

R.C. Dwivedi, C.M. Nutting, P. Rhys-Evans, K.J. Harrington, R. Kazi

Future Perspectives for Health related Quality of life (HRQOL) studies in Head and Neck Cancer

Head & Neck Unit, Royal Marsden NHS, Fulham Road, London SW3 6JJ

ABSTRACT. *The impact of a head and neck cancer (HNC) diagnosis on a person and the consequences of its treatment across multiple functional domains can profoundly alter quality of life (QOL).*

By pursuing patient-centered management and considering the entire gamut of physical, psychological and social problems, QOL studies contribute more than just routine mortality and morbidity data. Assessments can now be made using a variety of both specific and generic measures to optimise patient care and to aid the development of informed rehabilitation services. Unfortunately, there exists no 'gold-standard' questionnaire in the literature and the choice is largely based on clinician preference, research objectives and psychometric properties. Future efforts must be made to effectively use modern technological and computational advances to set up item banks and newer theoretical models.

Longitudinal studies with pre-determined priori should be encouraged as should the utilisation of minimalist approaches and incisive item response theory. Most importantly, in order to link research to clinical practice, health related QOL (HRQOL) studies should be devised and utilised in a way as to provide clinically meaningful data to the treating physician useful for patient' care.

Key words: *questionnaire, head neck cancer, quality of life.*

RIASSUNTO. L'impatto sulla persona di una diagnosi di cancro del collo e della testa e le conseguenze del trattamento che interagisce su domini funzionali multipli può profondamente alterare la qualità della vita (Qdv). Accingendosi a una gestione paziente-centrata ed in considerazione della completa gamma di problemi fisici, psicologici e sociali, gli studi di Qdv offrono più del solo dato relativo al tasso di mortalità e di morbilità. Per la sua valutazione oggi si possono avere a disposizione una varietà di misure specifiche e generiche le cui informazioni possono consentire di ottimizzare l'attenzione, il prendersi cura del paziente ed aiutare lo sviluppo di servizi di riabilitazione informati possono essere fatti. Sfortunatamente, in letteratura non esiste nessun questionario indicabile come 'gold standard' e la scelta è basata su preferenza clinica, gli obiettivi di ricerca e le proprietà psicometriche del questionario. Si devono dunque orientare gli sforzi futuri al fine di usare efficacemente tecnologia e la modellistica statistico-informatica con obiettivo di generare banche di item e modelli teorici più evoluti.

Studi longitudinali con pre-determinamento a priori dovrebbero essere incoraggiati come pure l'utilizzo di approcci minimalisti e i modelli basati sulla "item response theory". Di ancora maggior rilievo per collegare la ricerca alla pratica clinica, la Qdv correlata alla salute (in inglese acronimo HRQOL) dovrebbe essere concepita ed essere utilizzata in modo tale da offrire al medico specialista curante dati di significato e rilievo clinico utili il prendersi cura della persona malata.

Parole chiave: questionari; cancro al collo e testa, qualità di vita.

Introduction

Quality of life (QOL) is a multi-dimensional global concept that is defined by subjective experiences, states and perceptions. The evaluation of QOL and performance outcomes in cancer is critical to optimal patient care, comprehensive evaluation of treatment alternatives, and the development of informed rehabilitative services and patient education (1-3). QOL studies put the patient at the centre of treatment interventions and aid routine clinical practice, governance and audit. QOL measures have now become a vital part of health outcomes appraisal and an effective way of capturing the personal and social context of patients. Patients with HNC are rendered vulnerable to psychosocial problems because social interactions and emotional expression depends to a great extent upon the structural and functional integrity of the head and neck region. The impact of a HNC diagnosis on the person and the consequences of its treatment cross multiple functional domains that have a clear and direct influence on one's post-treatment QOL (1). Quality of life is a broad concept that has developed over the past three decades in response to the perceived need to assess the patients overall sense of well-being and how it relates to disease and its treatment. QOL is directly affected by key intrinsic characteristics of each individual patient including: beliefs, expectations and experiences. In the literature, some researchers have used the term health-related quality of life (HRQOL) instead of QOL because factors such as income and family support, usually assessed by QOL questionnaires, are often largely unaffected by treatment and not under the control of the treating clinician. This article will consequently address only the HRQOL in head and neck cancer patients.

