The impact of chronic rhinosinusitis and nasal polyposis in quality of life

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1. ABSTRACT

Multiple studies indicated that chronic rhinosinusitis is associated with a dramatic reduction in patient quality of life. The presence of asthma and atopy may have cumulative and negative impact on quality of life. To assess quality of life, specific and generic questionnaires may be used. Specific questionnaires are usually focused on one particular area such as a disease state, a selected population, or a certain function or problem. Generic

questionnaires are also available to assess the burden of illness in different conditions and enable the comparison of patients suffering from chronic rhinosinusitis with other patient groups. On the basis of our review of the existing questionnaires concerning rhinosinusitis, we identified two adequate levels of discriminant validity the RSOM-31 and RhinoQol. The SF-36 is one of the most widely used generic questionnaires in chronic rhinosinusitis.

2. INTRODUCTION

Chronic rhinosinusitis including nasal polyps is a chronic inflammatory disease of the nasal and paranasal sinus mucosa that, despite differing hypotheses of its cause, remains poorly understood. CRS is defined as inflammation of the mucosa characterised by two or more symptoms, one which should be either blockage/obstruction/congestion or nasal discharge, ± facial pain/pressure, ± reduction or loss of smell; and either endoscopic signs of polyps and/or mucopurulent discharge primarily from middle meatus and/or; oedema / mucosal obstruction primarily in middle meatus, and/or CT changes showing mucosal changes within the ostiomeatal complex and/or sinuses (1). CRS is frequently associated with asthma and other pulmonary disorders such as cystic fibrosis, primary ciliary dyskinesia, and aspirin sensitivity

Although CRS is not a life-threatening disease it can significantly decrease patient's Quality of Life (QoL) (3-5). However, it is of interest that the severity of nasal symptoms or findings do not always correlate with QoL scales (6). Schipper *et al.* defined QoL as "the functional effects of an illness and its consequent therapy upon a patient, as perceived by the patient" (7). Juniper has commented that the last phrase is particularly important because it emphasizes that these are the impairments that the patients consider to be important (8). QoL is a general term integrating several aspects of life such as physical, psychological, social, economical, spiritual, cognitional and sexual dimensions. A disturbance in any one aspect will in turn affect the other domains and this influences the overall QoL (9).

Psychometric theory has been applied to the development of patient-oriented health assessments of health. These health measures focus on multiple domains of health in an effort to present a complete picture of health and illness. Patient-perceived subjective outcome is an integral part in reporting results of health care (10). As the use of patient report outcome measures is arguably not yet an integral part of the reporting of health care outcomes, though there use is clearly increasing and perhaps they should be an integral part of such reporting (11). This revision is intended to be a state-of-the art review to provide an evidence-based documented review of the QoL and chronic rhinosinusitis. We reviewed the English literature up to 2007 to identify studies of interest using the terms: QoL, rhinosinusitis, sinonasal, nasal polyposis (NP).

3. QUALITY OF LIFE QUESTIONNAIRES

Generally, there are two major types of QoL instruments used in clinical trials: specific and generic. Specific questionnaires are usually focused on one particular area such as a disease state, a selected population, or a certain function or problem. Generic questionnaires are also available to assess the burden of illness in different conditions and enable the comparison of patients suffering from CRS with other patient groups.

3.1. Generic questionnaires

Generic instruments are applicable to all health conditions and they allow a comparison of QoL impact in different diseases as well as healthy and diseased subjects. EuroQol 5D, McGill Pain Questionnaire, Short Form-36 Health Survey, and Short Form-12 Health Survey are the most used generic questionnaires in chronic rhinosinusitis. All these questionnaires have been translated into numerous languages.

3.1.1. EuroQol 5D (EQ-5D)

It is a standardised instrument for use as a measure of health outcome. Applicable to a wide range of health conditions and treatments. EQ-5D is designed for self-completion by respondents and is ideally suited for use in postal surveys, in clinics and face-to-face interviews. It is cognitively simple, taking only a few minutes to complete. The EQ-5D descriptive system comprises 5 dimensions of health (mobility, self-care, usual activities, pain/discomfort, anxiety/depression). Each dimension comprises three levels (no problems, some/moderate problems/extreme problems). The EQ VAS (visual analogue score) records the respondents self-rated health status on a vertical graduated (0-100 mm) visual analogue scale (12). It allows the incorporation of general population and patient preference values and thereby the generation of Quality Adjusted Life Years, hence its relevance for pharmacoeconomic studies.

