The Sino-Nasal Outcome Test 22 validated for Danish patients

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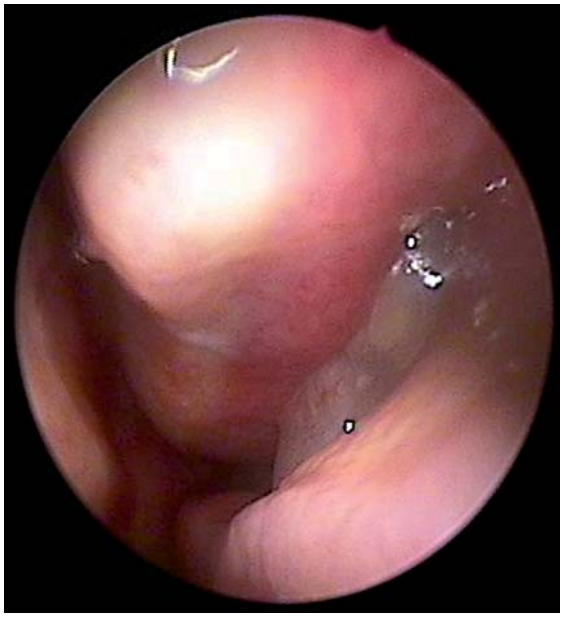
ABSTRACT

INTRODUCTION: Chronic rhinosinusitis (CRS) is a significant health problem whose incidence and prevalence is rising. It calls into attention consensus about diagnosing, assessing symptoms and treatment of patients with CRS. Therefore, a validated Danish measure of health-related quality of life in sinonasal disease is needed.

MATERIAL AND METHODS: The Sino-Nasal Outcome Test 22 (SNOT-22) was translated into Danish and its reproducibility was evaluated by test-retesting 40 patients with CRS. The statistical analyses used were Pearson's correlation coefficient, Cronbach's alpha, kappa and Bland-Altman's plot. Reproducibility was also tested for SNOT-22 subscales.

RESULTS: The results show good internal correlation with a Cronbach's alpha of 0.83 in the initial test and one of 0.92 in the retest. Pearson's correlation coefficient was 0.70 ($p < 0.001$), revealing good correlation between the initial scores and the retests scores. Kappa was calculated for each item with a mean value of 0.61 showing substantial agreement. The paired t-test revealed no significant difference between the subscales.

CONCLUSION: The Danish version of SNOT-22 is recommended for Danish clinicians and researches as a patient-reported measure of outcome in sinonasal disorders such as rhinosinusitis and nasal polyposis.



Polyp tissue beneath concha media.

ORIGINAL ARTICLE

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Chronic rhinitis and chronic sinusitis are terms that are often used separately. Since consensus was reached as formulated in the 2007 European Position Paper on Rhinosinusitis and Nasal Polyps (EPOS), the correct term has been chronic rhinosinusitis (CRS) [1, 2]. CRS is defined as inflammation in the nose and paranasal sinus and it is characterized by two or more cardinal symptoms. Either endoscopic signs or computed tomography (CT) changes should be present. A CT was not an option in our study and the diagnosis therefore rests on symptoms and endoscopy. Disease duration is defined as > 12 weeks. If the person was known in advance with a diagnosis of CRS and had been receiving medical treatment, the diagnosis stated was that which appeared in the person's medical history. The EPOS definition of CRS is shown in **Table 1**.

CRS is a health problem, the significance of which is believed to be rising both in terms of incidence and prevalence. It is a multifactor disease that affects the patient's quality of life (QoL). In this respect, it is comparable to diabetes and heart disease [2, 3]. In the US, the prevalence of CRS is higher than that of arthritis and hypertension. Affecting 15% of the grown-up US population, it is the most common chronic disease in the US [4]. It causes 13 million visits to the doctor, 2 million visits to the hospital and results in significant healthcare expenditures [5]. Similar patterns are seen in Germany [6]. The effect on the patient's QoL and the concomitant need for healthcare are well-described. Treatment is symptomatic and often leads to repeated surgery and lifelong nasal steroids supplemented with systemic steroid treatment and other types of treatment.

