Subjective Outcomes Assessment in Chronic Rhinosinusitis

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Abstract: The treatment of chronic rhinosinusitis (CRS) requires an increasing use of medical and economic resources. Therefore, the assessment of objective and subjective outcome of different treatment strategies is of considerable interest.

Validated quality of life (QOL) instruments are one important means to assess subjective outcome of the patients. Frequently used generic instruments are the Short Form 36 Health Survey (SF-36) for prospective evaluations and the Glasgow Benefit Inventory (GBI) for retrospective evaluations. Normative data and numerous comparative data sets collected from various diseases are available for the SF-36.

Disease-specific QOL instruments for CRS have been developed over the last 15 years. In this review 11 disease-specific instruments are discussed. Only four of these instruments cover all four main symptoms of CRS and are completely validated as well. Most frequently used instruments (Sino-Nasal Outcome Test, SNOT-20; Chronic Sinusitis Survey, CSS) do not query all the main symptoms of CRS.

Keywords: Quality of life, measuring instrument, validation, SF-36, SNOT-20.

INTRODUCTION

Chronic rhinosinusitis (CRS) is a common health condition in industrial countries concerning 10-15% of the German population [1]. In the US it was the most frequently reported chronic disease in a representative cohort of 100.000 adults participating in the National Health Interview Survey 1988 [2]. Negative effects of CRS on QOL of the patients have frequently been underestimated. Nevertheless, many patients report higher impacts of CRS on QOL dimensions like bodily pain or social functioning compared with other diseases like angina pectoris, pulmonary emphysema or chronic bronchitis [3].

Economic impact of CRS has rarely been investigated. In 2006, nearly 45.000 patients with CRS were operated in German hospitals [4]. In 1996, the healthcare expenditures for sinusitis in the US were 5.8 billion Dollars [5]. Gliklich and Metson [6] performed a break-even analysis and calculated a time period of 7 years until amortization of treatment costs can be achieved by reduced postoperative use of resources.

Under these conditions effective and successful treatment of CRS has an increasing medical and economic importance. The outcomes assessment of CRS treatment have been discussed in the literature for many years. In 1942, the revision surgery rate in 190 patients after transfacial extranasal procedures was nearly 31% [7]. Modern functional endonasal sinus surgeries (FESS) result in stable subjective success rates between 70% and 92% [8-10].

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Until the nineteen-nineties the evaluation of success was straitened to the reporting of complications, revision surgery rates etc. It was postulated that normal and non-inflammatory endoscopic clinical findings were always a successful result even for the patient. However, frequently strong divergences between clinical findings and subjective patient reports had to be noted [10]. Furthermore, computed tomography (CT) which is the most important imaging method in these patients could not establish significant correlations between imaging and symptom severity.

Since the nineteen-eighties quality of life (QOL) instruments were systematically developed and validated for use in clinical medicine to achieve the goal of measuring the subjective outcome of the patients. The first instruments for use in patients with CRS were developed in the nineteen-nineties. In the following general and disease-specific QOL instruments which are in use in patients with CRS are presented.

GENERAL (GENERIC) INSTRUMENTS

General instruments are applicable in different diseases. They measure general QOL and/or general health status of the patients. Different diseases can be compared regarding their impact on general QOL.

SHORT FORM 36 HEALTH SURVEY (SF-36)

The SF-36 questionnaire consists of 36 single items which form eight scales [11]. Every single item is a part of a scale or forms a scale by itself. For every single item the patient has to mark that given answer mostly approximating to his or her subjective experiences. The scales are:

1. Physical function
2. Role physical

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3. Bodily pain
4. General Health
5. Vitality
6. Social function
7. Role emotional
8. Mental health

The SF-36 is the most frequently used instrument worldwide for the measurement of general health-related QOL [12].

Several SF-36 studies including one study by our group demonstrated improved health-related QOL after endonasal sinus surgery in patients with CRS [13-15]. A prospective longitudinal study detected significantly improved scores in 6 out of 8 scales three years after surgery [16].

The SF-36 questionnaire has frequently been used concurrently with disease-specific instruments. Thus, in a prospective controlled study medical as well as surgical therapy of CRS lead to QOL improvement in the SF-36 and in the SNOT-20 while no differences in treatment success between the two cohorts could be detected [17].

