Health Related Quality Of Life (Hrqol) In COPD

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Citation

Abstract

Over the past decade, more and more research on the development and validation of questionnaires has been undertaken to quantify the impact of disease on daily life and well-being from the COPD subject's point of view. Health-related quality of life is an important outcome of medical care. HRQOL incorporates several dimensions experienced by the patient that are affected by disease and health. COPD patients come to physicians seeking relief of symptoms that include breathlessness, cough, sputum production, and functional limitation due to exertional dyspnea. Therefore interventions that would reduce these symptoms and improve function of patients are of prime importance. HRQoL measures do not substitute for physiologic parameters, but can complement these by incorporating aspects of health and disease that are directly perceived by the patient.

INTRODUCTION

In the past three decades, a number of important advances have been made in the treatment of patients with chronic obstructive pulmonary disease (COPD) (Pauwels RA et al ,2001) . For example, supplemental oxygen therapy and smoking cessation have resulted in improved traditional outcome measures, such as mortality (Nocturnal Oxygen Therapy Trial Group,1980) and rate of forced expiratory volume in one second (FEV_1) decline (Anthonisen NR et al ,1994) . Although these end-points are important to clinicians and patients alike, survival and physiological measures do not fully represent the experiences of patients with COPD. Relying exclusively on mortality and physiological outcomes for evaluating treatment effectiveness could result in the decision that some treatments offer no benefits, when in fact they provide significant and important benefits to patients and their families. A treatment that has no effect on mortality or FEV_1, for example, may significantly improve the patient's vitality or other functional areas of daily living. Needless to say, reducing the personal and social burden of disease by improving patient's symptoms, functional status and quality of life are important goals. Self-perceived health outcomes are often most relevant and important to patients and their loved ones because they capture the patient's experiences and perspectives.

Increasingly, it has been recognised that health status, especially health-related quality of life, is an important outcome of medical care (Guyatt GH et al ,1993) . The

development of reliable and valid tools that measure health status has contributed to a substantial increase in the use of these instruments. Since more of these tools are being used and reported, it is important for clinicians and researchers to understand their strengths and limitations.

HRQOL - TERMS, DEFINITION AND CONCEPTS

Health outcomes represent a broad group of end-points used in clinical research to assess the efficacy or effectiveness of interventions and to assess disease outcomes (Clancy CM & Eisenberg JM , 1998). Traditional health outcomes include mortality, number of hospital admissions and FEV1. More recently, there has been a growing body of research concerning endpoints that are assessed directly by patients and can be termed "patient-reported health outcomes" (PRO) .It is an umbrella term used for all patient-based assessments. PROs are by definition subjective and multidimensional. Examples of PROs are outcomes such as health status, health utilities, adherence to treatment and patient satisfaction with healthcare. Health status can be defined as the impact of health on a person's ability to perform and derive fulfilment from the activities of daily life. A patient's self-reported health status thus includes health related quality of life and functional status.

Various definitions of HRQL exist. The World Health Organization (WHO) definition of health is "not merely the absence of disease, but complete physical, psychological, and social well-being" (WHO, 1958) . HRQL refers to the physical, psychological and social domains of health that are

unique to each individual (Testa MA & Simonson DC, 1996) . Each of these domains can be measured by the objective assessments of functioning or health status and the subjective perceptions of health. Other valued aspects of life exist that are not generally considered as "health," including income, freedom, and the environment It has been defined as follows: "HRQL is defined as the value assigned to duration of life as modified by impairments, functional states, perceptions, and social opportunities that are influenced by disease, injury, treatment, or policy" (Patrick DL, Erickson P,1996) . Another definition is "HRQL can be defined as the functional effect of an illness and its consequent therapy upon a patient, as perceived by a patient" (Schipper H et al, 1996).

Conceptually, HRQOL incorporates several dimensions experienced by the patient that are affected by disease and health Figure 2.5 .This includes symptoms, physical function, cognitive performance, psychosocial condition, emotional status, and adaptation to disease. Though the severity of disease is an important determinant of the patient's health, patient perception and adaptation largely defines the overall quality of life.

