REVIEW

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Patient reported outcome measures in rhinology*

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SUMMARY

Patient rated outcome measures (PROMs) are increasingly being used to supplement clinical measures of disease in order to assess how disease and medical intervention impacts on quality of life. As the primary aim of treatment for most rhinological conditions is to improve quality of life they have particular relevance in our sub-specialty.

Some PROMs have been developed for particular conditions or treatments (disease-specific measures) while others were developed to be used in all patient groups or healthy individuals (generic measures). There are an increasing number of both disease-specific and global measures available for use in rhinological conditions, and they are reviewed. Both factors limiting wide scale adoption of PROMs into routine practice, and limitations of PROMs are also discussed.

Key words: outcomes assessment, effectiveness, health-care research, evaluation

INTRODUCTION

The primary aim of treatment for most rhinological conditions is to improve quality of life as perceived by the patient. Health Related Quality of life may be defined simply as 'the degree of well-being felt by an individual', or more scientifically as "those aspects of an individual's subjective experience that relate both directly and indirectly to health, disease, disability, and impairment" [(1)]. This will be influenced by the patient's age, culture, expectations, and physical and mental capabilities. A growing desire to measure how disease and medical intervention impacts on quality of life has led to the development of patient rated outcome measures (PROMs). These measures are increasingly being used to supplement objective clinical or biological measures of disease, to assess both the need for and effectiveness of healthcare. Since health related quality of life in sinonasal disease was last reviewed in this journal [(2)], there has been an explosion in number of available outcome measures and interest in applying these in clinical settings. The Department of Health (DoH) in England has recently made a pledge to publish extensive data relating to PROMs; collection of PROMs will be compulsory for health care providers in England, and income in part will be related to this [(3)]. This review therefore aims to review outcome measures available for use in rhinological conditions, and discusses how they may be applied and their limitations.

What are they?

Patient Reported Outcome Measures (PROMs) are measures of health-related quality of life that are self-rated and reported directly by patients [(4)]. They usually refer to a single time point or clearly defined preceding period. The impact of medical or surgical management may then be determined by comparing the patient's self-reported health status before and after the intervention.

Why measure them?

Measurement of surgical outcome has traditionally focused on mortality or complication rates. Fortunately, in rhinological surgery the former, and often the latter are rare events, so these measures tell us little about the effectiveness of our treatment. Furthermore, as the aim of most rhinological procedures is to improve patient symptoms and quality of life, it seems incongruous to measure outcome without reference to the patient's self-reported health status. The importance of such patient-rated evaluation was noted nearly forty years ago in relation to the success of surgery for chronic rhinosinusitis; "little is achieved by quoting figures and statistics, as the results depend to a great extent on subjective response of a patient..." [(5)]. Despite this, the use of PROMs has not yet received widespread acceptance.

Using PROMs in clinical practice ensures that medical care is focused on the patient and their symptoms rather than the disease. The measures are potentially useful in both the clinical encounter and in quality improvement. They can be used to facilitate the consultation, to identify and prioritise problems, define aims of treatment and measure the subsequent response. PROMs also facilitate comparative audit (the comparison of provision of healthcare by different providers or different methods of treatment) and can thus improve future healthcare provision.

How do we measure them?

Quality of life is measured using one of a growing number of 'instruments'; typically these are questionnaires, but in some cases visual scales or grading systems can be used. These allow quantitative assessment of otherwise subjective results. So why not simply ask the patients if they are satisfied with their treatment? Although this is easy to do, patient satisfaction is influ-

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enced by many variables [6,7], such as the availability and convenience of health care, the 'bedside manner' of the doctor, affability of the extended team and perceived cleanliness of the hospital. While these are all important, they complicate evaluation of clinical outcome. To avoid this, the questionnaires require the patient to rate the impact of their disease across a number of specified 'domains' or areas of interest.

For any measure to have clinical usefulness it must valid, appropriate to the disease in question, reliable, responsive to change, and easily interpreted. It must also be simple and quick to complete, easy to score, and provide useful clinical data [8]. The development of PROMs involves clearly defined steps and psychometric analysis to ensure these needs are met. Some PROMs have been developed for particular conditions or treatments (disease-specific measures) while others were developed to be used in all patient groups or healthy individuals (generic measures).

