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Cross-cultural adaptation and validation of the SNOT-22 into Italian

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Corresponding Author:	Francesco Mozzanica L. Sacco Hospital, University of Milan ITALY
Corresponding Author Secondary Information:	
Corresponding Author's Institution:	L. Sacco Hospital, University of Milan
Corresponding Author's Secondary Institution:	
First Author:	Francesco Mozzanica
First Author Secondary Information:	
Order of Authors:	Francesco Mozzanica
	Andrea Preti
	Roberto Gera
	Stefania Gallo
	Chiara Bulgheroni
	Francesco Bandi
	Francesco Ottaviani
	Paolo Castelnuovo
Order of Authors Secondary Information:	
Funding Information:	
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	recommended for clinical practice and outcome research.

CROSS-CULTURAL ADAPTATION AND VALIDATION OF THE SNOT-22 INTO ITALIAN

Mozzanica F[1], Preti A[2], Gera R[1], Gallo S[2], Bulgheroni C[1], Bandi F[2], Ottaviani F[1], Castelnuovo P[2]

[1] Department of Clinical Sciences and Community Health, San Giuseppe Hospital, Università degli Studi di Milano, Milan, Italy

[2] Department of Otolaryngology, Di Circolo Hospital, Universita degli Studi, Varese, Italy.

Corresponding author

Francesco Mozzanica

Ospedale San Giuseppe

Via San Vittore 12, Milan, Italy

Telephone: +39 3404662852

Email: Francesco.mozzanica@gmail.com

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Abstract

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Results: All the enrolled subjects managed to complete the I-SNOT-22 without needing any assistance. Internal consistency was satisfactory ($\alpha = 0.86$). Test-retest reliability was also satisfactory (ICC = 0.85). A significant difference in the I-SNOT-22 scores between the CRS patients and the asymptomatic subjects was found ($p < 0.008$). Positive significant correlations were found between I-SNOT-22 and VAS scores, while no significant correlations were found between I-SNOT-22 scores and Lund-Mackay scores. I-SNOT-22 scores obtained in the pre-treatment condition were significantly higher than those obtained after surgery.

Conclusion: I-SNOT-22 is reliable, valid, responsive to changes in QOL, and recommended for clinical practice and outcome research.

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Introduction

Health is a multidimensional concept, incorporating physical, mental and social state of being [1]. For this reason, the evaluation of a patient has moved from a traditional assessment, related only to physical well-being, to a more holistic approach that includes quality of life (QOL) measures. The latter focus on the impact any given health status might have on QOL; they may influence treatment planning and may be used as outcome measures. This is particularly useful in the assessment of patients affected by chronic rhinosinusitis (CRS), with or without nasal polyps, since it has a profound influence on the QOL of the people suffering from it because of nasal obstruction, impaired olfaction, fatigue, social dysfunction or emotional manifestations [2]. Such impact has been proven using global measures of QOL such as the SF-36 [3, 4]. However, generic instruments may not be capable to factor the effects of interventions and treatment [5]. In addition, neither objective measures, nor videoendoscopic or radiological ratings can measure the level of handicap that a person perceives as a result of CRS; thus, patient-based, rhinologic-specific outcomes measures can potentially provide additional information to biological and physiological variables and impact on treatment planning.

In rhinological practice several questionnaires are available [6]. Morley and Sharp [7] compared 15 QOL questionnaires and concluded that the Sino-Nasal Outcome Test-22 (SNOT-22) was the most appropriate for the evaluation of patients with CRS. The latter is a simple and fast questionnaire structurally composed of 22 CRS-related items which evaluate the severity of complaints that the patient has been experiencing over the past weeks. SNOT-22 is a modification of SNOT-20, adding to the latter two specific rhinological symptoms: (a) nasal obstruction and (b) loss of sense of taste and smell [2]. All items are scored from 0 to 5. The sum of each item results in a maximum score

of 110. High score indicates poor outcome. The questions composing the SNOT-22 can be divided into 2 categories: questions about physical symptoms (12 questions) which cover rhinologic symptom as well as ear and facial symptom, and questions about health and QOL (10 questions) which cover sleep function and psychological issues [8].

The SNOT-22 has been adapted and validated in several languages [5, 6, 8-16], has been used in different outcome researches and is gaining popularity in an increasingly diverse range of rhinological conditions and interventions, for example septoplasty and septorhinoplasty [17-18]. The questionnaire has demonstrated good internal consistency and adequate reliability thus suggesting that the SNOT-22 could be a useful tool to assess the impact of CRS on the patient's QOL as well as for outcomes research in rhinology [7].

