

Health related quality of life in sinonasal disease*

V.J. Lund

Institute of Laryngology & Otology, University College London, 330 Gray's Inn Road, London, United Kingdom

SUMMARY

Objective measurements of sinonasal disease have proved difficult to standardise and correlate poorly with the severity of symptoms. Quality of life, which has been defined as the gap between expectation and experience allows the impact of disease to be quantified thus enabling comparison of different diseases and enabling examination of therapeutic response. A range of generic and disease specific questionnaires have been developed of varying complexity. These have been applied to a range of sinonasal conditions including allergy, infection and neoplasia. With increasing refinement they may become the main primary outcome measures in both clinical trials and practice.

Key words: quality of life, sinonasal disease

INTRODUCTION

The nose and sinuses, whilst the source of significant symptoms, have proved remarkably resistant to the application of objective investigation. Susceptible to environmental change and manifesting a wide range of physiological responses and reflexes, the sinonasal region has proved difficult to quantify in a clinical setting. Some diagnostic techniques (Table 1) (Lund et al., 1994) have been applied sequentially in clinical research to assess therapeutic response but many are known to correlate poorly with symptoms even though they may provide important entry criteria in a particular trial (Lund and Kennedy, 1997). Even the semiquantitative assessment of symptoms using visual analogue scores can only really be applied to intra-individual variation although they can provide an important baseline in clinical studies (Lund et al., 1991). However, there is a growing awareness that from a patient's perspective, the impact of a disease on daily functioning is of considerably greater relevance than whether their ciliary beat frequency increases by two or three Hertz. Furthermore there is increasing evidence that correlations between conventional clinical markers of nasal inflammation and a patient's rhinoconjunctivitis - specific quality of life are only weak to moderate (de Graaf et al., 1996; Juniper and Guyatt, 1991).

Quality of life may be defined as the gap between expectation and experience (Calman, 1984). Health related quality of life (HRQL) is the component of overall quality of life which is determined primarily by the patient's health and which can be influenced by clinical intervention. Specifically it has been characterised as "the functional effects of an illness in and its consequent therapy upon a patient as perceived the patient"

(Schipper et al., 1990). Traditionally medicine has relied on assessment of change using laboratory or clinical tests but HRQL is increasingly recognised as an important alternative outcome measure. It has been used in a wide range of medical conditions including rheumatoid arthritis, vascular disease and respiratory tract diseases such as asthma and cystic fibrosis but it is only relatively recently that it has been applied to sinonasal disease.

MEASUREMENT OF HEALTH RELATED QUALITY OF LIFE

Generic health instruments

A number of generic instruments have been designed which may be used in patients with any medical condition. These include the short form 36 (SF-36) (Ware and Sherbourne, 1992), European Quality of Life Measure (EuroQol, 1996), Nottingham Health Profile (NHB) (Hunt et al., 1986) and the Sickness Impact Profile (SIP) (Bergner et al., 1981). Of these, the SF-36 is one of the most widely used with its 36 items divided into eight domains: physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional and mental health. Scores for each domain vary between 0 and 100 with 100 representing perfect health and the domains can be combined into two primary functions, mental and physical. The SF-36 is well validated, widely used and normative values are available for the general population.

The advantage of generic instruments such as the SF-36 is that the impact of illness can be compared between different medical conditions but in being broad, they lack depth and cannot encompass individual weighting of specific domains which

Table 1. Diagnostic techniques in sinonasal disease (after Lund et al, 1994).

History	
General ENT examination	
Allergy tests	<ul style="list-style-type: none"> • skin tests • total serum IgE • serum specific IgE
Endoscopy	<ul style="list-style-type: none"> • rigid • flexible
Expired nitric oxide	
Nasal smear	<ul style="list-style-type: none"> • cytology
Nasal swab	<ul style="list-style-type: none"> • bacteriology
Radiology	<ul style="list-style-type: none"> • plain sinus radiograph • CT • MRI • CXR
Mucociliary function	<ul style="list-style-type: none"> • nasal mucociliary clearance (NMCC) • ciliary beat frequency (CBF) • electron microscopy
Nasal airway assessment	<ul style="list-style-type: none"> • nasal inspiratory peak flow (NIPF) • rhinomanometry (anterior and posterior) • acoustic rhinometry
Nasal challenge	
Olfaction	<ul style="list-style-type: none"> • threshold testing • 'scratch and sniff' tests
Blood tests	<ul style="list-style-type: none"> • full blood count and white cell differential • erythrocyte sedimentation rate • thyroid function tests • anti-neutrophil cytoplasmic antibody (ANCA) • immunoglobulins and IgG subclasses • antibody response to immunisation with protein and carbohydrate antigens

may be of greater importance to the patient. Consequently different results may be obtained after the same intervention in the same patient cohort. Klassen et al. (1999) found markedly different results in the same patients undergoing cosmetic rhinoplasty using the SF-36 and EuroQol measures.