GENERIC OUTCOME MEASURES

Generic PROMS allow comparison between conditions or treatments, and therefore can be used to determine the impact of different diseases on patient groups, the relative cost utility of different interventions and to inform commissioning decisions.

The short form 36 **(SF-36)** is a multipurpose, 36-item survey that measures eight domains of health: physical functioning, role limitations due to physical health, bodily pain, general health perceptions, vitality, social functioning, role limitations due to emotional problems, and mental health. It has been widely used in many medical conditions and over 5000 publications, with normative values available for the general population [9]. Using the SF-36, chronic rhinosinusitis has been shown to have a negative impact on several aspects of quality of life, and has a greater impact on social functioning than chronic heart failure, angina or back pain [10].

The **Health Utilities Index** [11] (HUI) includes 8 domains (vision, hearing, speech, ambulation, dexterity, emotion, cognition, and pain). While more suitable for conditions affecting the ear, this again is likely to lack sensitivity for rhinological conditions. The Scottish ENT Outcomes Study (SENTOS) found only a small benefit from nasal surgery (of all types grouped together) using the HUI [12].

EQ-5D, a generic measure of health-related quality of life [13], has been recommended for future use by a working group of the DoH [4]. The EQ-5D measures health related quality of life across 5 domains; walking and mobility, ability to self-care, ability to perform usual activities, pain and anxiety or depression. While suitable for common surgical procedures such as hip and knee arthroplasty, for which it is currently being used by the DoH, global measures such as the EQ-5D may lack the sensitivity to assess changes in health status in many conditions. For example, when applied to cataract surgery, the DoH pilot study found that although the majority of patients (93.1% of 566 included in study) reported that their vision was better following cataract surgery, there was no change in the EQ-5D (pre-op mean 0.81, post-op mean 0.78) [4]. Similar results have been shown in patients with conductive hearing loss [14]. One might also expect that the EQ-5D will fail to capture the impact of rhinological disease or the effectiveness of treatment. This is of concern if such measures are used for demand management to ration healthcare. Furthermore, application of these different instruments, the SF-36, HUI and EQ-5D, in the same patient group can yield significantly different results [15].

The Glasgow Benefit Inventory (GBI) is a validated generic quality of life instrument that has been widely used in otolaryngology [16]. It measures change in health status following interventions, allowing comparison between different types of treatment. It is a post-intervention questionnaire that is administered once only, and contains 18 questions, which can be filled in by the patient or completed by an interviewer. The scores range from +100 (maximum positive change) to -100 (maximum negative change). The GBI has been used to show benefit from functional and cosmetic septorhinoplasty (+58.3 [17]), endoscopic sinus surgery (+23 [18]), endoscopic DCR (+16.8 [19]) and septoplasty (+11.3 [20]). Although the once only administration of the instrument is likely to increase compliance, it means that baseline data regarding casemix is not collected and therefore precludes controlling for this in comparative studies. It also does not contribute to an understanding of the severity of patients' symptoms prior to treatment.

DISEASE SPECIFIC OUTCOME MEASURES

The time needed to collect PROMs is commonly cited as a barrier to routine clinical use. However, disease specific instruments readily identify the most important symptoms to patients, focus the consultation, and provide a useful clinical record, thus may help facilitate the patient's visit. They can be used to define the aims of treatment, and are likely to be more sensitive to small but clinically relevant changes in outcome than global measures. There are a growing number of disease specific tools available for many rhinological conditions.

RHINOSINUSITIS AND ALLERGY

Two recent literature reviews have identified numerous disease-specific instruments designed for use in patients with either rhinitis or rhinosinusitis (either acute or chronic) [21,22]. These were evaluated in terms of their reliability, validity, responsiveness and ease of use. Key features (with references) are summarised in Table 1.

Both the Taskforce on Rhinosinusitis and the European Position Paper on Nasal Polyposis have recommended the collection of PROMs, but have been unable to advocate a single

Table 1. Key features of studies disease-specific instruments designed for use in patients with either rhinitis or rhinosinusitis.