3.1.2. McGill Pain Questionnaire

It consists primarily of 3 major classes of word descriptors: sensory, affective and evaluative, that are used by patients to specify subjective pain experience. It also contains an intensity scale and other items to determine the properties of pain experience. The questionnaire was designed to provide quantitative measures of clinical pain that can be treated statistically (13).

3.1.3. Short Form-36 Health Survey (SF-36)

It is one of the most widely used generic questionnaires (14). In 1991, the International Quality of Life Assessment (IQOLA) project was initiated to translate, adapt, and validate SF-36 for the use in some fifteen countries, showing good reproducibility and validity (15). The SF-36 questionnaire consists on 36 self-administered questions divided over eight domains, covering both physical and mental health. The physical component summary includes 4 domains: physical functioning, role physical functioning, bodily pain, and general health. The mental component summary includes 4 domains: vitality, role emotional functioning, social functioning, and mental health. The sum of the score is calculated for each domain and transformed to a percentage of the total possible score. Scale scores range from 0 to 100, representing the percentage of the total possible score achieved. High scores indicate good quality of life while low scores indicate low quality of life.

3.1.4. Short Form-12 Health Survey (SF-12).

SF-12 is a shorter version of the SF-36 Health Survey designed to reproduce the physical and the mental component summary scores. It includes 12 questions from the SF-36 Health Survey: two questions concerning physical functioning; two questions on role limitations because of physical health problems; one question on bodily pain; one question on general health perceptions; one question on vitality (energy/fatigue); one question on social functioning; two questions on role limitations due to emotional problems; and two questions on general mental health. The scoring of individual items is identical to the SF-36 Health Survey (16).

3.2. Specific questionnaires

Several specific questionnaires for patients with CRS such as Rhinosinusitis Disability Index, Chronic Sinusitis Survey Score, SinoNasal Outcome Test-20, and SinoNasal Outcome Test-16 have been developed.

3.2.1. Rhinosinusitis Disability Index (RSDI)

In this 30 item validated questionnaire, patient with CRS is asked to relate nasal and sinus symptoms to specific limitations on daily functioning. RSDI is a valid measuring instrument for patients with sinus disease, and test-retest validity reveals reliability over time (17).

3.2.2. Sinonasal Outcome Test 20 (SNOT-20)

The SNOT-20 is a modification of the 31-Item Rhinosinusitis Outcome Measure, and it contains 20 nose, sinus, and general items. To complete the instrument, patients indicate how much they are affected in each area and identify the 5 most important items (18). However, the lack of the SNOT-20 is that it does no contain questions on nasal obstruction and loss of smell and taste. These questions are included in the SNOT-22 questionnaire which however is not validated.

3.2.3. Sinonasal Outcome Test 16 (SNOT-16)

The SNOT-16 is a reliable, valid, and responsive instrument for measuring rhinosinusitis specific health-related QoL (19).

3.2.4. Rhinosinusitis outcome measure (RSOM)

RSOM contains 31 items classified into 7 domains and has been well validated and allows measurement of symptom severity and importance to the patient (nasal, eye, ear, sleep, general, emotional, functional problems). The severity and importance scales, however, make it somewhat difficult for the patient to fill the questionnaire (20).

3.2.5. Rhinoconjunctivitis quality of life questionnaire (RQLQ)

The RQLQ was developed to measure the problems that adults with rhinoconjunctivitis, both atopic and non-atopic, experience as a result of their nose and eye symptoms. It has 28 questions in 7 domains (activity limitations, sleep problems, non-nose/eye symptoms, practical problems, nose symptoms, eye symptoms and emotional function) (21). Although it is optimal to use patient-specific activities, Juniper *et al.* have developed a version of the RQLQ in which the 3 activities are standardised for all patients with rhinoconjunctivitis. The

RQLQ has been fully validated and shows strong measurement properties.

4. PSYCHOMETRIC CHARACTERICS OF QoL OUESTIONNAIRE

4.1. Reliability

There are several types of reliability that should be examined.

4.1.1. Test-retest reliability

We estimate test-retest reliability when we administer the same test to the same sample on two different occasions. This approach assumes that there is no substantial change in the construct being measured between the two occasions. The amount of time allowed between measures is critical. We know that if we measure the same thing twice that the correlation between the two observations will depend in part by how much time elapses between the two measurement occasions.

4.1.2. Internal consistency reliability

In this estimation we use our single measurement instrument administered to a group of people on one occasion to estimate reliability. In effect we judge the reliability of the instrument by estimating how well the items that reflect the same construct yield similar results. We are looking at how consistent the results are for different items for the same construct within the measure. There are a wide variety of internal consistency measures that can be used. It is usually estimated by calculating Cronbach's α (range 0 to 1). If a scale has an alpha of at least 0.7 the scale is considered to be reliable for group level comparison and a value of 0.9 or more for assessment at the individual level (22).