SHORT FORM 12 HEALTH SURVEY (SF-12)

The SF-12 is a shortened version of the SF-36 which contains items from all eight SF-36 scales. Two summary scales were established: physical and mental summary score. The SF-12 is a reliable, valid and sensitive QOL instrument [18]. An improvement of physical and mental summary scores was demonstrated after FESS in patients with CRS [19].

CHILD HEALTH QUESTIONNAIRE (CHQ)

If QOL measurements in childhood are performed it is always a matter of discussion whether the patients (children) or their parents are the adequate persons to answer the questionnaire. Frequently, the parents serve as proxies for their children as they might have a better understanding for the evaluated subject and might better understand the questionnaire. While growing up children are increasingly competent to assess their health status [20].

The CHQ offers a 50-item version which is filled out by the parents as proxies for their children (CHQ-50PF, parent form) and an 87-item version to be filled out by the child itself (CHQ-87CF, child form). The questionnaire has 14 scales being assigned to two summary scores which are the physical and the psychosocial health score. The CHHQ-50PF is available in 60 languages. Normative values are available for the Australian and the US populations [21, 22].

Compared with the normal population and with other chronic paediatric diseases children with recurrent CRS showed a significantly reduced QOL in the scales of the CHQ [23].

GLASGOW BENEFIT INVENTORY (GBI)

The GBI was developed in 1996 in order to evaluate outcomes of surgical otorhinolaryngologic interventions [24]. It consists of 18 items which query changes of health status after an intervention. Choices of answers per item on a five point Likert scale are: extremely positive, positive, no change, negative, extremely negative. One overall scale and three subscales for the assessment of general health, social support and physical functioning are calculated from the 18 single items. The scores for the GBI range from -100 to +100, with positive scores indicating improvement in QOL and benefits, whereas 0 indicates no change and negative values a change for the worse.

The GBI was used for reporting the outcomes of many surgical procedures in the field of otolaryngology like tonsillectomy, rhinoplasty, or vestibular schwannoma surgery [25-27].

The benefit of FESS in CRS patients is shown in Table **1**. In addition, the study of Salhab [28] revealed a higher benefit of FESS for CRS with polyposis nasi compared with CRS without polyposis.

DISEASE-SPECIFIC INSTRUMENTS

Nasal Symptom Questionnaire, synonym: Fairley Nasal Symptom Score

The Nasal Symptom Questionnaire was the first validated QOL instrument to measure subjective nasal impairments [31]. It was developed on the basis of a non-validated instrument by Lund [32]. The instrument has 12 items which can be assessed on a four point Likert scale from 0 (no problem) to 3 (severe problem). Fairley performed a validation on 411 patients which showed a good reliability (Cronbach's alpha=0,776) and proved a good content validity and construct validity [33].

The Nasal Symptom Questionnaire was used in different studies on patients with CRS and nasal septal surgery [34, 35].

Rhino-Sinusitis Diability Index (RSDI)

The RSDI was developed in 1997 by Benninger and Senior [36] with the goal to combine the assessment of general health status and disease-specific QOL in CRS patients in one instrument. Therefore, when using the RSDI the application of a general QOL instrument is not obligatory.

Table 1. Glasgow Benefit Inventory Results in CRS Patients

	n	Overall Benefit	General Health	Social Support	Physical Functioning
Salhab, [28]	77	11,1	12,5	0	0
Baumann, [29]	82	22,6	26,8	2,9	23,7
Newton, [30]	50	25,0	29,2	0	16,7

The RSDI consists of 30 items. Validity, reliability and responsiveness of the instrument have been proved [37]. It has been used in a number of clinical studies in CRS patients [38-41].

General Nasal Patient Inventory (GNPI)

The GNPI was published in 2003 by Douglas *et al*. [23]. It consists of 45 items which were specified by 211 patients in an open questioning. Because of the high number of items specificity of the GNPI is reduced. Furthermore, the length of the questionnaire might potentially reduce the compliance of the patients to fill out the questionnaire. These might be the reasons for the rare using of the GNPI.

Sinonasal-5 Quality of Life Survey (SN-5)

The SN-5 was developed for QOL assessment in children with CRS [42]. The questionnaire is filled out by the parents who serve as proxies for their children. Five QOL domains are investigated: paranasal sinus infection, nasal obstruction, restriction of activities, allergic symptoms, and emotional impairment. Reliability, validity and responsiveness of the SN-5 could be demonstrated. In a clinical study using the SN-5 a long-lasting significant improvement of sino-nasal symptoms after adenoidectomy or paranasal sinus surgery in children could be demonstrated [43, 44].