Rhinitis		
Rhinoconjunctivitis Quality life questionnaire (RQLQ)[23]	1991	28 items, 7 domains, validated for use in allergic rhinitis of well validated, but poor ease of use
Exists in a number of derivatives; Rhinitis quality of life questionnaire[24]	1993	24 items, 6 domains
Standardized RQLQ[25]	**1999**	**as above**
Mini RQLQ[26]	**2000**	**14 items over 5 domains, greater ease of use**
Nocturnal RQLQ[27]	2003	16 items over 4 domains, specific to sleep disturbance and nocturnal symptoms
Rhinitis Outcome questionnaire[28]	2001	26 items, 4 domains; nose, eye, chest, systemic.
Rhinosinusitis		
Fairley's symptom Questionnaire[29]	1993	12 item, fully validated tool
Chronic Sinusitis Type specific questionnaire[30]	1993	Extensive tool with 3 forms. High respondent burden and complexity limits usefulness
Sinusitis Survey[31]	1994	5 items, lacks psychometric validation
Chronic sinusitis Survey usage[32]	1995	6 items, focused on duration of symptoms and medication
Rhinosinusitis Outcome added severity and importance Measure[33] (RSOM-31)	**1995**	**31 items, 7 domains with scales**
Rhinosinusitis Disability Index[34]	1997	30 items, linked to impact on daily functioning
Rhinosinusitis Utility Index[35]	1998	10 items. Designed for cost-effectiveness analysis
Sinonasal Outcome Test-16[36]	1999	16 item modification of the SNOT-20
Sinonasal Outcome Test-20[37]	2002	Modification of RSOM derived by item reduction of symptoms including nasal obstruction and loss of sense of smell.
Sinonasal Assessment Questionnaire[38]	2002	11 item modification of the SNOT-20.
Cologne questionnaire[39]	2002	7 items focusing on symptom severity, but lacks validation
SN-5[40]	2003	5 item survey for use in paediatric population only
Rhinosinusitis Symptom Inventory[41]	2004	12 items, focused on demonstrating change in symptoms and medication usage
Rhinoqol[42]	**2005**	**17 items, includes measure of frequency and impact of symptoms**
Sinonasal Outcome Test-22[43]	2006	Further modification of SNOT-20, returning 2 deleted items, nasal obstruction and loss of sense of smell

outcome tool suitable for all studies, and the choice will depend partly on the clinical setting. Morley and Sharp [(22)], based on their appraisal of the available measures concluded that the SNOT-22 [1)] was the most suitable tool in terms of reliability, validity, responsiveness and ease of use. The SNOT-22 was excluded from the systematic review by Fokkens and colleagues [(21)], as at time of publication it had not undergone formal validation. This review, based on extensive quality assessment, recommends the standardized Rhinoconjunctivitis Quality of Life Questionnaire for rhinitis, and both the RSOM-31 and the Rhinoqol for CRS. The SNOT-20 was also highly rated, but was found to be less responsive to change.

The SNOT-22 was used to collect prospectively the outcomes of 3,128 patients undergoing a range of surgical procedures for chronic rhinosinusitis, who were recruited by the National Comparative Audit of Surgery for Chronic Rhinosinusitis and Nasal Polyposis [(43)]. This is the largest published outcome study to date in CRS, and therefore provides useful benchmarking data against which future studies may be compared. Significant reductions in SNOT-22 scores were achieved by surgery, and maintained across a 5-year period. Psychometric validation has been completed, and normative data using the SNOT-22 also collected.

NASAL OBSTRUCTION AND SEPTAL SURGERY

Objective measurements of nasal obstruction can be performed in a number of ways, but are largely confined to research settings, with little agreement on the most acceptable tool. The Nasal Obstruction Septoplasty Effectiveness (NOSE) questionnaire is a validated 5-item instrument for use in patients with nasal obstruction, and has been used to measure improvements in QOL in septoplasty, functional septorhinoplasty and nasal valve surgery [(44)]. The SNOT-22 has also been used in septoplasty, although it has not been validated for use in this patient group [(45)].

