferences have been proposed but agreement has not been reached regarding their validity and reliability (52, 53). There is controversy about other aspects that may affect preferences (28, 47, 54). Some authors have suggested that socio-demographic characteristics of people as well as the experience may influence QoL values (55). It is also important to mention that studies might be inconsistent because their results are based on small numbers of observations and on non-valid and/or reliable measures. It is also possible to get contrasting results which are related to the nature of the scaling methods (34, 41, 48, 56–58) used in these studies.

Personality. Subjective quality of life scores can also be influenced by personality factors. Personality and QoL suggests that personality factors can impact on health outcomes people receive, which in turn can impact favorably or unfavorably on life quality and QoL scores. Scores can be affected by the characteristics that predate the maintenance treatment (25, 26, 55).

With regard to predicting different levels of QoL indicators, it might be that personality is particularly related to broader indicators of life quality, such as life satisfaction. Given that personality affects an individual's characteristic pattern of behaviors across a large number of life domains, we might be more successful in identifying the beneficial effects of personality if we look at aggregated indicators of QoL. Thus, a person may be more successful in establishing objective indicators of QoL and may also report high levels of subjective well-being. We may improve our understanding of pathways to QoL by conceptualizing personality as part of the theoretical model (54).

Changes over time. How patients evaluate their QoL may also change over time. The internal standard by which patients appraise their current state shifts and the same questionnaire items on well-being can elicit fundamentally different answers over time. To the extent that subjective well-being reflects psychological adaptation, the connection between subjective QoL and maintenance treatment response. For example: patients who are not prepared for the possibility of precipitated withdrawal are more likely to be distressed and confused by its onset, with potential negative consequences (e. g. treatment drop-out, abuse of other medications). Therefore, reported changes in QoL over time need not necessarily derive from actual changes in health or symptoms (47, 56).

Extraneous factors. Subjective quality of life indices ideally should not be influenced by patient characteristics that are outside of the domain of disease and health care. Patterns of response in questionnaires do vary with marital status, education, income, race, and geography, and, furthermore, are influenced by a variety of extraneous psychological factors (26, 47, 59).

Discussion

No single definition of QoL is universally accepted (60). QoL represents a broad range of human experiences related to overall well-being. It implies value based on subjective functioning in comparison with personal expectations (36, 61) and is defined by subjective experiences, states and perceptions (36). Scope of the concept of QoL should be centered on the individual's subjective perception of the life quality because QoL, by its very nature, is idiosyncratic to the individual (36, 40, 60, 62) and intuitively meaningful and understandable to most people. There is, however, a degree of consensus regarding the minimal requirements for an operational definition of QoL for employment in health status assessment and research. The term QoL has meaning beyond an individual's health (62) and is influenced by perception physical, psychological, social, economic, and political environment. A distinguishing characteristic of QoL assessment is the incorporation of patient values and judgments, which is, their individual preferences (60).

Assessment of QoL is now acknowledged as a central component of health care and healthcare research. QoL measures need to be more routinely included in evaluations of alterative treatments. Self-reported information obtained from QoL questionnaires enables us to understand the total burden of treatment experienced by drug-addicted persons (63). Choosing an appropriate measure and using it in practice can be problematic. Difficulties in assessing the relative impact of the complex experiences that ultimately determine perception of QoL can be resolved by covering a certain number of conventionally defined domains (64) and it is recommended to concentrate research on aspects of life quality that are related to health and drug addiction (22, 32, 34, 61, 64). Conceptual and methodological issues that underlie matters of definition, measurement objectives, and instrument validity have received insufficient attention and thereby constrain permissible interpretation of the current medical literature. The practical problems in developing QoL measures are real (65, 66). The demand that measures have robust statistical properties is very difficult to meet, since satisfactory determination of reliability and validity requires the involvement of large numbers of drug addicted persons.

We must always be sensitive to individual circumstances of drug-addicted person and acknowledge that some may find it to be influencing reporting on QoL scores. Deciding to use a measure, however, presupposes that patients are able to assess their own life quality and complete a QoL measure. Some drug addicted patients in some conditions are unable to do this because of cognitive impairments, communication deficits, severe distress caused by their symptoms, or because the QoL measure is too burdensome physically or emotionally (66).

Despite the growing interest in this area, there remains some skepticism about the ultimate value of including QoL assessments either in clinical trials or as part of routine assessments. Different approaches of QoL measurement underlying the economic or psychological approaches and methods of data collection and analysis vary substantially. Lack of theoretical direction to definition and measurement of QoL still exist. New measures need to be theoretically driven and take more account of developmental changes in QoL (36, 41, 65).

Conclusions

Quality of life refers to complex aspects of life that cannot be expressed by using only quantifiable indicators; it describes an ultimately subjective evaluation of life in general. Quality of life research in drug-addicted patients should employ a combination of generic and specific instruments to maximize validity of the data. There are several instruments, which can be regarded as adequate quality of life measures for drug-addicted patients. Deciding which to use will

be dependent on the aims, methodological concerns, and practical constraints of the investigation but we must always be sensitive to individual circumstances of drug-addicted person and acknowledge that some may find it to be influencing reporting on quality of life scores.

Pakaitinis priklausomybės nuo opioidų gydymas ir gyvenimo kokybės įvertinimas

Giedrius Vanagas, Žilvinas Padaiga, Emilis Subata[1]
[1]*Kauno medicinos universiteto Profilaktinės medicinos katedra*
[1]*Vilniaus universiteto Medicinos fakulteto Psichiatrijos klinika*

Raktažodžiai: priklausomybė nuo opioidų, pakaitinis gydymas, gyvenimo kokybė, klausimynai, metodika.

Santrauka. Gyvenimo kokybės įvertinimas – plačiai naudojamas atliekant vaistų klinikinius tyrimus, taip pat sėkmingai gali būti taikomas daugeliui sveikatos priežiūros paslaugų, tarp jų ir priklausomybės nuo opioidų pakaitinio gydymo rezultatams įvertinti. Tyrimai rodo, kad priklausomybės nuo opioidų pakaitinis gydymas veiksmingas, bet iki šiol atlikta vos keletas tyrimų, kur buvo įvertintas šio gydymo poveikis gyvenimo kokybei. Nėra visuotinai priimtinos nuomonės, kokie klausimynai turi būti naudojami, trūksta specifinių gyvenimo kokybės vertinimo klausimynų, kur būtų vertinamas priklausomybės nuo opioidų pakaitinio gydymo poveikis programos dalyvių gyvenimo kokybei.

Šiame straipsnyje aprašoma gyvenimo kokybės definicija, jai vertinti naudojami klausimynai, jų parinkimo kriterijai ir pritaikomumas priklausomybe nuo opioidų sergančių žmonių gyvenimo kokybei ir gydymo veiksmingumui vertinti.

Adresas susirašinėjimui: G. Vanagas, KMU Profilaktinės medicinos katedra, Eivenių 4, 50009 Kaunas
El. paštas: vanagas.g@kmu.lt

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