In Denmark, no population-based studies regarding CRS have so far been conducted. Furthermore, doctors have used different standards for diagnosing CRS and for measuring the degree of symptoms and the effectiveness of treatment. There is a growing need for a simple, reliable, system-specific standardized outcome measure that can help us explore CRS in a more uniform way and help us take into account the patient's QoL.

TABLE 1

The latest definition on rhinitis (EPOS 2007) has sharpened the diagnosis and the correct terminology is now rhinosinusitis. The disease is defined as inflammation in the nose and paranasal sinus and should be characterized by two or more symptoms, one of which should be either nasal blockage/obstruction/congestion or nasal discharge, +/– facial pain/pressure, +/– reduction or loss of smell. One endoscopic finding and/or findings on computed tomography should be present. Symptom must have been present for > 12 weeks.

	+	–
Symptoms		
Nasal blockage/obstruction/congestion		
Nasal discharge (anterior/posterior nasal drip)		
Facial pain/pressure		
Reduction or loss of smell		
Endoscopic findings		
Polyps		
Mucopurulent discharge		
Oedema/mucosal obstruction		
Computed tomography		
Mucosal changes within the osteomeatal complex and or sinus		

The Sino-Nasal Outcome Test 20 (SNOT-20) and 22 (SNOT-22) are validated patient-reported measures of symptom severity and health-related QoL in sinonasal conditions [7, 8]. The Danish and English version of the SNOT-22 are shown in **Table 2** and **Table 3**. SNOT-22 is a modified version of SNOT-20 and the 31 item Rhinosinusitis Outcome Measure (RSOM-31). In SNOT-22, two items have been added to the 20-item version: one item on nasal blockage and one item on sense of taste and smell. SNOT covers a broad range of health and health-related QoL problems including physical problems, functional limitations, and emotional consequences, as described by Browne et al [9]. They showed that SNOT covers four different clinical constructs. In this study, we tested the reproducibility of six subscales of the SNOT-22 to assess whether these subscales may be used in further CRS research.

The main purpose of the present study was to evaluate the reproducibility of the Danish version of SNOT-22 as a diagnostic tool for evaluation of CRS severity in Danish patients.

MATERIAL AND METHODS

The present study is based on the EPOS criteria described above. SNOT-22 contains 22 questions on CRS-related symptoms. Symptom severity is graded zero to five – with zero indicating no problem at all and five indicating the worst possible symptom. For each item, scores are added to produce a sum score on a scale ranging from zero to 110 with high scores indicating a large rhinosinuitis-related health burden. The patients are also asked to identify which five items are most important to them. At the end of the questionnaire, the patient may state if he or she has had any symptoms that were not included among the 22 items. The questionnaire invites the patient to indicate symptoms experienced over the past two weeks.

The English SNOT-22 was forward backward translated by an English/Danish interpreter according to standard procedures [10, 11].

As part of a trans-European Global Allergy and Asthma European Network (GA2LEN) based project, a cross sectional survey study was performed in Denmark during the summer of 2008. A short questionnaire including questions on CRS and asthma was posted to a representative random sample of 5,000 subjects between 15 and 75 years of age residing on the island of Funen in Denmark. We received 3,362 valid replies. A total of 362 persons participated in a follow-up where they were examined by an otolaryngologist who, among others, performed a nasal endoscopy. SNOT-22 was completed by the patients in the company of the otolaryngologist. CRS was diagnosed in 102 persons. Those who were diagnosed with CRS were eligible for a second SNOT-22 which was posted after 14 days.