4.2. Validity

It is defined as the degree to which an instrument measures what we intend to measure (23). There are different types of validity (24).

4.2.1. Convergent validity

Is demonstrated when scores on the test being examined are highly correlated to scores on a test thought to measure similar or related concepts.

4.2.2. Discriminant validity

Discriminant validity is demonstrated when scores on the test being examined are not correlated to scores on a test meant to measure a very different construct (25).

4.3. Responsiveness

Responsiveness it has been defined as the ability of an instrument to accurately detect change when it has occurred (26). Two types of responsiveness have been identified.

4.3.1. Internal responsiveness

Internal responsiveness is defined as the ability of a measure to change during a pre-specified time frame. Table 1. Generic quality of life questionnaires in chronic rhinosinsusitis with and without nasal polyposis

Study	Number of	Treatment	QoL	Impact on QoL	Level	of
	Patients		questionnaire		evidence	
Gliklich, 199531	158	Not defined	SF-36	Decreased levels	III	
Gliklich, 1997 ²⁷	108	Surgery	SF-36	Decrease preop	IIb	
Winstead, 1998 ²⁸	125	Surgery	SF-36	Improve post-op Decrease preop Improve post-op	IIb	
Radenne, 1999 ⁵	49	Steroids vs surgery	SF-36	Decrease pre-treatment Improve post-treatment	IIa	
van Agthoven, 2001 ³³	56	Filgrastim	EQ-5D SF-36 MPQ	Decrease pre-treatment Improve after treatment	Ib	
Baumann, 2005 ³²	123	Surgery	SF-36 EQ-5D	Decrease preop Improve post-op	III	
Alobid, 2005 ⁴	109	Steroids vs surgery	SF-36	Decrease preop Improve post-op	Ib	
Alobid, 2005 ³	130	Not defined	SF-36	Negative impact of asthma and atopy	III	
Atlas, 2005 ³⁴	50	Surgery	SF-12	Decrease preop Improve post-op	IIb	
Videler, 2006 ³⁵	23	Surgery	SF-36 MPQ	Decrease preop Improve post-op	IIb	
Alobid, 2006 ⁴⁹	78	Oral and intranasal steroids	SF-36	Decrease pre-treatment Improve after treatment	Ib	

EQ-5D: EuroQol 5D, MPQ: McGill pain questionnaire, QoL: quality of life, SF-36: short form-36 health survey, SF-12: short form-12.

Internal responsiveness is often examined by administering a measure before and after a treatment of known efficacy.

4.3.2. External responsiveness

External responsiveness reflects the extent to which changes in a measure relate to changes in other measures of health status.

5. CHRONIC RHINOSINUSITIS

There are many generic and disease specific QoL questionnaires available to rhinosinusitis studies. However, most of the questionnaires are not yet validated.

5.1. Generic questionnaires

Generic measurements enable the comparison of patients suffering from CRS with other patient groups (table 1). Of these the SF36 is by far the most widely used and well validated and this has been used both pre- and post-operatively in chronic rhinosinusitis. Using the SF-36 and compared with a healthy population, many studies demonstrated that CRS has a considerable impact on all SF-36 domains except for physical functioning (27-30). Patients with CRS and no prior surgery underwent crosssectional evaluation by use of the SF-36. Significant differences were seen in several domains, including bodily pain, general health, vitality, and social functioning compared from the eight subscales of general health assessment with similarly derived data for the United States general population. Comparisons with other chronic diseases revealed more bodily pain and worse social functioning for rhinosinusitis patients than in patients with congestive heart failure, angina, chronic obstructive pulmonary disease, and back pain.

These findings suggest that the health burden of CRS is far greater than is currently appreciated (31). Baumann and Blumenstock demonstrated significant impairment for all SF-36 subscales compared with normbased scoring of the general German population. Compared

with male patients, female patients scored a significantly worse score in all SF-36 and one EQ-5D domains (32). van Agthoven et al (33). investigated the influence of filgrastim administration on the QoL of refractory CRS patients who did not respond to regular treatments. The QoL was assessed with EuroQol, SF-36, and McGill pain questionnaire. The QoL scores were all well below population norm scores and scores in a group of patients with chronic sinusitis who had sinus surgery. QoL scores of the filgrastim group suggested a better QoL than the placebo group, although none of the differences were statistically significant (33). Using SF-12, Atlas et al. (34) studied the impact of CRS (N=50) on QoL. In this study, the SF-12 physical component score strongly correlated with the symptom impact score, while the SF-12 mental component score showed a low correlation with the disease-specific measures but correlating with symptoms (34). In patients who underwent Denker's procedure for refractory CRS (N=23), QoL and pain were evaluated before surgery and after 12 months and 2 years of surgery with MPO. A significant improvement in pain and most of the subscores after surgery was observed (35).