There has been increasing attention paid to QOL studies in the literature in recent years. With knowledge of existing data, clinicians already have the potential to improve not just survival figures but HRQOL for patients. Although QOL work has now evolved into a more organised and scientific discipline, more work needs to be done. There is lack of understanding of the real importance of HRQOL in HNC, its true clinical significance and implications and how best to interpret and implement the data into clinical practice. Further work needs to be done

to convert HRQOL assessment from a collection of loosely linked ideas into a well-organized scientific discipline. This article makes recommendations for future studies in HRQOL. By understanding these recommendations, we may bridge the gap between research and clinical practice and ultimately improve HRQOL in HNC patients.

Future directions for HRQOL

A major and long-standing criticism of HRQOL studies is that they have largely been utilized in the research setting and the available data, at times, have failed to provide the clinician with clinically meaningful information that can actually guide management (3, 4). Further work needs to be done on the real significance of HRQOL studies in clinical practice. To facilitate easy clinical interpretation of HRQOL data, the Scientific Advisory Committee of the Medical Outcomes Trust suggests that studies should focus on pre-defining the changes in score that are clinically significant or, in other words, use a pre-mentioned priori. Only if a particular treatment improves a score by a certain pre-defined set amount would it then be considered to have provided the patient with a meaningful clinical benefit and, therefore, be judged clinically applicable (4, 5). When interpreting QOL data, one must consider the influence of numerous psycho-social factors and their potential interdependence if accurate representations of HRQOL status are to be gathered (3). Often HRQOL studies in HNC have been riddled with problems relating to the study design - retrospective or cross-sectional data collection and sample size which can influence the results. Inconclusive findings in such situations, or a failure to capture information from a cohort that may have a substantially decreased HRQOL, may be more related to inadequate sample size or the study design rather than an actual causal effect.

Interpreting what a given change in score or difference in scores means is still incompletely understood as measures may prove sensitive to differences in HRQOL scores between groups or changes over time (3) It is as yet not entirely clear how changes in these scores should be interpreted over long periods and over the broader context of a patient's HRQOL. This is because such changes are likely to be influenced by psycho-social events occurring throughout the patient's life. In some situations, patients with severe symptoms and functional deficits fail to demonstrate a logical reciprocal decrease in their overall HRQOL scores. This may be because the specific issue which is multi-variable dependant may not be severe enough or may be too specific to affect the global rating/score. Or it may be due to the phenomenon of adaptation/coping and needs further clarity (3, 6).

Too often HRQOL studies suffer from the time burden and fatigue they cause patients, especially in elderly patients. Item Response Theory (IRT) has been already applied in the development of several questionnaires including HRQOLs (7, 8) Future efforts should be directed towards using an IRT in the development of HRQOL instruments for HNC that adopt a minimalist approach or, in

other words, which are a trade-off between maximizing crucial clinical information and minimizing patient burden (9, 10). IRT uses logistic probability models to compare single-item and multi-item HRQOL scales and by selecting questions with maximum discrimination ability and with least inconsistent response patterns (9-11). Another area that can be probed further is the use of personalised or individualised measures in HRQOL studies to identify and detect an individual's unique problems. They reflect the fact that HRQOL cannot be adequately assessed using standardised measures that ask every patient the same questions and require responses to be selected from a pre-determined set (6). Further efforts to develop more sensitive and reliable instruments that are able to avoid the problems of response shifts, adaptation, floor (ability of detect worsening of symptoms and HRQOL in patients with an existing poor HRQOL) and ceiling (ability to detect an improvement in those with a good HRQOL) effects are required. A clinician in a busy practice may not have sufficient time to wait for the conclusion of a study to decide on his/her treatment. Perhaps in such situations, the use of scales for regular outpatient appointments could be probed further in the future.

Some researchers feel that understanding the complex factors that contribute to overall QOL is critical to obtaining a comprehensive and complete picture of the patient's "total life experience." However, others feel that future emphasis should be placed on 'health-related quality of life' (HRQOL) instead of the 'overall QOL'. This is because factors such as family support and income are not under the direct control of the treating clinician (2, 3, 6) New research should be targeted at studies focusing on proxies, their relationships and the extent of influence on the QOL scores (12). Measuring the degree of agreement between proxies and identifying the ways in which proxies' own life experiences of caring for the patient influence their judgment of the patient's QOL would be informative. Another term that has gained importance in recent years and is worth further examining is the 'QOL-adjusted survival time'. This is based on how much patients value their present lives when given a hypothetical option for a better QOL.