The aim of this study was 1) to culturally adapt into Italian the SNOT-22, 2) to evaluate its internal consistency and reliability, 3) to evaluate its validity and responsiveness. The underling hypothesis are: 1) the SNOT-22 can be culturally adapted into Italian; 2) the Italian version of the SNOT-22 presents strong internal consistency and reliability; 3) the validity and responsiveness of the Italian version of the SNOT-22 are strong.

The importance of this study lies in the fact that a validated SNOT-22 for Italian language will improve its applications in Italian patients with CRS, allowing a deeper knowledge of their QOL related to nasal impairment, adding important information for the clinician, and facilitating both the diagnostic work-up and the decision making process on treatment options. Besides, an Italian version of the SNOT-22 will allow the accomplishment of national, cross-cultural and cross-country studies.

Method

The study consisted of 5 different phases: item generation (phase 1), internal consistency and reliability analysis (phase 2), normative data generation (phase 3), validity analysis (phase 4) and responsiveness analysis (phase 5). The COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) checklist was followed for the different phases [19].

The study was carried out according to the Declaration of Helsinki and it was previously approved by the Institutional Review Boards of the hospitals where the study was performed.

Participants

Different groups of patients were recruited for each of the five different phases of the study (Table 1). All subjects enrolled in the study gave their written informed consent. Only patients with normal cognitive function (Mini Mental State Examination score > 24 for subjects older than 65) and those with preserved reading skills were included in the study. Data for phases 2, 3, 4 and 5 were gained from different rhinologic centers in Italy to ensure applicability of the SNOT-22 in different settings. All data were collected prospectively.

Phase 1: I-SNOT-22 generation

Cross-cultural adaptation of the SNOT-22 was performed using standard techniques [20]. Items of the original questionnaire were translated into Italian by one professional translator and one bilingual investigator (step 1: forward translation). Two independent otolaryngologist, familiar with the process of instrument validation, examined semantic, idiomatic and conceptual issues and further refined these versions. A final

consensus version was obtained (step 2 of 5: synthesis) and given to two professional translators to produce literal translation into English (step 3 of 5: back translation). Once this task was completed, the two translators and an expert committee reviewed all reports in order to produce a pre-final version of the instrument (step 4 of 5: expert committee review). Thirty patients, 15 females and 15 males, affected by CRS were enrolled in in a pilot study (step 5 of 5: pretesting). CRS diagnosis was defined, accordingly to the "European Position Paper on Rhinosinusitis and Nasal Polyps 2012", as an inflammation of the nose and paranasal sinuses characterized by 2 or more symptoms, one of which should be either nasal blockage, obstruction/congestion or nasal discharge, ± facial pain/pressure ± reduction/loss of smell. One endoscopic finding (nasal polyps, mucopurulent discharge) and/or findings on computed tomography (mucosal changes within the ostiomeatal complex and/or sinus) should be present. Symptoms should last for more than 12 weeks [21].

Each patient autonomously filled out this version of the SNOT-22 and discussed the wording and meaning of each item with the senior clinician. The wordings of the questionnaire were modified on the basis of the suggestions given by the patients and this led to the final version of the Italian SNOT-22 (I-SNOT-22, see Appendix A).

Phase 2: Reproducibility of I-SNOT-22

The aim of the 2nd phase of the study was to evaluate the reproducibility of the I-SNOT-22. The latter was assessed using two methods: internal consistency and test-retest reliability. Clinical data were obtained from 222 consecutive patients (117 men and 110 women) consulting for CRS. Median age of the participants was 55 years (range 22-79). Inclusion criteria were: age older than 18 years, CRS diagnosed based on "European Position Paper on Rhinosinusitis and Nasal Polyps 2012" [21]. Exclusion

criteria were sinonasal malignancy, radiation therapy to the head and neck, previous surgery of the nose (including sinus surgery, septoplasty, rhinoplasty, turbinoplasty), septal perforation, cranio-facial syndrome, acute nasal trauma or fracture in the past 3 months, nasal valve collapse, adenoid hypertrophy, sarcoidosis, Wegener's granulomatosis, uncontrolled asthma, pregnancy, and illiteracy [22]. Each patient autonomously filled out the I-SNOT-22 during a clinic visit.