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Over the past decade, more and more research on the development and validation of questionnaires has been undertaken to quantify the impact of disease on daily life and well-being from the COPD subject's point of view. This is because of recognition of the following factors:

Individual patients are most concerned about their symptoms (eg, dyspnea) and their function (eg, ability to perform physical tasks), rather than objective measures such as expiratory airflow;

HRQOL is a unique construct that is different from physiologic measures or survival (Feinstein AR ,1983)

The goals of therapy have been expanded to include relief of symptoms and improvement in HRQOL in addition to the standard physiologic outcomes. (Guyatt, GH et al 1987)

WHY MEASURE HEALTH-RELATED QUALITY OF LIFE IN COPD?

Specific outcomes, such as spirometric measurements, may have greater appeal because of their relative simplicity and apparent link with pathophysiology. Besides, the combined effect of different treatments presumed to improve a particular physiologic parameter may not necessarily lead to

better patient comfort and quality of life. Miravitlles et al. observed worse HRQoL in patients who received three or more drugs for COPD despite adjustment for severity of disease and comorbidities. Though the possibility of confounding by indication exists, this can also be due to unwanted side effects of overzealous treatment. Even from a physiologic standpoint, a single parameter such as the FEV_1 may be a good indicator for airflow obstruction, but may not be a good indicator of dynamic hyperinflation causing dyspnea. (Belman MJ et al 1996) Perhaps the most important, though often overlooked, reason to consider HRQoL as an outcome is the patient's perspective. COPD patients come to physicians seeking relief of symptoms that include breathlessness, cough, sputum production, and functional limitation due to exertional dyspnea. Therefore interventions that would reduce these symptoms and improve function of patients are of prime importance. HRQoL measures do not substitute for physiologic parameters, but can complement these by incorporating aspects of health and disease that are directly perceived by the patient.

HEALTH-RELATED QUALITY OF LIFE: INSTRUMENTS FOR MEASUREMENT

A number of instruments have been developed to assess HRQoL. These can be classified into three main types: generic, disease-specific/situation-specific and Preference based questionnaires

GENERAL HEALTH QUESTIONNAIRES

Generic HRQOL instruments are broadly applicable to different health problems. Generic measures are broader in scope and applicability. The strengths of generic measures are that they are capable of detecting the effects of the diverse aspects one disease beyond those captured by a disease-specific measure and they are capable of comparing health status across multiple diseases (Ren XS et al 1988). In addition, these measures may be more likely to detect unexpected effects of an intervention that does not relate to respiratory health. No definitive evidence in head-to-head comparisons supports the use of one generic health-status measurement over another in COPD. Domains that reflect physical limitations generally share similar correlations to a 6-min walk and FEV_1 (Guyatt, GH et al 1987)

A number of generic health-related, quality-of-life instruments have been used to characterise COPD. The following is a discussion of the instruments that are most widely used.

Sickness Impact Profile (SIP) The Sickness Impact Profile (SIP) was developed in 1972 as a result of collecting statements describing behavioural dysfunction attributable to illnesses from sick and healthy patients, as well as professional and non professional caregivers. This 136-item questionnaire covers a broad number of domains and dimensions that include physical activity (ambulation, mobility, body care and movement), psychosocial functioning (societal interactions, alertness behaviour, emotional behaviour and communication), as well as five independent domains: sleep and rest, eating, work, home management, and recreation and past-times (Bergner M et al, 1981). The SIP has been well validated and demonstrated to be reliable and responsive among patients with COPD (Engstrom EP et al, 2001). It has been used to describe the effect of COPD on patient's health status, although it may not be discriminative of mild COPD. This instrument was designed to be either interviewer- or self-administered. Its major disadvantage is the relatively long time it takes to complete, which isy20–30 min. Another potential disadvantage is that no studies clearly demonstrate how to define the MID in scores.