The ability to administer QOL measures over the computer using touch screen technology or Interactive Voice Response System (IVRS) using voice recognition software could help in the administration, collection, storage and consequently the reduction of manpower (4, 5, 9-11, 13-16). Targeted software can allow data to be automatically linked to individual patient records and then reviewed in the context of their treatment and clinical outcomes during outpatient appointments. Researchers and institutions should be encouraged to develop and maintain an item bank of questions on the lines of the European Organization for Research and Treatment of Cancer (EORTC) QOL group and the Functional Assessment of Chronic Illness Therapy (FACIT) general item bank (9-11). This bank could be an exhaustive collection of questions that represent generic areas of the domain as well as those pertaining to the specific disease in study. Table I summarises some of the features of commonly used HRQOL in HNC patients.

Table I. Showing some of the commonly used health related quality of life (HRQOL) questionnaires in head and neck cancer patients

Questionnaire	Mode of administration	Number of items	Internal reliability	Repeat reliability	Validity
EORTC-QOL-HN 35 (17)	Self	35	Yes	Not demonstrated	Yes
FACT-HN (18)	Self	11	Yes	Not demonstrated	Yes
UWQOL (19)	Self	12	Not demonstrated	Partially demonstrated	Partly demonstrated
HRQOL (20)	Self	22	Yes	Not demonstrated	Partly demonstrated
QOL-RTI/HN (21)	Self	39	Yes	Yes	Partly demonstrated

An important issue in future HRQOL research is to evaluate the relationship between symptoms and HRQOL scores. This is because, although symptom evaluation can provide important information, it is not the only outcome measure that impacts on HRQOL. Future work in HRQOL should be driven to distinguish symptom surveys and HRQOL measures. Studies should focus on furthering our understanding of the assessment of HRQOL by developing newer practically-applicable theoretical models (22). The QOL model as proposed by Sprangers and Schwartz theorises that a change in QOL status of an individual could be a result of multiple, important inter-linked interactions. These could be between a so-called catalyst (such as a change in health status), antecedents (personality traits), mechanisms (behavioural, cognitive) and a response shift (change in internal standards) and needs further rigorous testing (23).

Finally, and most importantly, although there is a growing interest in HRQOL studies, it should not be viewed as an alternative to effective communication with patients. Here it is important for the caring staff to remember the underlying reason for using HRQOL measures in clinical practice is to ensure that treatment plans and evaluations are patient-centred. HRQOL scales are an aid to optimise care by being an adjunct, and not a substitute, for measuring outcomes associated with disease.

Conclusion

The impact of a diagnosis of HNC, and the consequences of its treatment across multiple functional domains, has a profound impact on the associated QOL of patients. By keeping the patient at the centre of the management plan and considering the entire gamut of physical, psychological and social problems, QOL studies can contribute more than just routine mortality and morbidity data. The evaluation of HRQOL data in HNC is crucial for the development of informed rehabilitative services and importantly to optimise patient care. If accurate representations of HRQOL status are to be gathered, one must consider the influence of the numerous inter-linked factors and that HRQOL is an individual perception that can be affected not only by the current health status but by psycho-social issues. Future efforts must be made to effectively use modern technological and com-

putational advances to set up item banks and newer theoretical models. Longitudinal studies with pre-determined priori should be encouraged as should the use of minimalist approaches and incisive item response theory. Most importantly, in order to link research to clinical practice, HRQOL studies should be devised and utilised in a way as to provide clinically meaningful data to the treating physician.