Internal consistency assesses the extent to which each item in a factor measures the same underlying construct. Cronbach's alpha estimates between 0.7 and 0.9 were taken to indicate acceptable internal consistency [23]. For this analysis, the I-SNOT-22 scores obtained in the group of 222 patients were used. The I-SNOT-22 scores obtained in this group of patients were also used for clinical validity analysis in phase 4 of the study.

Sixty patients out the 222 patients affected by CRS were randomly selected for test-retest reproducibility analysis. For this purpose, the I-SNOT-22 was administered twice, approximately two weeks spaced out. This interval period was selected because no substantial change was expected to take place in subjects' nasal condition within this period. While completing the second I-SNOT-22, subjects did not have any chance to check over their responses from the first questionnaire. Test-retest reliability was assessed through Spearman test and ICC, both for total score and for scores of single questions included in I-SNOT-22. A Minimum test-retest correlation coefficient of 0.7 was considered acceptable.

Phase 3: Normative data generation

The aim of the 3rd phase of the study was to establish the baseline distribution for I-SNOT-22 scores by collecting data from a wide, randomly selected, representative sample of subjects with no history nor symptoms of CRS, and with no disease leading

to sinonasal disorders.

For this reason, a group of 119 control subjects, 59 males and 60 females, with a median age of 53 years (range 18-75) and with no past medical history of nasal, voice, swallowing, reflux, airway, neurologic, rheumatologic, hematologic or neoplastic disorders were enrolled. The cohort included hospital personnel, medical and nursing students, and visitors to the medical center or patient's companions who agreed to participate in the study. Each subject managed to complete the I-SNOT-22 without any help and underwent nasal endoscopy in order to exclude CRS. The data obtained from this group of patients were also used for clinical validity analysis in phase 4 of the study.

Phase 4: Validity

The aim of the 4th phase of the study was to assess the degree to which the I-SNOT-22 measures the construct it purports to measure (validity) [24]. Construct validity is the degree to which I-SNOT-22 scores are consistent with the hypotheses. In order to analyse construct validity, the I-SNOT-22 scores of the 222 patients affected by CRS recruited for internal consistency analysis were compared with the normative data obtained from asymptomatic individuals (n = 119).

Criterion validity is the degree to which I-SNOT-22 scores are an adequate reflection of a gold standard. In order to analyse criterion validity, a different group of 50 patients with CRS (29 males and 21 females with a mean age of 51 years) were enrolled. Each patient managed to complete autonomously the I-SNOT-22 and a visual analogue scale (VAS) assessing the severity of his/her disease. A 100-mm line with the extremes "worst condition possible" (100 mm) and "no symptoms" (0 mm) was used. In addition, each CT scan of the enrolled patients was scored according to the Lund-Mackay scale.

Phase 5: Responsiveness

Responsiveness refers to the ability of the questionnaire to detect important changes over time in the construct to be measured. In order to assess the responsiveness of I-SNOT-22, a novel cohort of 59 patients affected by CRS and who were surgically treated following the guidelines of EPOS 2012 [21] were recruited. Each patient completed the I-SNOT-22 before and 3 months after the surgical procedure. All the surgical procedures were performed by a single surgeon. The surgeon was blind to I-SNOT-22 scores in order to ensure stability and accuracy of the data. The I-SNOT-22 scores obtained in the pre-treatment condition were compared with those obtained in the post-treatment condition. In addition, in order to define a clinically relevant (difference) score for purposes of group comparisons, Cohen's effect sizes (ES) were calculated for each of the subscales of the I-SNOT-22 as well as for its total score. By convention, an effect magnitude between 0.2 and 0.5 is considered a mild improvement; between 0.5 and 0.8 – moderate improvement; and greater than 0.8 – a great improvement in the quality of life [9].

Statistical Analysis

Statistical tests were performed using SPSS 19.0 statistical software (SPSS, Inc., Chicago, IL). Internal consistency was assessed using Cronbach's alpha coefficient. Spearman correlation test and ICC were used to evaluate test-retest reliability of I-SNOT-22 by comparing the baseline and retesting responses. Comparison of I-SNOT-22 scores in CRS patients and in the control group was assessed using Student t test. The correlations between I-SNOT-22 scores and VAS and Lund-Mackay results were assessed using Spearman test. The distribution of I-SNOT-22 scores obtained in pre- and post-treatment assessment were compared using the Wilcoxon test. The effect size

was calculated as the difference between the pre-treatment group mean minus the post-treatment group mean, divided by the standard deviation of the initial values. For all statistical comparisons an $\alpha = 0.05$ and a power of 0.80 were used.