Medical Outcome Study Short Form -36 The MOS questionnaire has undergone a number of revisions. The most commonly used form is the previously mentioned SF-36. This instrument has been demonstrated to be reliable and responsive in COPD(Mahler DA & Mackowiak JI. 1995). The SF-36 is divided into eight domains: physical-functioning, role-physical, bodily pain, general health, vitality, social-functioning, role emotional and general health. The SF-36 also has two summary scores, a physical component scale and a mental component scale that were developed with factor analysis. The SF-36 offers significant advantages in that it is self-administered, easily completed in 5 min and has been translated and validated in several languages. Although not originally designed to be a utility measure, attempts have been made to create a single index to be used in the calculation of QALYs (Brazier JE, et al 1998) . The MID of the SF-36 is reported to be five units, although this has not been replicated in patients with COPD (Ware JE Jr et al 1993)

Nottingham Health Profile (NHP) The NHP uses statements that measure departures from "normal" functioning by affirming particular statements or items that describe health status. The first part contains 38 items that fall into six domains: physical mobility, energy, sleep, pain, social isolation and emotional reactions. The second section contains seven items that address areas of daily living affected by a patient's health status (Hunt SM, et al 1980) . This instrument has been demonstrated to be valid and reliable among patients with COPD (van Schayck CP, et al 1995) and has been administered among patients with COPD in trials of LVRS , inhaled corticosteroids, bronchodilator and pulmonary rehabilitation. Very little data exist regarding how much difference represents an MID. This instrument is self-administered and can be completed iny10 -15 min.

Quality Well Being (QWB) The QWB is a health-status instrument that was developed as part of the Health Status Index (Fanshel S & Bush J. 1970) . It contains three scales: mobility, physical activity and social activity. Questions determine the functional level of each scale. Weighted values for the different combinations of functional level and symptomatology on each scale were assigned from a randomly selected population-based sample. Interviewees responding to questions were assigned values derived from the population based sample. This method of scoring allows for the QWB to be transformed to a scale from zero to one and has the unique advantage of being able to be used to calculate QALYs in cost-effectiveness analysis, meaning that the QWB is the only health-status measure described here that allows for the calculation of QALYs. A single cross-sectional study has been performed; demonstrating validity among patients with COPD (Kaplan RM, et al 1984) and it is unclear what scoring difference counts as an MID. This instrument can be either interviewer or self-administered and takes 20 min to complete.

DISEASE SPECIFIC QUESTIONNAIRES

The disease- or condition-specific instruments focus on one condition and attempt to define its effects on a patient's health status.

Chronic Respiratory Disease Questionnaire (CRDQ) CRDQ was developed more than 10-yrs-ago through qualitative interviews of patients with chronic lung disease and it has been used comprehensively in examining health status of COPD patients (Guyatt GH et al, 1987) An interviewer administered questionnaire, it contains 20 items that cover 4 domains: dyspnea (five item) fatigue (four item) emotional function (seven items) and mastery (a domain that explores how patients cope with their illness (four items). The CRDQ individualizes the dyspnea domain by asking this patient to identify the activities that make them dyspnoeic and to rate the degree of dyspnea. In order to assist their selection, patients are offered a list of 26 activities. The structure of the

other domains is conventional, each patient being asked identical questions. The respondents are asked to grade their function in each item using seven point Likert scale. The total for each domain is divided by number of items, yielding a potential score of one to seven with high number representing better function. The CRQ has been used to assess the effects of bronchodilators and to make comparisons between bronchodilators or aerosol delivery mechanisms, modes of ventilation , long-term oxygen therapy and pulmonary rehabilitation

SGRQ is a standardized, self-administered questionnaire for measuring impaired health and perceived HRQL in airways disease. It contains 50 items with 76 weighted responses that cover three domains: symptoms, activity and impact. In addition to the domain scores, a total score is calculated .Each item has an empirically derived weight. The SGRQ is scaled from zero to 100 (with zero representing the best health-related quality of life). This instrument has been demonstrated to be valid, reliable and responsive among patients with COPD (Jones PW et al 1991)

Seattle Obstructive Lung Disease Questionnaire (SOLDQ) The SOLDQ, a relatively new instrument, was designed to examine patients with asthma or COPD (Tu SP, et al 1997) . The instrument contains 29 items that cover three health domains and a satisfaction with care domain. These domains are the physical function, emotional function, coping skills and treatment satisfaction. Each domain score is transformed (but not normalised) on a scale of one to 100. The MID in the score of the physical function domain, adapted from the SF-36 physical function domain, has been estimated to be six points. The SOLDQ instrument has been demonstrated to be valid and responsive to change among American veterans, but has yet to be used extensively outside this population. Overall, the SOLDQ physical function score had greater predictive validity than the SF-36 physical component score. The SOLDQ is self-administered and can be completed in 10–15 min.