This has led to the development of individualised measures of quality of life which are receiving increasing attention but also have their own intrinsic problems (Carr and Higginson, 2001). Some, such as the Schedule for the Evaluation of Individualised Quality of Life (SEIQOL) (Bernheim, 1999) and the Patient Generated Index (PGI) (Skevington, 1999) are administered by an interviewer and use visual analogue scales to assess the five areas which the patient identifies as being the most important to them. However, both the completion and analysis of these assessments can be quite complex and their applicability in severely ill patients may be limited.

There is clearly a need for multilingual and multidimensional quality of life assessments which are sensitive to the importance of certain areas on an individual basis.

Disease specific questionnaires

These questionnaires focus on the symptom or symptom complex pertinent to a particular disease.

Rhinoconjunctivitis quality of life questionnaire (RQLQ) (Juniper and Guyatt, 1991)

This 28-item questionnaire describes symptoms in 7 domains (sleep, non-hay fever symptoms, practical problems, nasal symptoms, eye symptoms, activities and emotional function). Patients rate each item on a scale of 0-6 (where 6 indicates severe problems) allowing a mean value for each domain and an overall measure to be determined. The higher the score, the poorer the quality of life. It was originally developed for adults with seasonal allergic rhinitis and has been widely validated both for seasonal and perennial allergic rhinitis. Both standardised and shortened versions are available (Juniper et al., 1999, 2000) and questionnaires applicable to adolescents and children have also been developed (Juniper et al., 1994, 1998).

Rhinosinusitis outcome measure (RSOM-31) and the sinonasal outcome test (SNOT-20) (Piccirillo et al., 1995)

The original 31-item rhinosinusitis-specific questionnaire contains 7 subscales: nasal, eye, sleep, ear, general, practical and emotional and offered two rating scales, encompassing magnitude and importance. Refinement of the test reduced the number of items to 20 and modified both the magnitude and importance scales, producing an easy self-administered test.

Chronic sinusitis survey (Gliklich and Metson, 1997)

This is a 6-item duration-based assessment of sinusitis with specific outcomes divided into a symptom-based section and a medication-based section. The symptoms are divided into

three (sinus headaches, facial pain or pressure; nasal discharge; nasal congestion or obstruction) which are considered over a two-month period. Two scores, one for symptoms and one for medication can be delivered together with a total score presented as a scale from 0-100 with 0 being the worst possible score and 100 the best.

Rhinosinusitis disability index (RSDI) (Benninger, 1997)

In this test, presented in a first person descriptive format, patients are asked to relate sinonasal symptoms to specific daily functional limitation on a 5-point scale, scored as 0 for 'never' to 4 for 'always'.

Health outcomes institute chronic sinusitis - Type specific (Hoffman et al., 1993)

This more complex assessment consists of three forms (nasal and sinus symptoms before and after surgery and clinical classification of sinus disease) combined with a modified SF-36 and a survey of health conditions and health risk inventory as part of a "Patient Outcomes Following the Surgical Management of Chronic Rhinosinusitis" Project. The complexity and time taken to complete this undoubtedly limits its wide application.

Symptom score (Lund et al., 1991)

In this self-administered test patients mark on a 10 centimetre line (between 0 and 10) where symptom severity falls for five sinonasal symptoms (facial pain or pressure, headache, nasal blockage or congestion, nasal discharge and olfactory disturbance) (where 10 indicates the greatest severity). The relative length from the origin of the line is measured and rounded to the nearest integer. Patients are also asked to rank in order of severity their three worst symptoms allowing distinction between symptoms given the same visual analogue score.

Utilities

A further refinement popular with health economists is the measurement of utilities which represent the value that either patients or society place on various health states. From these quality adjusted life years (QUALYS) (Torrance, 1986) may be derived but there are difficulties in applying these measurements to non-life threatening conditions such as rhinitis. A Rhinitis Symptom Utility Index (Revicki et al., 1998) has been developed in an attempt to measure the value that society places on the condition. It consists of ten questions on the severity and frequency of ENT symptoms with an algorithm based on societal responses to various nasal and ocular symptom dates using the Standard Gamble and Rating scale. (Torrance, 1986). However, this does not take into account the value patients place on rhinitis-induced quality of life impairment such as sleep disturbance.