RHINOPLASTY AND FACIAL APPEARANCE

Perhaps more so than in any other aspect of rhinology, patient satisfaction and quality of life must be the measure against which successful aesthetic facial plastic surgery should be judged. Patient satisfaction will be achieved by not only meticulous surgical technique, but also by clearly defining which

[1)] Footnote: The SNOT-22 form is included in the pdf file of this article, available for members at the journals website: www.rhinologyjournal.com

aspects of cosmesis the patient would like altered by the procedure. A recently published study identified 23 patient-reported instruments targeted to facial plastics [46]. These covered a wide range of procedures including rhinoplasty, blepharoplasty, face lift, facial nerve dysfunction and scar management and there was considerable variation in the rigor with which the measures had been validated. The Rhinoplasty Outcomes Evaluation (ROE) [47] was the only QOL instrument designed specifically for rhinoplasty. This has 6 domains including appearance and function of the nose, friends or loved one's opinion of their nose, limitation in social or professional activities, confidence in nasal appearance and wish for future surgery. It has been fully validated [48].

There remain few published studies including patient rated satisfaction following rhinoplasty. Three studies show significant improvement in ROE scores following rhinoplasty [48–50].

SINONASAL MALIGNANCY

Malignant tumours of the sinonasal cavity are relatively uncommon, but treatment for advanced sinonasal malignancy often has significant adverse effects on many aspects of quality of life and daily functioning, including facial image, eating, breathing, bodily pain, speech sleep and social functioning. As the 5-year survival for advanced head and neck malignancy remains at 50%, it is vital to consider the impact of different treatment modalities on quality of life, which has been shown to be poorer than in survivors of lung and colon cancer [51].

There are several disease specific tools available, but three have been used most extensively, and are free to use. The University of Washington Head and neck Cancer Questionnaire [52] is the shortest and easiest to use of the three, with 12 disease specific items, and 3 global health question. It is available for download from www.depts.washington.edu/otoweb/research/head_neck_cancer/uw_qol_r_v4.pdf.

The European Organisation for research and treatment of cancer (EORTC) have developed and validated and disease specific measure for patients with head and neck cancer53, which is used in conjunction with a generic tool, with a total of 65 items. The Functional Assessment of Chronic Illness Therapy (FACT) also combines a generic tool (27 items) with a head and neck module (10 items) [54]. These may be preferable of more detailed quality of life data is required.

Several studies demonstrating reduced quality of life in head and neck cancer patients have included patients with sinonasal malignancy with the study group, although there are no published studies looking exclusively at this group of patients [55].

SKULL BASE SURGERY

A disease-specific instrument has been designed and validated for those undergoing resection of anterior skull base tumours [56]. This instrument includes generic questions, items drawn from head and neck questionnaires, and also includes more detailed questions regarding altered taste, smell, appearance, epiphora, nasal secretions, and visual disturbances. Surprisingly, a study using this instrument in 40 patients undergoing a endonasal approach for an anterior skull base lesion (of which 33% were malignant) found that most of patients (75%) reported that the surgical procedure improved or did not interfere with their overall QOL [57]. Published studies addressing surgery for pituitary lesions have used global measures, and have identified reduced quality of life following treatment [58-60].

NOSE SPECIFIC PROMS

Wilson and colleagues argue that the disease specific measures highlighted above suffer from the need to diagnose the appropriate disease before the measure can be applied, and therefore have developed a 'general nasal patient inventory' [61]. The resulting 45-item questionnaire has the benefit of capturing many different symptoms associated with a range of rhinological conditions. However, it may lack the sensitivity of the more disease specific instruments, and having not been subjected to item reduction by psychometric validation, has a higher respondent burden that may reduce compliance. It will be useful for studies wishing to compare different rhinological conditions and their impact on quality of life.

WHY ARE WE NOT ROUTINELY MEASURING PROMS?

There are a number of problems commonly cited as barriers to routine use of PROMs, and these will be discussed below.

- *It takes too long to do*

It is hoped that as health care providers make collection of PROMs data compulsory, they acknowledge the time required to do so, and remunerate it appropriately. In the meantime, PROMs may be incorporated into clinical practice with little disruption to the clinic by encouraging patients to complete forms whilst waiting to be seen.