The Quality of Life for Respiratory Illness Questionnaire (QLRIQ) It is a disease-specific, quality-of-life measure designed for patients with reversible and fixed airway obstruction. Patients are asked how much of a problem each item has been during the past year. This instrument contains seven domains and 55 items and each item is rated on a seven-point Likert scale. The domains are breathing problems, physical problems, emotions,situations triggering or enhancing breathing problems, daily and domestic activities, social activities, relationships and sexuality, and

general activities. Although test/retest reliability and responsiveness have not been reported, the instrument shows internal consistency and constructs validation (Maille AR, et al 1994)

Finally, there is an additional health-status instrument that was developed for use among a subset of patients with COPD, those with chronic respiratory failure. The Maugeri Foundation Respiratory Failure Questionnaire-28 has 28 items and was developed in Italian but has been translated into many languages. Although this instrument is only validated in this subset of patients with severe COPD, in this group, the instrument has been shown to be reliable, valid and responsive to change with treatment with non invasive ventilation (Carone M et al 1997)

PREFERENCE BASED QUESTIONNAIRES

Euro Qol 5D The Euro Qol 5D (EQ-5D) is a generic, preference-based utility questionnaire and consists of two parts, the EQ-5D VAS and the EQ-5D index (Kind P. 1996) The EQ-5D VAS is a visual analogue scale ranging from 0=death/worst possible health to 100=best possible health. The EQ-5D index is a five-item questionnaire. The items consist of mobility, self-care, usual activity, pain/discomfort and anxiety/depression. Each item has three levels: no problem, some problem and severe problem. For the EQ-5D index, 0.03 has been regarded as the MID.

Short Form 6D The Short Form 6D (SF-6D) is a health-state classification system constructed post hoc from 11 selected items from the SF-36 generic HRQL questionnaire. The SF-6D is composed of six HRQL domains: physical functioning, role limitations, social functioning, pain, mental health and vitality, and is based on 11 selected items from the SF-36 instrument. The number of response options varies between four and six, depending on domain. In practice, subjects fill in the SF-36 questionnaire and their responses are then used to determine SF-6D scores.

Time Trade-Off The Time Trade-Off (TTO) includes a direct question offering a choice between twenty years in current health or shorter length of life in perfect health (Torrance GW. 1976)

Feeling Thermometer with Health Marker States for COPD (HS-COPD) A future instrument for preference-based utilities may be the Feeling Thermometer using pre-defined Health Marker States or Clinical Marker States. The HS-COPD is being developed using Health Marker States relevant for COPD, and the instrument to complete is a

visual analogue scale. This gives the HS-COPD a possibility to be used as a utility instrument, which has to be a generic instrument in order to compare various diseases/conditions.

The characteristics of selected general and disease-specific questionnaires for measuring HRQOL in patients with COPD are listed in Table 2.8

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HEALTH-RELATED QUALITY OF LIFE - LINGUISTIC VALIDATIONS

With a few exceptions, most questionnaires have been developed in English. There are many examples in the literature of the translation of HRQL questionnaires, but few publications describe the guidelines to be followed (Hunt SM 1988) .In recent years a standardised procedure has been worked out, comprising three main steps. The first step is the production of a culturally and linguistically adapted version of the source questionnaire. The second step is the comparison of the source and the target versions. The third step is the comparison of all target versions (international harmonisation). Each translation should follow the same established forward-backward translation procedure, with independent translations and counter-translations (Aaronson NK et al 1992)

USES OF HRQOL QUESTIONNAIRE IN COPD

There are at least three ways in which an HRQoL questionnaire can be used, namely as an evaluative, discriminative or predictive measure.