Sino-Nasal Assessment Questionnaire 11 (SNAQ-11)

The SNAQ-11 was validated in the year 2000 [45]. It is noteworthy that three items of this questionnaire (blocked nose, nasal congestion, and facial pain/pressure) are to be weighted by multiplying the item values with 3 respective 2 before calculating the overall score. The questionnaire covers all main symptoms of CRS. Comparing the results of the questionnaire with the results of SNOT-20 it showed higher post-operative score changes [46]. A Medline search revealed the use of the SNAQ-11 in three studies.

Chronic Sinusitis Survey (CSS)

In 1995, Gliklich and Metson developed the CSS [13]. Since then, this measuring instrument besides the SNOT-20 was the most frequently used instrument for the measurement of QOL in CRS patients. It contains six single items and has proven validity and reliability [47-49]. The CSS consists of two parts: a symptom-based and a medication-based part. Loss of smell as one major symptom of CSS is not implemented in the instrument. In contrast to other QOL instruments the time span but not the severity of symptoms is queried as this resulted in higher retest reliability during the development process of the instrument [13].

In patients with CRS the CSS demonstrated a high sensitivity to change. It could be verified that endonasal sinus surgery reduces nasal impairments of CRS patients [6, 13, 37, 47]. Another study with this questionnaire dealing with cost-benefit analysis after endonasal sinus surgery revealed that the treatment of mild forms of CRS is more cost-effective when compared with the treatment of pansinusitis [49].

Rhinosinusitis Quality of Life Survey (RhinoQoL)

This instrument might be regarded as an enhancement of the Chronic Sinusitis Survey (CSS) since the questioning techniques as well as the authors of the questionnaires are identical. Atlas *et al*. [50] validated this 17-item instrument using the data of 50 patients. RhinoQoL was partially superior to the CSS. However, also RhinoQoL does not inquire smell disturbances which are one major symptom of CRS. Also in this instrument, the time span but not the severity of symptoms is queried. RhinoQoL was not used in further published studies until now.

Sino-Nasal Outcome Test 20 (SNOT-20), SNOT-16 and SNOT-22

Piccirillo *et al*. [51] developed and validated the 31-item Rhinosinusitis Outcome Measure (RSOM-31) which contains rhinosinusitis-specific and general items. A condensed 20-item version of this questionnaire called SNOT-20 (Sino-Nasal Outcome Test-20) was validated as well [52]. The latter questionnaire showed a higher patient compliance because of the lower time and effort for the patients. It queries 20 symptoms of rhinosinusitis which can be assigned to five subgroups (nasal symptoms, paranasal symptoms, sleep-related symptoms, social impairment and emotional impairment). The patients rate the severity of the symptoms on a 6-point Likert scale. The score of the SNOT-20 is calculated by summation of all the symptom scores. Therefore, scale values of the SNOT-20 range from 0 to 100. Additionally, patients can circle those 5 symptoms which have the highest impact on the impairment.

During the last years the SNOT-20 was increasingly used for QOL measurements in patients with CRS. Therapy of CRS with nasal steroids resulted in a reduction of SNOT-20 scores [53]. In a prospective, randomized study to compare medical versus surgical therapy of CRS the QOL instruments SNOT-20 and SF-36 did not detect significant outcome differences between the two therapeutic strategies [17].

Further studies investigated the impact of nasal polyposis in patients with CRS on the subjective outcome assessment of endonasal sinus surgery. While Ragab *et al*. [17] as a result of their study do not consider nasal polyposis as a prognostic factor; Deal and Kountakis [54] found that symptoms are more severe in nasal polyposis. Furthermore, they stated lesser improvements after surgery and a significantly higher rate of required revision surgeries when comparing polyposis patients with non-polyposis patients.

Another validated version named SNOT-16 was applied to investigate the impact of smoking on post-operative QOL in patients with CRS [55]. Smokers scored significantly higher scores compared with non-smokers indicating reduced QOL (27.5 *vs* 18.2; $p<0.001$).