- *Patient rated outcomes are unreliable*

'Objective' (clinician rated) outcome measures are often thought to be more reliable than 'subjective' (patient rated) outcomes, and are more readily accepted by clinicians. However, we must remember that when clinicians use grading scales they are prone to error, and may be biased by preconceived ideas of disease severity, or what treatment they wish to offer. Different observers, or the same observer on repeated scoring create variation in scores generated using objective scales. Even 'hard' outcome measures such as revision surgery rates may be biased by the surgeon's attitude to further surgery.

We have to remember what drives our patients to seek medical treatment for rhinological conditions – and that is most frequently impairment of their quality of life. There is little point demonstrating an increase in ciliary beat frequency if this is not accompanied by improvement in patients' symptoms. We

must have some trust in patients to be honest about their symptom severity, and value their rating of disease burden.

- *They do not correlate to objective measures*

Several publications have demonstrated the lack of correlation between patient rates measures of symptom severity in chronic rhinosinusitis and objective measures, such as the radiological Lund-Mackay scoring system [62-65].

The relationship between biological, physiological and radiological variables and symptoms is complex. Physiological variables can be profoundly abnormal in some asymptomatic patients, while others may report severe symptoms in the absence of change in biological markers of disease. Studies in many medical specialties demonstrate that patient reported measures of symptoms are poorly correlated with clinical measures. For example, in studies of benign prostatic hypertrophy there was no association between urodynamic indices of obstruction and obstructive symptoms [66], while in asthma and COPD there is little or no correlation between subjective dyspnoea and FEV1 [67].

It has been proposed that patients' symptoms and quality of life are the result of an interaction between many factors, in which biological or physiological variables are only a piece of the final jigsaw (Figure 1) [68]. Clinicians probably overestimate the impact that these measurable biological variables have on symptoms and functioning. It is therefore not surprising that there should be little correlation between a patient-based symptom severity-scoring systems such as the SNOT-22 and the Lund-Mackay score. The absence of correlation does not suggest that either patient rated or objective scores are invalid, but that they are measuring different aspects of the disease process, and therefore are useful adjuncts in outcome measurement.

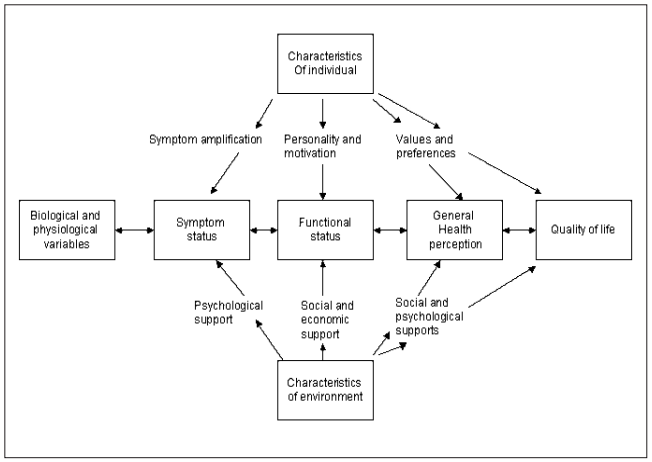

Figure 1. Relationships between physiological measures of disease and patients' symptoms.

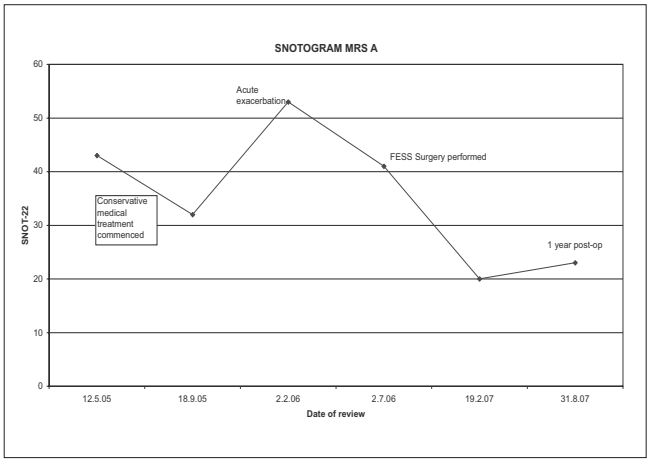

Figure 2. A 'snotogram' plotting repeated PROMs over time easily demonstrates both acute exacrnations and response to treatment in CRS

- *They do not predict outcome*

Detractors of the use of PROMs as a primary outcome measure argue that they do not predict the outcome of surgical intervention. Kennedy reported that symptomatic improvement following FESS surgery does not correlate with resolution of mucosal disease in patients with chronic rhinosinusitis, and therefore suggests that symptomatic improvement alone may not be a reliable outcome measure [69]. However, for the reasons discussed above, it is unlikely that a patient rated measure will predict outcome if measured using a clinician rated 'biological' marker. In contrast, patient rated scores are strong predictors of symptomatic improvement following surgical intervention [43].