The number of publications on the use of HRQL questionnaires to measure the effect of interventions is increasing (evaluative measure). The term evaluative means that the instrument has the ability to detect within-subject changes over time that occur either spontaneously or as a result of treatment or other intervention. COPD is a disease characterised by a faster decline in FEV_1 than the physiological decline with increasing age that occurs in healthy subjects (Burrows B, et al 1987) papers include evaluation of HRQL after rehabilitation programmes (Wijkstra PJ, et al 1994)

The usage of HRQoL questionnaires as a discriminative measure in COPD has been considered. This means that a questionnaire has the ability to differentiate between subjects, or groups of subjects, with different levels of impairment, i.e. those with mild, moderate or severe impairment of HRQoL. One group of researchers (van den Boom G, et al 1998) showed that many subjects are not likely to visit their doctor until their HRQL is heavily affected.

A predictive measure can be explained as having the ability to predict a future event or disease prognosis. The option of using HRQoL questionnaires as a predictive measure is demonstrated in a study where poor scores on the SGRQ were associated with re hospitalisation for COPD and increased use of resources, such as nebulisers .Another study concluded that improving physical performance and teaching adequate coping strategies should be considered in order to improve HRQL (Ketelaars CA ,et al 1996)

In summary, HRQoL questionnaires in COPD may have a value to evaluate changes after intervention.

HRQoL and mortality One possible use of HRQoL measures is for prognostication. Previous studies show a correlation between measures for quality of life and mortality independent of disease severity. Anxiety, nutritional status, and psychosocial factors such as marital support have been implicated as predictors of mortality (Anthonisen NR, et al 1986)

Health-Related Quality of Life and Resource Utilization Worsening health status may lead to increased health resource utilization. Thus, evaluating HRQoL may be useful in identifying patients at risk of precipitous decline for which preventive measures may be instituted

References

r-0. Anthonisen NR, Connett JE, Kiley JP, Altose MD, Bailey WC, Buist AS, et al. Effects of smoking intervention and the use of an inhaled anticholinergic bronchodilator on the rate of decline of FEV1. The Lung Health Study. JAMA 1994;272(19):1497-505.
r-1. Belman MJ, Botnick WC, Shin JW: Inhaled bronchodilators reduce dynamic hyperinflation during exercise in patients with chronic obstructive pulmonary disease. Am J Respir Crit Care Med 1996, 153:967-975
r-2. Bergner M, Bobbitt RA, Carter WB, Gilson BS. The Sickness Impact Profile: Development and final revision of a health status measure. Med Care 1981; 18: 787–805.
r-3. Brazier JE, Usherwood T, Harper R, Thomas K. Deriving a preference-based single index from the UK SF-36 Health Survey. J Clin Epidemiol 1998; 51: 1115–1128.
r-4. Burrows B, Bloom JW, Traver GA, Cline MG. The course and prognosis of different forms of chronic airways obstruction in a sample from the general population. New England Journal of Medicine 1987;317(21):1309-1314
r-5. Carone M, Anghisi F, Donner CF. Quality of life and chronic respiratory failure. Monaldi Arch Chest Dis 1997; 52: 525–528.
r-6. Clancy CM, Eisenberg JM. Outcomes research: measuring the end results of health care. Science 1998; 282: 245–246
r-7. Engstrom EP, Persson LO, Larsson S, Sullivan M.

Health related quality of life in COPD: why both disease-specific and generic measures should be used. Eur Respir J 2001; 18: 69–76

r-8. Fanshel S, Bush J. A health-status index and its application to health-services outcomes. Oper Res 1970; 18: 1021–1066

r-9. Feinstein, AR (1983) An additional basic science for clinical medicine: IV. The development of clinimetrics. Ann Intern Med 99,843-848

r-10. Guyatt GH, Berman LB, Townsend M, Pugsley SO, Chambers LW. A measure of quality of life for clinical trials in chronic lung disease. Thorax 1987; 42: 773–778.

r-11. Guyatt GH, Feeny DH, Patrick DL. Measuring health related quality of life. Ann Intern Med 1993; 118: 622–629.

