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ORIGINAL CONTRIBUTION

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Validation of the Dutch version of the 22-item Sino-Nasal Outcome Test (SNOT-22)*

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Abstract

Background: The 22-item Sino-Nasal Outcome Test (SNOT-22) is a widely used questionnaire to measure disease-specific health-related quality of life in patients with chronic rhinosinusitis (CRS). The Dutch version has not been validated yet.

Methods: The SNOT-22 was translated through a forward-backward translation technique and validated by a test-retest protocol in CRS patients, a responsiveness analysis in CRS patients treated with dupilumab, while using healthy individuals as controls.

Results: The Dutch SNOT-22 showed excellent test-retest properties, good responsiveness to treatment with dupilumab, and a clear distinction between outcomes of CRS patients and healthy controls.

Conclusion: The Dutch version of the SNOT-22 is a valid outcome measure in CRS patients.

Key words: sinonasal outcome test, health-related quality of life, SNOT-22, patient-reported outcome measure, chronic rhinosinusitis

Introduction

Chronic rhinosinusitis (CRS) is a relatively common chronic disease affecting between 4-11% of Western populations [1, 2]. The diagnostic construct is based on a combination of specific symptoms (nasal obstruction and/or rhinorrhoea, combined with loss of smell and/or facial pressure/fullness) and abnormalities upon nasal endoscopy and/or imaging [3]. CRS has a marked influence on health-related quality of life, and results in major health care costs [4, 5].

Currently, there is no cure for CRS and, as such, treatment should be aimed at attaining (some level of) disease control. Especially in this respect, the patient perspective on CRS is pivotal in determining treatment success. Over the past decades, several patient-reported outcome measures (PROMs) have been developed in the field of CRS. The 22-item SinoNasal Outcome Test (SNOT-22) is a widely accepted tool to measure disease-specific health-related quality of life (HRQoL) [6]. It is suggested as part of the Core Outcome Set for CRS research [7], and is used in large clinical trials as primary outcome measure [8-10].

The SNOT-22 was originally developed in 2009 as a modification of a 20-item questionnaire (SNOT-20), which in turn was derived from the 31-item Rhinosinusitis Outcome Measure (RSOM-31) [6]. Since then, the SNOT-22 has been translated and validated in many languages [11-28]. In-depth analyses of SNOT-22 metrics, such as the minimal clinically important difference have been performed as well [29].

The items in the SNOT-22 are not limited to nasal complaints only; the different domains also cover emotional complaints, and other physical areas, such as otologic symptoms. It is therefore not surprising that conditions or treatments affecting these domains, can influence SNOT-22 scores [30-32].

With the recent advent of biological therapy for CRS with nasal

polyps, a new emphasis is placed on PROMs such as the SNOT-22. It is used as one of the indication criteria to start biological therapy, and as a measure of treatment success as well [3]. Given the high costs of biological therapy, the debate of benefit over costs will require patient-reported input, and it is very likely the SNOT-22 will play an essential role in this discussion. Post-hoc analyses and real-life studies [33-38] already confirm the effectiveness of the three currently registered biologicals for CRS with nasal polyps (mepolizumab [39], dupilumab [40], and omalizumab [41]). Still, the patient perspective in these analyses and their effect on treatment algorithms is essential [42].

Although commonly used in many clinics in the Netherlands, the Dutch version of the SNOT-22 has not been validated yet. The aim of this study was to translate and validate the SNOT-22 for Dutch-speaking patients. We assessed the reliability, validity and responsiveness of the translated SNOT-22 questionnaire.

Materials and methods

SNOT-22

The SNOT-22 consists of 22 questions, 12 of which are relating to symptoms, (rhinologic, ear and facial symptoms), and 10 of which concern general health questions (sleep function and psychological issues). Per item, symptom severity is graded from 0 to 5: no problem (0), very mild problem (1), mild or slight problem (2), moderate problem (3), severe problem (4) and problem as bad as it can be (5). The total sum of item-scores can thus range from zero to 110 with higher scores indicating more severe disease.

Forward and backward translation

A professional translator translated the questionnaire from English into Dutch. The study group then evaluated that the meaning of the wording preserved that of the original English version. Next, the backward translation was again performed by a professional translator. Any deviations from the original English SNOT-22 were studied, and none were deemed relevant. The final Dutch SNOT-22 is provided as online supplemental material.