- *They do not help my practice*

As healthcare is provided within a team structure, it is difficult to attribute patient outcomes to a single doctor. Nevertheless, PROMs are likely to be part of the information required for revalidation in the UK and potentially in other healthcare systems. In this setting, they will also allow good baseline case-mix data that will facilitate fair comparison with national averages. Their routine use will also facilitate the use of electronic datasets.

In the clinical setting, repeated measures map the individual patient's journey, and allow improvements or exacerbations to be readily identified. For example, using repeated SNOT-22 measures a 'snotogram' can be constructed which highlights the impact of treatment (Figure 2). This was produced by an electronic database being developed on behalf of the British Rhinological Society.

LIMITATIONS OF PROMS

Quality of life measures are not a substitute for measuring outcomes associated with disease but are an adjunct to them. For example, while it is useful to measure symptomatic improve-

ment following septoplasty, this could be combined with an objective assessment of the nasal airway, such as nasal inspiratory peak flow. Patient satisfaction following rhinoplasty could be combined with photographic assessment using an objective scoring system such as the Rhinoplasty Assessment Scale [70]. In addition, quality of life is not the only way to measure patient centred outcomes; measures of disability, social interaction and support, and psychological well-being may be more appropriate in some settings.

Quality of life measures may not be truly patient centred, as they impose standardised domains derived from the population as a whole. They may restrict a patient's choice of symptoms to report, and fail to capture those of importance to the individual. In this circumstance they are unlikely to be responsive to change after treatment and their scores may be difficult to interpret. There are some individualised measures of quality of life available, but the complexity both in completing and interpreting these measures has limited their use [71,72]. An alternative is to apply a weighting scale to standardised items within a questionnaire, which modifies the overall score according to the importance the individual places on a given symptom. However, the added respondent burden may reduce compliance.

Scores from quality of life measures are usually presented as population means. While this is useful in testing one treatment against another in groups of patients, it is of less value in clinical practice. It is much more difficult to interpret scores on an individual patient basis, for example, is a score above the mean considered abnormal? Should intervention be restricted to those with scores above a certain point? In order to answer this, some studies have attempted to define the 'minimally important improvement' – this is the smallest change in symptoms that can be perceived as a real benefit by the patient. But again, this applies values derived from the whole population to individuals who may differ widely in their responses.

The department of Health in England suggest that PROMs may be used for 'demand management'. We have already highlighted the problems using a global measure such as the EQ-5D to compare procedures such as hip arthroplasty with rhinological procedures, and as a specialty we should oppose attempts to ration health care provision by these means. Similarly, it is unlikely that at the current time patient rated outcomes measures will be suitable for 'performance management', or linked to financial reward.

Finally, there is concern that routine collection and publication of outcome data may encourage surgeons to become risk averse, and refuse treatment to the most high risk cases. However, it will be harder for a surgeon to predict which patients may derive most symptomatic benefit, as for reasons stated above, this may not relate to markers of disease severity. There is also no evidence of case selection in cardiothoracic surgery following publication of mortality data.

CONCLUSIONS

PROMs are likely to play an increasing role in measuring the success of medical treatments. If used in conjunction with clinical markers of disease severity, they can add much to our understanding of the burden of disease on our patients, and may help us to identify who will benefit most from treatment. However, they may be used to restrict the availability of procedures not shown to achieve sufficient improvement in quality of life. There is a wide range of PROMs available, both global and disease specific, and it is therefore important to choose the most suitable tool for each individual study.

PROMs are here to stay – we can ignore them to our peril or we can embrace them and use them to our advantage.

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