Measures of quality of life in head and neck cancer

A large number of standardised and validated questionnaires

have been developed, some of which have been modified for head and neck cancer. These include the EORTC QLQ-H+N-37, (Bjordal et al., 1994) the University of Washington QOL Head and Neck Questionnaire (Hassan and Weymuller, 1993) and the Functional Assessment of Cancer Therapy Scale (FACT-G and H&N Additional Concerns) (Cella, 1993). Sinonasal tumours fortunately remain relatively rare but we should not underestimate the general and specific effects of radiotherapy and surgery in this area, particularly on the sense of smell and perception of flavour.

SINONASAL DISEASE

Allergy

Both generic (SF-36) and specific (RQLQ) questionnaires have proved extremely helpful in demonstrating the impact that allergic rhinitis can have on quality of life. Studies by Bousquet and colleagues (Bousquet et al., 1994a; Bousquet et al., 1994 b) have demonstrated a burden of illness not only comparable but greater than that of asthma, something not readily appreciated by the health community at large. The SF-36 has also been used to show the difference between seasonal and perennial allergic rhinitis (Ostinelli and Bousquet, 1998) as well as the effects of therapy such as non-sedating H₁ antihistamines (Bousquet et al., 1996). The RQLQ has been used in several therapeutic trials looking at the effect of nasal corticosteroids (Meltzer, 1998; Juniper et al., 1992; Juniper et al., 1993a; Juniper et al., 1993b; Juniper et al., 1998; Ståhl et al., 2000; Svensson et al., 2000), H₁ antihistamines (Harvey et al., 1996) and the combination of these drugs (Ratner et al., 1998).

The impact on quality of life of immunotherapy has also been considered (Fell et al., 1997) and the use of both steroids and topical steroids and anticholinergic drugs have been examined. (Dockhorn et al., 1999; Grossman et al., 1995; Milgrom et al., 1999) in perennial non-allergic rhinitis.

Infection

Recent attention has focussed on chronic rhinosinusitis as a societal burden suggesting it may be as great as rheumatoid arthritis, chronic obstructive airways disease and insulin dependent diabetes. The application of these instruments to surgical outcome also provide another dimension of assessment which may be of considerable importance in the context of health economics (Gliklich and Metson, 1997; Metson and Gliklich, 1998; Winstead and Barnett, 1998). These have largely considered the impact of endoscopic sinus surgery. However, attempts to develop ratings of appropriateness for sinus surgery have not proved successful in predicting patient outcomes (Jones et al., 1998).

The impact on social life of recurrent upper respiratory tract infections in the paediatric population may be looked at indirectly by measures of parental quality of life (Berdeaux et al., 1998).

Neoplasia

Nasal and sinus tumours comprise a relatively small component of head and neck cancer and as a consequence have not featured in any significant numbers in the studies done to date. However, these patients often present late and require major and potentially disfiguring surgery such as maxillectomy and orbital clearance together with radiotherapy and occasionally chemotherapy. In our own study of 48 head and neck cancer patients using a modified EORTC questionnaire, 11 patients were included undergoing craniofacial resection who despite good cosmesis experienced problems with the sense of smell and taste and scored higher on a Hospital Anxiety and Depression Scale than those undergoing laryngectomy (Jones et al., 1992). Greater emphasis will need to be paid to this area in the future. (Cusimano, 1999).

CONCLUSION

Many sinonasal conditions have a significant impact on quality of life which may be demonstrated by both general and/or disease specific questionnaires. They have proved very useful providing comparative data with other medical conditions which many would regard as more serious. They have also proved of use in demonstrating therapeutic response, both medical and surgical though it should be recognised that they may be less good in this respect when considering chronic conditions as opposed to acute. At present the questionnaires do not allow for individualised bias but with additional refinement could become the main primary outcome measures in clinical trials. The measurement of quality of life is not the ultimate panacea in the assessment of disease and therapeutic outcome. (Gill and Feinstein, 1994) but it is an increasingly respected evaluation and we ignore it at our peril.

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Valerie Lund MS FRCS FRCS Ed
 Professor of Rhinology
 Institute of Laryngology &
 Otolaryngology
 University College London
 330 Gray's Inn Road
 London WC1X 8DA
 United Kingdom

Tel: +44 71 915 1497

Fax: +44 71 833 9480

E-mail: v.lund@ucl.ac.uk