Results

All of the patients and control subjects included in the study managed to fully complete autonomously the I-SNOT-22 without any need of assistance. The time required to fulfil the questionnaire never exceeded 10 minutes.

Internal consistency and reliability analysis

Internal consistency scores are reported in Table 2; Cronbach alpha scores were satisfactory for the I-SNOT-22 total score as well as for its 2 subscales, ranging from $\alpha = 0.82$ for the physical symptoms subscale to $\alpha = 0.87$ for the heath and QOL subscale. ICC and Spearman correlation scores for the 60 patients recruited for test-retest reliability analysis of the I-SNOT-22 scores are reported in Table 2. Test-retest reliability was satisfactory for all the items, ranging from $r = 0.71$ for Item 17 to $r = 0.93$ for item 4.

Normative data

The mean age of asymptomatic subjects (n = 119) was 53 years (18-75). Males accounted for 49.6%. The mean I-SNOT-22 score for the normal cohort was 14.3 ± 8.6 (0-33). The mean plus 2 standard deviation yielded an upper limit of normal for the I-SNOT-22 score of 31.5.

Clinical validity analysis

The mean scores obtained from patients and from asymptomatic subjects are reported in table 3. These data show consistently lower values of I-SNOT-22 for asymptomatic subjects on Student's t test analysis ($p = 0.008$).

The correlation between I-SNOT-22, VAS and Lund-Mackay scores obtained in a

group of 50 patients with CRS was analysed for criterion validity. Positive significant correlations were found between I-SNOT-22 and VAS scores (see Table 4) on Spearman test. In particular, the highest correlation was found between the I-SNOT-22 physical symptoms subscale scores and the VAS scores ($r = 0.54$). No significant correlations were found between I-SNOT-22 scores and Lund-Mackay scores on Spearman test.

Phase 5: Responsiveness

I-SNOT-22 scores obtained by a group of 59 patients affected by CRS and who were surgically treated following the guidelines of EPOS 2012 [21], were compared for responsiveness analysis. I-SNOT-22 scores obtained in the pre-treatment condition were significantly higher than those obtained after the surgical treatment ($p = 0.001$) (Table 5). ES results are reported in Table 5, showing a significant effect size for the two I-SNOT-22 subscales scores as well as for the I-SNOT-22 total score.

Discussion

The SNOT-22 is a health-related QOL assessment tool, first developed by Hopkins et al [2], and then adopted, using a standardized method, into different cultural and linguistic contexts [5, 6, 8-16]. Also in the present study the five-step procedure suggested by Beaton et al [24] was followed. This method ensures equivalence to the original questionnaire and allows the comparability of responses across populations divided by language or culture.

In the present study the psychometric properties of the Italian version of the I-SNOT-22 were studied. The results showed good internal consistency, test-retest reliability and good clinical validity and responsiveness. These results further support the application of the I-SNOT-22 scale as a reliable tool for QOL assessment in patients affected by CRS.

Specific findings related to the I-SNOT-22 are noteworthy. In particular, all of the subjects completed the questionnaires, suggesting that they understood the whole of the questions and were comfortable answering them. Consequently, it might be speculated that the I-SNOT-22 is not a burdensome instrument and is easily self-administered. The I-SNOT-22 internal consistency appeared good with an overall Cronbach α coefficient value of 0.86 in 222 patients. These results are similar to those previously reported (Table 6). In particular, the overall Cronbach α coefficients ranged from 0.83 in the study by Lange et al [14] to 0.94 in the study by Galitz et al [10].

As far as the reliability of the I-SNOT-22 is concerned, the scores obtained in the test-retest analysis support the idea that the I-SNOT-22 has a high stability and reproducibility over time. In fact, the Spearman and ICC correlation score for the I-SNOT-22 total score were both 0.85, a value which can be considered satisfactory. Also in previous studies the reliability of the questionnaire was considered satisfactory,

ranging from 0.70 [14] to 0.93 [2].