The effect of surgical treatment was also studied with generic questionnaires pre- and postoperatively. Winstead and Barnett (28) showed a significant improvement at 6- and 12-months following endoscopic sinus surgery for all domains of SF-36 and, at follow-up, QoL scores did not significantly differ from those of the American general population. Gliklich and Metson found that patients with CRS presented a significant improvement after sinus surgery in six SF-36 domains reaching near-normative levels Compared with the norm-based scores, both women's and men's SF-36 scores reached normal levels in seven domains of after 3 months endonasal sinus surgery (32). The Glasgow Benefit Inventory (GBI), a post interventional questionnaire with general, social support and physical health subscales, was posted to patients with CRS after functional endoscopic sinus

Table 2. Specific quality of life questionnaires in chronic rhinosinsusitis with and without nasal polyposis

Study	Patients number	Treatment	QoL questionnaire	Impact on QoL	Level of evidence
Anderson, 1999 ¹⁹	47	Local steroids vs surgery	SNOT-16 SF-36	Decrease at baseline Improvement after medical and surgical treatment	IIb
Senior, 2001 ³⁷	292	Not defined	RSDI	Greatest level of disability	III
Birch, 2001 ³⁹	53	Not defined	RSDI	Decreased levels	III
Piccirillo, 2002 ¹⁸	102	Local steroids	SNOT-20	Decrease at baseline Improvement after treatment	IIb
Ragab, 2004 ⁴¹	90	Local steroids vs surgery	SNOT-20 SF-36	Decrease at baseline Improvement after medical and surgical treatment	Ib
Briggs, 2004 ⁴²	82	Surgery	SNOT-16	Decrease at baseline Smoking is associated with worse outcomes	IIb
Javer, 2006 ⁴³	95	Surgery	RSOM-31	Decrease preop Improve post-op	Ib
Ebbens, 2006 ⁴⁴	116	Amphoterycin nasal lavage	RSOM-31 SF-36	Decrease at baseline No improvement after treatment	Ib (-)
Hissaria, 2006 ⁵¹	40	Oral steroids	RSOM-31	Decrease at baseline Improvement after treatment	Ib
Friedman, 2006 ⁴⁵	42	nasal irrigation	RQLQ	Decrease at baseline Improve only Dead Sea salt solution group	Ib
Wallwork, 2006 ⁴⁰	64	Roxithromycin	SNOT-20	Decrease at baseline Improvement after treatment	Ib
Robinson, 2007 ³⁸	123	Surgery	RSDI	Decrease preop Improve post-op	III

QoL: quality of life, RQLQ: rhinoconjunctivitis quality of life questionnaire, RSDI: rhinosinusitis disability index, RSOM-31: rhinosinusitis outcome measure 31, SNOT-16: sinonasal outcome test 16, SNOT-20: sinonasal outcome test 20, SN-5: sinonasal 5 survey. (-) study with negative outcome.

surgery. The GBI scores were mainly positive, indicating a benefit from the surgery (36).

5.2. Specific questionnaires

In these questionnaires specific symptoms for rhinosinusitis such as nasal blockage, loss of smell, rhinorrhea, headache, facial pain, and sneezing are included. They are usually more sensitive than general health status instruments (table 2).

5.2.1. Rhinosinusitis Disability Index (RSDI)

Senior *et al.* have found that individuals with rhinologic disease in general have lower physical scores, followed by functional scores and emotional scores. Individuals with CRS and allergic rhinitis have the greatest level of disability, while those with aspirin triad are least affected (37). Similar proportions of ASA-tolerant and ASA-intolerant patients with CRS showed improvement on QoL measures after endoscopic sinus surgery using RSDI and Chronic Sinusitis Survey (CSS) (38). Birch *et al.* demonstrated no correlation between endoscopic score and either the patient's self-rated symptom score or RSDI score. The correlation between the self-rated symptom score and total quality of life score was significant (39).