In the present study, SNOT-22 was evaluated as a single construct, even if it obviously covers more than one construct. The 12 first items cover physical symptoms (items 1-12) and the last ten items (items 13-22) cover aspects of health-related QoL. Browne et al subdivided SNOT-20 into four subscales. We chose the same four subscales, but included the two extra items. The four subscales were rhinological symptoms (items 1-5, 7 and 8), ear and facial symptoms (items 9-12), sleep function (items 13-15) and psychological issues (items 17-22). The items “cough” and ”waking up tired” were not included in the four new subscales. These items were tested as single items. We tested the reproducibility of the Danish version using these four subscales together with the two first subscales mentioned above.

Statistical analysis

We analysed the internal consistency and test-retest reliability of the Danish version of SNOT-22. Internal consistency refers to the way in which the items relate to each other within an instrument. Cronbach’s alpha was used to represent and evaluate internal consistency for ordinal responses. Test-retest reliability, which reflects stability over time with repeated testing, was analyzed by correlating initial test and subsequent retest scores. The statistical tests used were Pearson’s test (parametric correlation coefficient), kappa (represents reproducibility) and Bland-Altman Plot (represents the extent of agreement). Paired t-test was used to compare test with retest scores in the individual subscales. In cases where normality of the differences was

not fulfilled, Wilcoxon's signed rank sum test was applied at subscale level.

All statistical analyses were performed using STATA statistical software, Release 10 (College Station TX, USA).

RESULTS

A total of 102 persons were diagnosed with CRS. Criteria for exclusion from test-retest were change of treatment (one person), acute change of symptoms due to common cold/influenza during the period between completing the test and the retest (16 persons), a very low SNOT score (six persons), and withdrawal from the study before the test was offered or non-acceptance of test (27 persons). The retest was thus administered to 52 patients and 44 patients replied (84.6%). Among these 44 patients, one missed 16 of the 22 questions, and three patients' disease had aggravated at the time of retesting and they were therefore excluded. Test-retest was accepted for 40 patients. The mean age was 52.39 years (range 29.9 to 74.1 years) and 40% were male. The mean time between the initial test and the subsequent retest was 13.65 days (range 3-35).

The mean SNOT-22 sum score was 29.73 (range 7-67) in the initial test and 29.57 (range 7-70) in the retest.

TABLE 2

Sino-Nasal Outcome Test (SNOT-22) – Danish translation.

Id: _____ Dato: _____

Nedenfor finder du en oversigt over symptomer og sociale/følelsesmæssige følger af din næselidelse. Vi vil gerne vide mere om disse problemer og beder dig besvare følgende spørgsmål, så godt du kan. Der findes ingen rigtige eller forkerte svar, og det er kun dig, der kan give os disse oplysninger. Du bedes vurdere dine problemer, sådan som de har været de sidste to uger. Tak fordi du har indvilliget i at deltage

	A. Du bedes vurdere hvert enkelt spørgsmål i forhold til alvorlighed og hyppighed ved at sætte kryds i den boks der svarer til beskrivelsen						**B. Marker de vigtigste emner, der påvirker dit helbred (maks. 5 punkter)**
	ikke noget problem	**et meget let problem**	**et let eller mindre problem**	**et moderat problem**	**et svært problem**	**det værst tænkelige problem**	
	0	**1**	**2**	**3**	**4**	**5**	
1. Behov for at pudse næse							
2. Nysen							
3. Løbenæse							
4. Tilstoppede næsebor							
5. Manglende lugte- eller smagssans							
6. Hoste							
7. Slim fra næsen løber ned bagtil i halsen							
8. Tykt sekret i næsen							
9. Trykken i ørerne							
10. Svimmelhed							
11. Ørepine							
12. Ansigtssmerter/trykken							
13. Vanskeligheder ved at falde i søvn							
14. Opvågnen om natten							
15. Manglende god søvn om natten							
16. Vågner op og er træt							
17. Træthed							
18. Nedsat produktivitet							
19. Nedsat koncentrationsevne							
20. Frustreret/rastløs/irritabel							
21. Trist							
22. Flov							
Sum:							
C. Opfør venligst andre punkter, som er vigtige for dig, og som du ikke synes er nævnt ovenfor							