Concerning the normative data, the group of Italian asymptomatic subjects scored 14.3 ± 8.6. These data appear higher than those found in the original study of Hopkins et al [2], who reported a mean SNOT-22 score of 9.3 in the control group. Also de Dorlodot et al [10], Kosugi et al [13], and De los Santos et al [11], reported a mean SNOT-22 score lower than those found in the present study (8.3, 11.4 and 4.5 respectively). On the other hand, the mean score for the control groups reported in other studies [6, 8-9, 12] appear more similar to those reported in the present one. These differences might be related to a number of factors, including the demographic characteristics of the enrolled asymptomatic populations. The mean age of the Italian control group (53 years) was older as compared with those reported by de Dorlodot et al [10], Kosugi et al [13], and De los Santos et al [11] (45.2 years, 23.4 years, and 41 years respectively). In addition, the control group enrolled in the study of Hopkins et al [2] comprised members of a local indoor tennis club, which, as physically active people, might have had fewer general health complaints [9].

CRS patients scored significantly higher values of I-SNOT-22 than healthy subjects. These findings are in agreement with previous reports. In the original study, Hopkins et al [2] demonstrated excellent between group discrimination. It is possible to speculate that I-SNOT-22 may be a sensitive tool to identify CRS patients. Moreover, the significant difference between I-SNOT-22 scores before and after surgical treatment for CRS suggests that I-SNOT-22 may be useful also in monitoring the treatment response. In particular, the magnitude of the effect of the surgery after 3 months was 1.070, and was considered to be high [9]. Also Hopkins et al [2] reported similar results, while Kosugi et al [13] and Vaitkus et al [9] found that the magnitude of the effect of surgery was higher (1.57 points, and 1.48 points respectively). It is possible that these

differences could be related to the pre-treatment SNOT-22 scores. In the study of Hopkins et al [2], the mean pre-treatment SNOT-22 score was 41.7 ± 19.7. In the present study the mean pre-treatment I-SNOT-22 score was 44.4 ± 22.7, while in the studies of Kosugi et al [13] and Vaitkus S et al [9] the mean pre-treatment SNOT-22 scores were higher (52.43 ± 20.2 and 62.39 ± 25.30 respectively). The mean post-treatment SNOT-22 scores were almost the same in these 4 studies, thus suggesting that the differences in the magnitude effect of surgery might be related to more severe complains of CRS patients in Kosugi et al [13] and Vaitkus S et al [9] studies.

Examining the correlations between the I-SNOT-22 and the VAS, the results here reported appear similar to those reported by de Dorlodot et al [10], further supporting the criterion validity of the I-SNOT-22. Similar to previous reports [10, 25], also in the present study no significant correlations between I-SNOT-22 scores and Lund-Mackay scores were found.

In conclusion, the current findings support the reliability and validity of the I-SNOT-22 questionnaire for the assessment of QOL in Italian adult patients affected by CRS. The application of I-SNOT-22 in everyday clinical practice as well as in epidemiological, efficacy and outcome research is then recommended since it could facilitate the comparison of results of different studies.

Compliance with Ethical Standards:

Ethical approval: “All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent: “Informed consent was obtained from all individual participants included in the study.”.

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tomography in patients with chronic rhinosinusitis. Am J Rhinol; 19, 91–96.

Appendix A: Italian version of the SNOT-22 (I-SNOT-22)

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 you answering the following question 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 2 weeks. Thank you for your participation

Di seguito troverà una lista di sintomi e di conseguenze sociali/emotive del Suo problema nasale. Vorremmo sapere di più riguardo a questi problemi e La preghiamo di rispondere nel modo più sincero possibile alle seguenti domande. Non esistono risposte giuste o sbagliate e solo Lei è in grado di fornirci queste informazioni. Per favore dia un punteggio ai Suoi problemi per come si sono presentati nel corso delle ultime 2 settimane. Grazie per la collaborazione.