Study population

This study was approved by the Ethics Committee of the Amsterdam University Medical Centres, location AMC (W21_195 # 21.212). Three groups were defined. Group A consisted of adult patients (18 years or older) with CRS (based on EPOS criteria) visiting the outpatient clinic of the AMC. They were asked to fill in the Dutch SNOT-22 as part of their regular care, irrespective of their current disease control (baseline measurement). If patients agreed to participate, they were given a blank SNOT-22, and a small questionnaire for identification and to indicate whether their health status had changed over the past weeks. Patients were given a return envelope, and asked to return these questionnaires after 2-4 weeks (follow-up measurement). Only patients returning a complete SNOT-22 within 4 weeks, and indicating no change in health status were included in the analysis (n=22).
Group B consisted of 23 adult CRS patients starting on biological therapy (dupilumab). This group was formed to assess the responsiveness of the Dutch SNOT-22. Patients filled in a Dutch SNOT-22 as part of their regular care at the start of treatment (baseline measurement) and after 4 weeks (follow-up measurement; i.e. after two gifts of 300 mg dupilumab s.c.).
Group C consisted of adult healthy native Dutch volunteers that were recruited from the close circle of the study team members: a local padel club, a local tennis club, non-direct neighbours and family members from medical staff. Participation was voluntary. Information on the aim of the study was provided. The volunteers were asked to fill in the Dutch SNOT-22, along with a small questionnaire regarding baseline characteristics (age, gender, smoking), and whether they had ever been diagnosed with, or treated for (non-)allergic rhinitis, CRS, or asthma. Those confirming such a medical history were excluded from this group. This way, 75 subjects could be included in group C.

Table 1. Baseline characteristics of the study groups.

Group	A: test – retest	B: dupilumab treatment	C: healthy controls
N	22	23	75
Age (mean ± SD)	56.1 ± 11.0	50.7 ± 10.2	46.2 ± 13.2
Gender (n (%) female)	9 (40.9%)	7 (30.4%)	36 (48.0%)
Smoking (n (%))			
- Never	14 (63.6%)	12 (52.2%)	65 (86.7%)
- Former	7 (31.8%)	11 (47.8%)	5 (6.7%)
- Current	1 (4.5%)	0 (0%)^	5 (6.7%)

^ Smoking is a contra-indication for biological treatment in the Netherlands.

Statistical analysis

Data were analysed in SPSS (IBM SPSS Statistics, version 26). Data are presented as mean ± standard deviation, unless otherwise specified. In group A, a Pearson correlation test was used. In group B, a paired-samples t-test was used; differences between group B and C were tested with an uncorrected independent-samples t-test. Internal consistency was tested using Cronbach's alpha, both for the full SNOT-22, as by item-wise determination when leaving out a single question. A p-value <0.05 was considered significant.