The mean difference in the sum score was 0.15 (t = 0.12, standard deviation (SD) = 8.11, p = 0.91). Thus, there was no significant difference between the means of the two tests. The Bland-Altman Plot shows that the 95% limits of agreement ranged from −15.75 to 16.05. The results of the paired t-test for the subscales are shown in **Table 4**. No significant differences were observed between the subscales in the two tests apart from the subscale sleep where p = 0.03 which is considered random.

Cronbach's alpha was 0.83 in the initial test and 0.92 in the retest; both values suggesting good internal consistency within SNOT-22.

Pearson's correlation analysis was calculated for each item with a mean value of 0.70 (p < 0.001). Thus, a good correlation was obtained between the scores of the initial test and the retest. For the six subscales, Pearson's correlations were physical 0.82, health 0.87, rhinological 0.83, ear/facial 0.58, sleep 0.87 and psychological 0.78.

Kappa was calculated for each item. The mean value was 0.61 which indicates substantial agreement [12]. In other words, a high level of reproducibility was obtained.

DISCUSSION

Until now, it has not been possible to measure CRS patients' symptom severity and health-related QoL in a Danish context because of the lack of a Danish standardized questionnaire. The main diagnostic criteria for CRS used in the present study are the EPOS criteria, which include nasal endoscopy and symptoms of nasal blockage/obstruction/congestion, nasal discharge (anterior/posterior nasal drip), facial pain/pressure and reduction or loss of smell. Only two of these symptoms are included as items in SNOT-20, whereas all four are included as items in SNOT-22. This is the main reason why we chose to use SNOT-22. SNOT-22 is a validated tool in the English version, and its use is recommended by others [13].

TABLE 3

Sino-Nasal Outcome Test (SNOT-22).

Date _____ ID _____

Below you will find a list of symptoms and social/emotional consequences of your nasal disorder. We would like to know more about these problems and would appreciate your answering the following questions to the best of your ability. There are no right or wrong answers, and only you can provide us with this information. Please rate your problems as they have been over the past two weeks. Thank you for your participation.

	A. Considering how severe the problem is when you experience it and how frequently it happens, please rate each item below on how "bad" it is by circling the number that corresponds with how you feel using this scale						B. Please tick the most important items affecting your health (max of five items)
	no problem	very mild problem	mild or slight problem	moderate problem	severe problem	problem as bad as it can be	
1. Need to blow nose	0	1	2	3	4	5	
2. Sneezing	0	1	2	3	4	5	
3. Runny nose	0	1	2	3	4	5	
4. Nasal obstruction	0	1	2	3	4	5	
5. Loss of smell or taste	0	1	2	3	4	5	
6. Cough	0	1	2	3	4	5	
7. Post-nasal discharge	0	1	2	3	4	5	
8. Thick nasal discharge	0	1	2	3	4	5	
9. Ear fullness	0	1	2	3	4	5	
10. Dizziness	0	1	2	3	4	5	
11. Ear pain	0	1	2	3	4	5	
12. Facial pain/pressure	0	1	2	3	4	5	
13. Difficulty falling asleep	0	1	2	3	4	5	
14. Waking up at night	0	1	2	3	4	5	
15. Lack of a good night's sleep	0	1	2	3	4	5	
16. Waking up tired	0	1	2	3	4	5	
17. Fatigue	0	1	2	3	4	5	
18. Reduced productivity	0	1	2	3	4	5	
19. Reduced concentration	0	1	2	3	4	5	
20. Frustrated/restless/irritable	0	1	2	3	4	5	
21. Sad	0	1	2	3	4	5	
22. Embarrassed	0	1	2	3	4	5	
C. Please list any other items important to you, which you feel are not mentioned above							