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	No problem	Very mild problem	Mild or slight problem	Moderate problem	Severe problem	Problem as bad as it can be
	Per favore utilizzi questa scala per dare un punteggio a ognuna delle domande di seguito riportate tenendo in considerazione la gravità del problema e la sua frequenza,	*Nessun problema*	*Problema molto lieve*	*Problema lieve*	*Problema moderato*	*Problema severo*	*Problema molto severo*
1	Need to blow nose *Necessità di soffiarsi il naso*	0	1	2	3	4	5
2	Sneezing *Starnutazione*	0	1	2	3	4	5
3	Runny nose *Rinorrea anteriore*	0	1	2	3	4	5
4	Nasal obstruction *Ostruzione nasale*	0	1	2	3	4	5
5	Loss of smell or taste *Riduzione del gusto/olfatto*	0	1	2	3	4	5
6	Cough *Tosse*	0	1	2	3	4	5
7	Post nasal discharge (dripping at the back of your nose) *Rinorrea posteriore (scolo retronasale di secrezioni)*	0	1	2	3	4	5
8	Thick nasal discharge *Secrezioni nasali dense*	0	1	2	3	4	5
9	Ear fullness *Ovattamento auricolare*	0	1	2	3	4	5
10	Dizziness *Stordimento*	0	1	2	3	4	5
11	Ear pain	0	1	2	3	4	5

	Dolore auricolare						
12	Facial pain/pressure *Dolore/pesantezza al volto*	0	1	2	3	4	5
13	Difficulty falling asleep Difficoltà ad addormentarsi	0	1	2	3	4	5
14	Waking up at night *Risvegli notturni*	0	1	2	3	4	5
15	Lack of good night's sleep *Sonno poco riposante*	0	1	2	3	4	5
16	Waking up tidered *Stanchezza al risveglio*	0	1	2	3	4	5
17	Fatigue *Spossatezza*	0	1	2	3	4	5
18	Reduced productivity *Ridotte produttività*	0	1	2	3	4	5
19	Reduced concentration *Ridotta concentrazione*	0	1	2	3	4	5
20	Frustrated/restless/irritable *Senso di frustrazione/irrequietezza/irritabilità*	0	1	2	3	4	5
21	Sad *Tristezza*	0	1	2	3	4	5
22	Embarassed *Imbarazzo*	0	1	2	3	4	5
	Total *Totale*						

Table 1

Table 1: clinical and demographic characteristics of the samples. Age is reported as mean (range).

Phase of the study		**Type of study**	**Sample clinical characteristics**	**Age**	**Sex**	
					M	**F**
1	Item generation	Item generation	Patients with CRS (n = 30)	52 (26-74)	15	15
2	Internal consistency	Internal consistency	Patients with CRS (n = 222)	55 (22-79)	117	105
	Reliability analysis	Test-retest reliability	Patients with CRS (n = 60)	49 (27-79)	33	27
3	Normative data generation	Normative data	Asymptomatic subjects (n = 119)	53 (18-75)	59	60
4	Validity analysis	Construct validity	Asymptomatic subjects (n = 119)	53 (18-75)	59	60
			Patients with CRS (n = 222)	55 (22-79)	117	105
		Criterion validity (correlation between I-SNOT-22 scores and VAS and Lund-Mackay scores)	Patients with CRS (n = 50)	51 (29-78)	29	21
5	Responsiveness analysis	Comparison pre- and post-surgical treatment	Patients with CRS (n = 59)	57 (31-76)	33	26

Table 2

Table 2: test-retest reliability (n = 60) and internal consistency (n = 222) of the I-SNOT-22. The results of test-retest reliability of the single items, the 2 subscales of the questionnaire and the I-SNOT-22 total score are reported. The internal consistency analysis was performed for I-SNOT-22 total score as well as for the for the physical symptoms and the health and QOL subscales of the questionnaire.

I-SNOT-22	**Item**	**ICC (n = 60)**	**Spearman test (n = 60)**	**Internal consistency (n = 222)**
Physical symptoms	1	0.87 (0.82.0.91)	r = 0.86	
	2	0.92 (0.87-0.94)	r = 0.92	
	3	0.85 (0.78-0.90)	r = 0.85	
	4	0.93 (0.84-0.97)	r = 0.93	
	5	0.83 (0.74-0.86)	r = 0.84	
	6	0.81 (0.76-0.83)	r = 0.82	
	7	0.87 (0.82-0.92)	r = 0.86	
	8	0.80 (0.76-0.87)	r = 0.80	
	9	0.78 (0.73-0.81)	r = 0.79	
	10	0.85 (0.75-0.87)	r = 0.85	
	11	0.87 (0.79-0.92)	r = 0.86	
	12	0.77 (0.72-0.83)	r = 0.78	
	Total	0.87 (0.81-0.93)	r = 0.87	$\alpha = 0.82$
Health and QOL	13	0.90 (0.83-0.94)	r = 0.91	
	14	0.92 (0.88-.96)	r = 0.92	
	15	0.88 (0.81-0.96)	r = 0.88	
	16	0.84 (0.76-0.89)	r = 0.85	
	17	0.71 (0.65-0.75)	r = 0.71	
	18	0.74 (0.68-0.80)	r = 0.75	
	19	0.79 (0.76-0.87)	r = 0.80	
	20	0.85 (0.81-0.90)	r = 0.86	