r-12. Hunt SM, McKenna SP, McEwen J, Backett EM, Williams J, Papp E. A quantitative approach to perceived health status: a validation study. J Epidemiol Community Health 1980;34: 281–286

r-13. Jones PW, Quick FH, Baveystock CM. The St George's respiratory questionnaire. Respir Med 1991; 85: Suppl. B,25–31.

r-14. Kaplan RM, Atkins CJ, Timms R. Validity of a quality of well-being scale as an outcome measure in chronic obstructive pulmonary disease. J Chronic Dis 1984; 37: 85–95.

r-15. Ketelaars CA, Schlosser MA, Mostert R, Huyer Abu-Saad H, Halfens RJ, Wouters EF. Determinants of health-related quality of life in patients with chronic obstructive pulmonary disease. Thorax 1996;51(1):39-43.

r-16. Kind P. Chapter 22. The EuroQoL instrument: an index of health-related quality of life. In: Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Second ed. Philadelphia, Lippincott-Raven Publishers, 1996; pp. 191-201.

r-17. Mahler DA, Mackowiak JI. Evaluation of the short-form 36-item questionnaire to measure healthrelated quality of life in patients with COPD. Chest.1995;107:1585–1589

r-18. Maille AR, Koning CJM, Kaptein AA. Developing a quality-of-life questionnaire for patients with respiratory illness. Monaldi Arch Chest Dis 1994; 49: 76–78.

r-19. Nocturnal Oxygen Therapy Trial Group. Continuous or nocturnal oxygen therapy in hypoxemic chronic obstructive lung disease: a clinical trial. Ann Intern Med 1980; 93: 391–398.

r-20. Patrick DL, Erickson P. Applications of Health Status Assessment to Health Policy. In: Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Second ed. Philadelphia, Lippincott-Raven Publishers, 1996; pp. 717-727.

r-21. Pauwels RA, Buist AS, Calverley CR, Jenkins CR, Hurd SS, on behalf of Committee. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease, NHLBI/WHO Global Initiative for Chronic Obstructive Lung Disease (GOLD) Workshop Summary. Am J Respir Crit Care Med 2001; 163: 1256–1276.

r-22. Ren XS, Kazis L, Lee A, et al. Comparing generic and disease-specific measures of physical and role functioning: results from the Veterans Health Study. Med Care 1998; 36: 155–166.

r-23. Schipper H, Clinch JJ, Olweny CLM. Quality of Life Studies: Definitions and Conceptual Issues. In: Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Second ed. Philadelphia, Lippincott-Raven Publishers, 1996; pp. 11-23.

r-24. Testa MA, Simonson DC. Assessment of quality-of-life outcomes. New England Journal of Medicine 1996;334(13):835-840.

r-25. Torrance GW. Social preferences for health states: An empirical evaluation of three measurement techniques. Socio-Economic Planning Sciences 1976;10(3):129-136

r-26. Tu SP, McDonell MB, Spertus JA, Steele BG, Fihn SD. A new self-administered questionnaire to monitor health related quality of life in patients with COPD. Ambulatory Care Quality Improvement Project (ACQUIP) Investigators. Chest 1997; 112: 614–622.

r-27. van den Boom G, Rutten-van Molken MP, Tirimanna PR, van Schayck CP, Folgering H, van Weel C. Association between health-related quality of life and consultation for respiratory symptoms: results from the DIMCA programme. European Respiratory Journal 1998;11(1):67-72.

r-28. van Schayck CP, Dompeling E, Rutten MP, Folgering H, van den Boom G, van Weel C. The influence of an inhaled steroid on quality of life in patients with asthma or COPD. Chest 1995; 107: 1199–1205.

r-29. Ware JE Jr, Snow KK, Kosinski M, Gandek B. SF-36 Health Survey: Manual and Interpretation Guide. Boston, The Health Institute, 1993.

r-30. WHO. World Health Organization. The first ten years of the World Health Organization. 1958.

r-31. Wijkstra PJ, Van Altena R, Kraan J, Otten V, Postma DS, Koeter GH. Quality of life in patients with chronic obstructive pulmonary disease improves after rehabilitation at home. European Respiratory Journal 1994;7(2):269-273.

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