The Clinical Effectiveness Unit of the Royal College of Surgeons of England published the National Audit of Surgery for Nasal Polyposis and Chronic Rhinosinusitis in 2003, reporting QOL data of 3128 patients collected in 2000 in 87 hospitals in England and Wales with the SNOT-22 [56]. Though SNOT-22 is a non-validated questionnaire in contrast with SNOT-20 it covers all the major symptoms of CRS by adding the items “nasal obstruction” and “loss of smell”. All in all, a high contentedness with the results of paranasal sinus

surgery was stated. Clinically significant QOL improvements for the whole cohort could be observed 3 and 12 months post-operatively. Nevertheless, between 3 and 12 months after surgery QOL scores showed slight deterioration of the scores whereas only polyposis patients showed stable significant improvement compared with the pre-operative scoring. Only 43% of the patients with CRS without nasal polyposis reported a stable improvement of their symptoms after 12 months while 32% rated their symptoms same or deteriorated when compared with the pre-operative situation. Therefore, polyposis patients might benefit more from paranasal sinus surgery than CRS patients without polyposis.

This review of the literature clearly shows that SNOT-20 and its derivates found wide acceptance in the analysis of health-related QOL in patients with CRS.

PSYCHOMETRIC PROPERTIES OF DISEASE-SPECIFIC QOL INSTRUMENTS

Instruments for the measurement of disease-specific QOL in CRS patients should cover at least the major symptoms of CRS. Furthermore, psychometric appropriateness should have been proven by validation of the instrument.

The major symptoms of CRS with or without nasal polyposis are listed in the European Position Paper on Rhinosinusitis and Nasal Polyps 2007 (EP^3OS) [57]. CRS is defined as inflammation of the nose and the paranasal sinuses characterised by two or more symptoms, one of which should be either nasal blockage/obstruction/ congestion or nasal discharge (anterior/posterior nasal drip) with or without facial pain/pressure as well as with or

Table 2. Major Symptoms of CRS and Psychometric Characteristics in Different Disease-Specific QOL Instruments; NR = Not Reported

Instrument	Language	Main Symptoms of CRS				Psychometric Characteristics		
		Nasal Obstruction	Nasal Discharge	Facial Fulness/Pressure	Loss of Smell	Reliability	Validity	Sensitivity to Change (Responsiveness)
Nasal Symptom Questionnaire (Fairley, [31])	English	X	X	X	X	X	X	X
Rhinosinusitis Disability Index (RSDI) (Benninger, [36])	English, Turkish	X	X	X	X	X	NR	NR
Sino-Nasal Assessment Questionnaire (SNAQ-11) (Fahmy, [45])	English	X	X	X	X	X	X	X
General Nasal Patient Inventory (GNPI) (Douglas, [53])	English	X	X	X	X	NR	(X)	NR
Sinunasal-5 quality of life survey (SN-5) (Kay, [42])	English	X	X	X	X	X	X	X
Chronic Sinusitis Survey (CSS) (Gliklich, [13]	English, Chinese, Norwegian	X	X	X	-	X	X	X
Rhinosinusits quality of life survey (RhinoQoL) (Atlas, [50])	English	X	X	X	-	X	X	X
Sino-Nasal Outcome Test 20 (SNOT-20) (Piccirillo, [52])	English	-	X	X	-	X	X	X
Sino-Nasal Outcome Test 16 (SNOT-16) (Anderson, [55])	English	-	X	X	-	X	X	X
Sino-Nasal Outcome Test 22 (SNOT-22) (Brown, [56])	English	X	X	X	X	NR	NR	NR
Sino-Nasal Outcome Test 20 German Adapted Version (SNOT-20 GAV) (Baumann, [58])	German	X	X	X	X	X	X	X

without reduction or loss of smell for more than 12 weeks without complete resolution of symptoms.

Checking all disease-specific instruments for the covering of the major symptoms of CRS we found that the most frequently used instruments (Sino-Nasal Outcome Test, SNOT-20; Chronic Sinusitis Survey, CSS) do not query all these symptoms. Both instruments do not inquire for reduction or loss of smell. Furthermore, the item "nasal obstruction is not included in the SNOT-20. Nearly all the other instruments cover all major symptoms of CRS (see Table **2**).

As a validation process was not performed in all the instruments psychometric appropriateness for the use of those instruments in QOL measurements in CRS patients is not assured. Only four of eleven instruments cover all the requirements (Table **2**).

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