5.2.2. Sinonasal Outcome Test 20 (SNOT-20)

The SNOT-20 is a valid outcome measure for patients with rhinosinusitis; it describes the health burden and is sensitive to clinical change (18). Wallwork *et al.* found a significant improvement in SNOT-20 score after 3 months of macrolide treatment in patients with CRS (40). In a randomized study, Ragab *et al.* compared the medical (macrolide during 3 months) and surgical treatment of CRS using subjective and objective parameters including QoL. The authors administrated SNOT-20 before starting the treatment, and after 6 months and 1 year. They concluded that both the medical and surgical treatment significantly improved the QoL (41).

5.2.3. Sinonasal Outcome Test 16 (SNOT-16)

The SNOT-16 demonstrated excellent discriminant validity, and mean total SNOT-16 scores were significantly correlated with patient-reported overall health and bother (19). Briggs *et al.* (42) studied patients with CRS (N=82) and investigated whether smoking patients have poorer outcomes after endoscopic sinus surgery (ESS) based on a reliable validated rhinosinusitis-specific QoL outcome test. They concluded that smoking is statistically associated with worse outcomes after ESS based on average SNOT-16 scores.

5.2.4. Rhinosinusitis outcome measure (RSOM)

QoL restrictions in patients with CRS were greatest for the RSOM-31 in the areas of nasal symptoms and sleep deprivation, which were significantly improved by endoscopic sinus surgery (43). Ebbens *et al.* (44) studied the effect of intranasal treatment with amphotericin B compared to placebo in patients with chronic rhinosinusitis. The authors demonstrated that QoL measured by RSOM-31 were similar in both treatment groups at the time of randomization, and no significant differences were observed after 13 weeks of treatment (44).

5.2.5. Rhinoconjunctivitis quality of life questionnaire (RQLQ)

Friedman *et al.* presented a short-term study providing evidence on the superiority of hypertonic Dead Sea salt solution over saline nasal irrigation for treatment of chronic rhinosinusitis. Both groups had similar symptoms and RQLQ scores before treatment and had significant improvement after treatment. However, the Dead Sea salt solution patients had significantly better symptom relief and only this group showed improved RQLQ(S) scores (45).

6. NASAL POLYPOSIS

6.1. Generic questionnaires

There was a lack of evaluable data on NP and QoL, with no adequate randomized trails. Only few studies providing information about the effect of treatment of nasal polyps. Radenne et al. (5) investigated the impact of nasal polyps on QoL demonstrated that the SF-36 questionnaire presented a high internal validity and reliability and NP impaired QoL to a greater degree than perennial allergic rhinitis. Alobid et al. demonstrated that QoL in patients with NP is impaired in all SF-36 domains except for physical functioning. The mental health was lower than the physical health. No correlation was found between OoL and age, gender, nasal symptoms, CT scan, and polyp size (4). Patients with nasal polyps had lower scores in all SF-36 domains except for physical functioning and general health than patients with chronic obstructive pulmonary disease (46), coronary artery disease (47), and asthma (48). Asthma and atopy in patients with NP have a negative impact on QoL scores in role physical, body pain, vitality, and mental health. While aspirin sensitivity in these patients has no additional impact on QoL (4,49). Alobid et al. Demonstrated a significant improvement on all of SF-36 domains after both medical (oral steroids during two weeks and intranasal steroids during 12 months) and surgical treatment (endoscopic sinus surgery followed by intranasal steroids) reaching the levels of general population (4).

6.2. Specific questionnaires

The evaluation of NP is presently impeded by a lack of valid specific instruments to measure QoL. Also, there were insufficient data to assess the effect of gender, duration of therapy, or comorbidity with asthma or aspirin sensitivity on QoL. Using SNOT 22 Nasal polypectomy with additional surgery seems to have no benefit over simple polypectomy in terms of health-related quality of life improvement for patients with NP (50). Hissaria et al. studied the effect of short course of oral prednisolone in ameliorating the symptoms and improving the QoL of NP compared to placebo. RSOM-31 improved in both groups, but the prednisolone-treated group had significantly greater improvement than the placebo group. However, the subset of nasal-specific RSOM scores (6 parameters) showed significant improvement only in the prednisolone group (51).

7. SUMMARY

Specific and generic QoL questionnaires were used to assess the CRS and NP. These instruments are of interest to clinicians in a research context and during consultation. The authors limited the search to those articles whose primary objective was the development and validation of the questionnaire. On the basis of our review of the existing questionnaires concerning rhinosinusitis, we identified two adequate levels of discriminant validity the RSOM-31 and RhinoQol as reported also by van Oene *et al.* (45).

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Abbreviations: CRS: chronic rhinosinusitis; NP: nasal poliposis; QoL: quality of life

Key Words: Chronic rhinosinusitis, Nasal Polyposis, Quality Of Life, Steroids, Surgery, Review

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