References

- 1) Kazi R. Surgical voice restoration following total laryngectomy. *J Cancer Res Ther* 2007; 3(4): 188-9.
- 2) Singer MI, Blom ED. An endoscopic technique for restoration of voice after laryngectomy. *Ann Otol Rhinol Laryngol* 1980; 89: 529-533.
- 3) Hamaker RC, Singer MI, Blom ED, Daniels HA. Primary voice restoration at laryngectomy. *Arch Otolaryngol* 1985; 111: 182-186.
- 4) Stuart GW, Laraia MT, Ornstein SM, Nietert PJ. An interactive voice response system to enhance antidepressant medication compliance. *Top Health Inf Manage* 2003; 24(1): 15-20.
- 5) Cella D, Bullinger M, Scott C, Barofsky I. Clinical Significance Consensus Meeting Group. Group vs individual approaches to understanding the clinical significance of differences or changes in quality of life. *Mayo Clin Proc* 2002; 77(4): 384-92.
- 6) Hilgers FJM, Aaronson NK, Ackerstaff AH et al. The influence of a heat and moisture exchanger (HME) on the respiratory symptoms after total laryngectomy. *Clin Otolaryngol* 1991; 16: 152-156.
- 7) Vidotto G, Carone M, Jones PW, Salini S, Bertolotti G; Quess Group. Mageri Respiratory Failure questionnaire reduced form: a method for improving the questionnaire using the Rasch model. *Disabil Rehabil* 2007 15; 29: 991-8.
- 8) Vidotto G, Bertolotti G, Carone M, Arpinelli F, Bellia V, Jones PW, Donner CF A new questionnaire specifically designed for patients affected by chronic obstructive pulmonary disease: The Italian Health Status Questionnaire. *Respir Med* 2006; 100: 862-70).
- 9) Mandrekar S, Dueck A. Future directions in QOL research. *Curr Probl Cancer* 2005; 29(6): 343-51.
- 10) Sloan JA, Loprinzi CL, Kuross SA, Miser AW, O'Fallon JR, Mahoney MR, Heid IM, Bretscher ME, Vaught NL. Randomized comparison of four tools measuring overall quality of life in patients with advanced cancer. *J Clin Oncol* 1998; 16(11): 3662-73.
- 11) Revicki DA, Cella DF. Health status assessment for the twenty-first century: item response theory, item banking and computer adaptive testing. *Qual Life Res* 1997; 6(6): 595-600.
- 12) Kazi R, Singh A, De Cordova J, Al-Mutairy A, Clarke P, Nutting C, Rhys-Evans P, Harrington K. Validation of a voice prosthesis questionnaire to assess valved speech and its related issues in patients following total laryngectomy. *Clin Otolaryngol* 2006; 31(5): 404-10.
- 13) McIvor J, Evans PF, Perry A, Cheesman AD. Radiological assessment of post-laryngectomy speech. *Clin Radiol* 1990; 41: 312-316.

- 14) Lai JS, Cella D, Chang CH, Bode RK, Heinemann AW. Item banking to improve, shorten and computerize self-reported fatigue: an illustration of steps to create a core item bank from the FACIT-Fatigue Scale. *Qual Life Res* 2003; 12(5): 485-501.
- 15) Panter AT, Reeve BB. Assessing tobacco beliefs among youth using item response theory models. *Drug Alcohol Depend* 2002; 68 Suppl 1: S21-39
- 16) Buxton J, White M, Osoba D. Patients' experiences using a computerized program with a touch-sensitive video monitor for the assessment of health-related quality of life. *Qual Life Res* 1998; 7(6): 513-9.
- 17) Zotti P, Lugli D, Vaccher E, Vidotto G, Franchin G, Barzan L. The EORTC quality of life questionnaire-head and neck 35 in Italian laryngectomized patients. European organization for research and treatment of cancer. *Qual Life Res* 2000; 9(10): 1147-53.
- 18) D'Antonio LL, Zimmerman GJ, Cella DF, Long SA. Quality of life and functional status measures in patients with head and neck cancer. *Arch Otolaryngol Head Neck Surg* 1996; 122(5): 482-7.
- 19) Hassan SJ, Weymuller EA Jr. Assessment of quality of life in head and neck cancer patients. *Head Neck* 1993; 15(6): 485-96.
- 20) Browman GP, Levine MN, Hodson DI, Sathya J, Russell R, Skingley P, Cripps C, Eapen L, Girard A. The Head and Neck Radiotherapy Questionnaire: a morbidity/quality-of-life instrument for clinical trials of radiation therapy in locally advanced head and neck cancer. *J Clin Oncol* 1993; 11(5): 863-72.
- 21) Trotti A, Johnson DJ, Gwede C, Casey L, Sauder B, Cantor A, Pearlman J. Development of a head and neck companion module for the quality of life-radiation therapy instrument (QOL-RTI) *Int J Radiat Oncol Biol Phys* 1998; 42(2): 257-61
- 22) Addington-Hall J, Kalra L. Who should measure quality of life? *BMJ* 2001; 322: 1417-20.
- 23) Terrell JE, Ronis DL, Fowler KE, Bradford CR, Chepeha DB, Prince ME, Teknos TN, Wolf GT, Duffy SA. Clinical predictors of quality of life in patients with head and neck cancer. *Arch Otolaryngol Head Neck Surg* 2004; 130(4): 401-8.

Reprint request: Dr. Rehan Kazi - Head and Neck unit, The Royal Marsden NHS Foundation trust, Granard house, Fulham road, SW3 6JJ, London, UK - Email: rehan_kazi@yahoo.com