In our study, we forward backward translated SNOT-22 and evaluated the Danish version in a Danish population. The results revealed that the Danish SNOT-22 is a reliable measure of symptom severity and disease-specific health-related QoL in patients with CRS. The questionnaire is quick and easy for the patient to complete. For the researcher, SNOT-22 is a rational, easily applicable tool. It includes a range of items that are important to patients with CRS and allows patients to indicate which items are most important to them. Owing to this last feature, SNOT-22 may be used both to measure health status and QoL. The recently evaluated SNOT-22 [14] had no rating of symptoms. We included the importance rating in the Danish version because such rating is part of SNOT-20 and because importance is rated in most of the SNOT-22 items. However, because patients ascribe most importance to their severe symptoms, such rating does not necessarily add much to the evaluation of the actual severity of CRS, even if vital information on QoL is obtained that may inform both research and the clinic, as described by Piccirillo [7]. Piccirillo reported a Pearson's correlation coefficient of 0.90 (SNOT 20) [7] and Bauman one of 0.80 (SNOT-20) [6]. In the present study, the Pearson's correlation coefficient was 0.70 which indicates good reliability, but no other studies have used this test on SNOT-22.

One limitation in our study could be that the primary test was completed next to the otolaryngologist which gave the patient the opportunity of asking questions. The retest was completed at home with no opportunity for questions. The Bland-Altman plot gives an impression of agreement in the total score between the two tests. It shows a certain variation, but no systematic aberration. Considering Cronbach's alpha, Piccirillo showed an alpha of 0.90 (SNOT-20) [7], Bauman one of 0.865 (SNOT-20) [6] and Hopkins one of 0.91 (SNOT-22) [15], which is in agreement with our result (0.83). This level of agreement provides assurance that the two new items measure aspects of the same underlying construct as the original 20 items. Further item discrimination will require introduction of valuation scales or subscales as proposed by others [9, 16]. In the present study, we assessed six subscales and the results of this study will be used to guide further research and use of these subscales.

One of the strengths of this study is that the CRS patients were recruited from a random sample of the Danish population and are therefore free from selection bias. The patients comprised a mix of subjects who had never had medical treatment for their CRS and patients with maximal therapy in whom surgery had not yet been considered.

We believe that SNOT-22 may well be used on a regular basis by the clinician to obtain information about the full range of problems associated with rhinosinusitis. It can aid researchers in diagnosing and assessing the degree and effect of rhinosinusitis on health status, and of treating patients with CRS. If routinely used, it is suggested that the SNOT-22 can measure the effectiveness of treatment, including surgery, and maybe identify patient factors that predict maximum treatment response [7, 17].

Research on QoL is gaining more weight within otolaryngology. The use of a reliable outcome measure is a must in such research. This study contributes to extant research by demonstrating that SNOT items may be used as outcome measures of symptom severity and health-related QoL in sinonasal conditions in a Danish population.

TABLE 4

T-test for subscales.

Subscale	n	t-value	Mean 1	Mean 2	Mean difference	Standard error	Standard deviation	Confidence interval	p-value
Physical	38	Wilcoxon	–	–	–	–	–	–	0.11
Health	39	−1.23	11.08	12.05	−0.97	0.79	4.92	−2.57 to 0.62	0.22
Rhinological	39	0.12	13.31	13.23	0.08	0.66	4.13	−1.26 to 1.42	0.91
Ear/facial	38	0.68	3.32	3	0.32	0.46	2.85	−0.62 to 1.25	0.5
Sleep	40	−2.23	3.45	4.13	−0.68	0.3	1.91	−1.29 to −0.06	0.03
Psychological	39	−0.31	5.97	6.15	−0.18	0.59	3.66	−1.36 to 1.01	0.76

n = number of paired observations; Mean 1 = mean of the initial test; Mean 2 = mean of the retest.

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