	21	0.83 (0.78-0.87)	r = 0.84	
	22	0.91 (0.88-0.93)	r = 0.92	
	Total	0.84 (0.78-0.88)	r = 0.84	α = 0.87
Total		**0.85 (0.79-0.91)**	**r = 0.85**	**α = 0.86**

Table 3: Mean ± standard deviation of the I-SNOT-22 scores in CRS patients and in control subjects. Range are reported in brackets. The results of Student's t test comparison are also reported.

I-SNOT-22	**Normal subjects (n = 119)**	**CRS patients (n = 222)**	**p score**
Physical symptoms	7.1 ± 4.6 (0-17)	27.5 ± 10.9 (5-60)	p = 0.001
Health and QOL	7.3 ± 5.4 (0-21)	18.3 ± 12.2 (0-50)	p = 0.001
Total	14.3 ± 7.4 (0-29)	48.9 ± 23.2 (13-110)	p = 0.008

Table 4: Results of Spearman correlation test between I-SNOT-22 scores and VAS and Lund-Mackey scores on a group of 50 patients with CRS.

		VAS	Lund-Mackay
I-SNOT-22	**Physical symptoms**	0.54*	0.28
	Health and QOL	0.38*	0.21
	Total	0.42*	0.27

* = statistically significant ($p = 0.05$).

Table 5

Table 5: Mean ± standard deviation of the I-SNOT-22 scores in the pre- and post-treatment condition of CRS patients (n = 59). Range are reported in brackets. The results of Wilcoxon test are also reported as well as those of Cohen's effect size.

I-SNOT-22	**CRS patients Pre-therapy**	**CRS patients Post-therapy**	**p score**	**Cohen's *d***
Physical symptoms	26.1 ± 9.9 (7-60)	11.4 ± 12.6 (5-41)	p = 0.001	*d* = 1.485
Health and QOL	18.2 ± 11.3 (5-50)	8.6 ± 11.7 (5-48)	p = 0.001	*d* = 0.850
Total	44.4 ± 22.7 (17-110)	20.1 ± 23.8 (13-100)	p = 0.001	*d* = 1.070

Table 6: Comparison among data of different SNOT-22 translations studies. The results of Internal consistency (assessed through Cronbach's alpha coefficient), test-retest reliability (assessed through Spearman's coefficient, ICC or Pearson's coefficient), known-group validity (assessed through Student t test or Mann Whitney test) and responsiveness (assessed through Student t test or Mann Whitney test) are reported.

Study	**Internal consistency**	**Test-retest**	**Validity**	**Responsiveness**	**Mean score**	
					CRS	**Control**
Hopkins C et al [2] (English)	0.91	0.93	< 0.0001	<0.0001	42.0	9.3
Caminha GP et al [5] (Brazilian Portuguese)	0.88	0.91	NT	NT	NT	NT
Lachanas et al [6] (Greek)	0.84	0.91	< 0.0001	< 0.0001	49.6	13.0
Galitz et al [8] (Hebrew)	0.94	0.88	< 0.0001	< 0.001	50.4	13.2
Vaitkus S et al [9] (Lithuanian)	0.89	0.72	< 0.0001	< 0.0001	52.4	16.8
De Dorlodot C et al [10] (French)	0.93	0.78	< 0.0001	< 0.0001	41.0	8.3
De los Santos G [11] (Spanish)	0.91	0.87	< 0.0001	< 0.0001	47.2	4.5
Schalek P et al [12] (Czech)	0.86-0.90	0.86	V	V	38.5	10.2-13.7
Kosugi EM et al [13] (Brazilian Portoguese)	0.88	0.91	< 0.0001	< 0.0001	62.39	11.4
Lange D et al [14] (Danish)	0.83	0.70	NT	NT	29.7	NT
Mozzanica F et al (Italian)	0.86	0.85	0.008	0.001	48.9	14.3

V = tests reported as statistically significant without mention of *p* value

CRS = chronic rhinosinusitis

NT = not tested