Results

The baseline characteristics for the three groups are given in Ta-

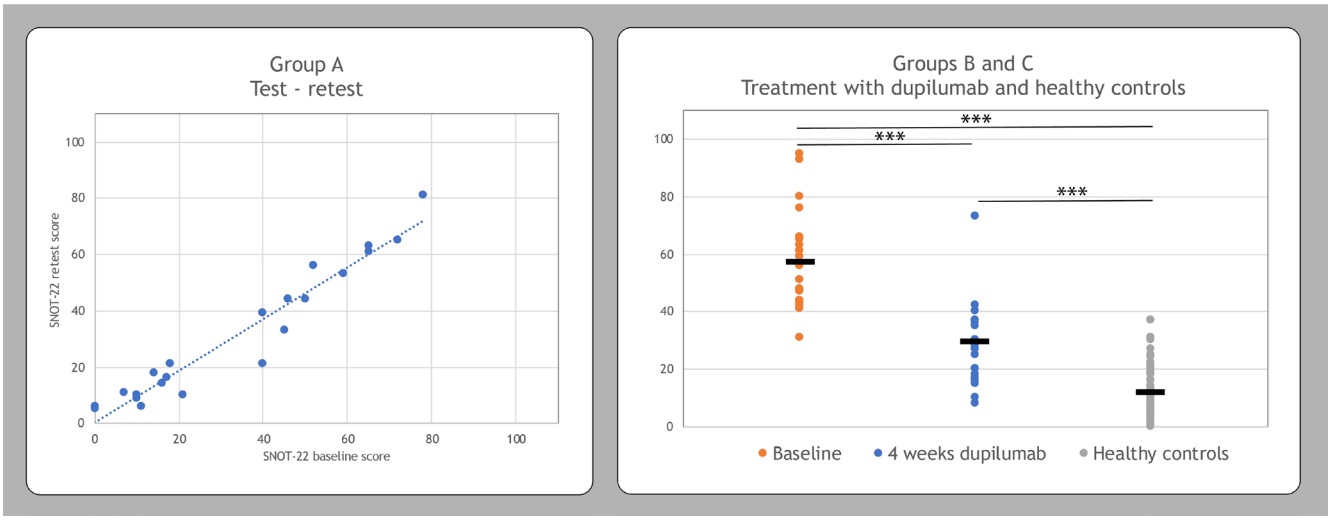

Figure 1. Left panel: outcomes for group A (test-retest): the x-axis shows the SNOT-22 scores at the baseline test; the y-axis shows those after 2-4 weeks. Dots indicate single patient outcomes. There is an excellent correlation between the two (dotted line). Right panel: SNOT-22 scores for group B before (orange dots) and after (blue dots) 4 weeks of dupilumab, and for group C (healthy controls; grey dots). Horizontal bars indicate the group mean SNOT-22 score. *** p<0.0001.

ble 1. For group A, the left panel of Figure 1 shows the baseline and retest measurements, with a Pearson correlation coefficient of 0.968, indicating excellent correlation (p<0.0001).

The right panel of Figure 1 shows the data from the dupilumab treated patients, starting at a mean SNOT-22 score of 57.4 ± 16.6. After four weeks of dupilumab treatment, this decreased to 29.6 ±16.7 (p<0.0001). The data from group C are also summarized in this panel. The mean SNOT-22 score for healthy controls was 11.8 ± 8.5 (p<0.0001 versus group B baseline and after 4 weeks of dupilumab). In this group, no effect on the SNOT-22 score was found for age, gender, or smoking (not shown).

Cronbach's alpha was 0.958 in group A for the baseline measurement, and 0.960 for the retest; in group B it was 0.901 at baseline, and 0.928 after 4 weeks of treatment with dupilumab. Item-wise analysis of Cronbach's alpha when deleting a single question showed a value of ≥0.893 in these groups.

Discussion

The current study shows that the Dutch version of the SNOT-22 is robust, valid, responsive, and has a good to excellent internal consistency. This is in line with the other studies describing its translation and validation in other languages. It validates the already common use of the SNOT-22 in Dutch clinics.

The limitations of the study include a relatively small sample size in groups A and B. Given the fact that group A covers a large range of SNOT-22 scores, we would not expect a large sample to give significantly different results. For group B the effects are already quite drastic and in line with a larger cohort using dupilumab [38]; therefore, we would not expect relevant changes from expanding this group either.
Another limitation is the recruitment of patients from a tertiary clinic, possibly leading to selection bias of more severe patients. The distribution of the SNOT-22 scores in group A suggests that this bias is limited.

Finally, strictly speaking it would be necessary to revalidate the Dutch SNOT-22 in other Dutch speaking areas such as parts of Belgium, or the former Dutch colonies, although it is very likely the current Dutch version can be used reliably in these patient / demographic groups as well.

Conclusions

The presented Dutch version of the SNOT-22 is valid and reliable and can be used to measure HRQoL in Dutch CRS patients.

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Authorship contribution

DDdL, WJF and SR designed the study and recruited the subjects. DDdL and SR constructed the database, analysed the data, and wrote the manuscript. All authors interpreted the data and reviewed the manuscript.

Ethics approval and consent to participate

This study was approved by the Ethics Committee of the Amsterdam University Medical Centres, location AMC (W21_195 # 21.212).

Consent for publication

Not applicable.

Availability of data and material

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Conflict of interest

None declared. WJF and SR are associated with the journal as (associate) editor, but were not involved in the reviewing process nor the decision to accept the paper.

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