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RHINOLOGY

Translation, cross-cultural adaptation, and validation of the sino-nasal outcome test (SNOT)-22 for Lithuanian patients

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Abstract The objective of this study was to perform translation, cross-cultural adaptation, and validation of the SNOT-22 in the Lithuanian language. This is a prospective case–control study. The study was conducted at the University clinic. The sino-nasal outcome test 22 (SNOT-22) was translated into the Lithuanian language; the pilot study involved 34 patients, the test–retest group consisted of 34 patients with chronic rhinosinusitis (CRS), and the control group of 115 patients with no CRS complaints; 36 patients were evaluated before surgery and 3 months after surgery. The results showed a good internal correlation with Cronbach's alpha—0.89 in the initial test, and 0.93 in the retest; both values suggesting good internal consistency within the SNOT-22. Pearson's correlation coefficient was 0.72 ($p < 0.001$), revealing good correlation between the initial scores and the retests scores. Our sample of healthy individuals had a median score of 12 points, and the instrument was capable of differentiating between the healthy and the patient group, demonstrating its validity ($p < 0.0001$). The statistically significant reduction in the post-operative scores, vis-à-vis pre-operative values, demonstrates the responsiveness of the instrument. The minimally important difference was 13 points in the SNOT-22 score. The Lithuanian version of the SNOT-22 is a valid instrument for assessing patients with CRS. It demonstrated good internal consistency, reproducibility, validity, and responsiveness.

Keywords SNOT-22 · Health-related qualify of life questionnaires · Chronic rhinosinusitis · With/without nasal polyps

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Introduction

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].

Clinical definition of rhinosinusitis

Rhinosinusitis (including nasal polyps) is defined as inflammation of the nose and the paranasal sinuses characterized by two or more symptoms, one of which should be either nasal blockage/obstruction/congestion or nasal discharge (anterior/posterior nasal drip), ±facial pain/pressure, ±reduction or loss of smell; and either endoscopic signs of polyps and/or mucopurulent discharge primarily from middle meatus and/or edema/mucosal obstruction primarily

in middle meatus and/or CT changes showing mucosal changes within the ostiomeatal complex and/or sinuses [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 multifactorial disease that affects the patients' health-related qualify of life (HRQoL). In this respect, it is comparable to diabetes and heart disease [2, 3].

CRS has been reported to affect 5–15 % of urban populations in Europe [4]. In the US, the prevalence of CRS is higher than that of arthritis and hypertension. Affecting 14–15 % of the grown-up US population, it is the most common chronic disease in the US [5, 6].

In Lithuania, no population-based epidemiological studies regarding CRS have so far been conducted.

ENT specialists have used different standards for diagnosing CRS and for measuring the degree of symptoms or the effectiveness of treatment in Lithuania. 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 to take into account patients' HRQoL [5].

For this reason, patient-reported outcome measures (PROMs) are widely used in clinical practice. Using PROMs in clinical practice ensures that medical care is focused on the patients and their symptoms rather than the disease. The measures are potentially useful in both the clinical encounter and in quality improvement. They can be used to facilitate the consultation, to identify and prioritize the problems, to define the aims of treatment, and to measure the subsequent response. PROMs also facilitate comparative audit (the comparison of the provision of healthcare by different providers or different methods of treatment), and can thus improve future healthcare provision [7].

There are over 15 known disease-specific sinonasal outcome questionnaires in English.

Many studies have tried to evaluate the effectiveness of treatments of CRS, but a single standard outcome tool has proved difficult to assemble. Certain criteria need to be met for health-related quality of life tools. These are: reliability, validity, responsiveness, and ease of use [8].

Morley and Sharp analyzed internal consistency and responsiveness of questionnaires (Table 1).

The SNOT-22 questionnaire showed better internal consistency and responsiveness than other questionnaires, and the SNOT-22 is already validated in the Brazilian (Portuguese), English, Swedish, Chinese, Czech, and Danish languages [9]. The SNOT-22 is a modified version of the SNOT-20 and the 31-item rhinosinusitis outcome measure (RSOM-31). In the SNOT-22, two items have been added to the 20-item version: one item on nasal blockage, and one item on the sense of taste and smell. The SNOT covers a broad range of health and HRQoL problems including physical problems, functional limitations, and emotional consequences, as described by Browne et al. [10].

To date, no specific HRQoL related to CRS has been adapted in Lithuanian. The SNOT-22 is characterized by an extensively tested content, concurrent and construct validity, and has a wide use in research and clinical practice. Therefore, the task of the present study was to adapt and test the Lithuanian version of the SNOT-22 for its psychometric properties, and to assess the quality of life among the general population and CRS patients before and after treatment.

Materials and methods

The study was approved by Kaunas Regional Biomedical Research Ethics Committee. All the patients gave their informed consent prior to their inclusion in the study.

Only CRS patients meeting EPOS criteria were included in the study.

The exclusion criteria were age below 18 years, pregnancy, and refusal to participate in the study.

Translation

The translation of the quality of life questionnaires required five main stages: translation and back-translation, a review by the translation and back-translation committee,

Table 1 Aspects of disease-specific tools

	RQLQ	SS	F	CST	CSS	RSOM	RSDI	RSI	SN20	SN16	RSUI	SNAQ	SN5	Col	SN22
Date	1991	1991	1993	1993	1995	1995	1997	1997	1998	1998	1998	2000	2001	2002	2000
Items	28	5	12	(7)	6	31	30	12	20	16	10	11	5	7	22
I.C.	0.94		0.78		0.73				0.90	0.89	0.40		0.70		0.91
R					0.82			1.25	0.59	0.69	0.72	1.08	0.74		0.81
Scale	7	10	4	(8)	4	6 + 5	5	6		5	4	5	7	5	5

RQLQ rhinoconjunctivitis quality of life questionnaire, *SS* sinusitis survey, *F* fairley's symptom questionnaire, *CST* chronic sinusitis type specific questionnaire, *CSS* chronic sinusitis survey, *RSOM* rhinosinusitis outcome measure, *RSDI* rhinosinusitis disability index, *RSI* rhinosinusitis symptom inventory, *SN20* sinonasal outcome test-20, *SN16* sinonasal outcome test-16, *RSUI* rhinitis symptom utility index, *SNAQ* sinonasal assessment questionnaire, *Col* cologne questionnaire, *SN22* sinonasal outcome test-22, *R* responsiveness, *IC* internal consistency

equivalence pre-test with monolingual individuals, and reexamination of the score weights, when relevant, as proposed by Guillemin [11]. All five stages where completed in the Lithuanian version of the SNOT-22.

Missing data imputation

In case if some SNOT-22 items were incomplete, a total score was calculated from the mean of the completed items if more than 50 % of items had been completed [12].

Pilot study

After the pre-final version of the questionnaire was developed, we recruited the subjects for the pilot study. The pilot study included 34 patients. After the pilot study, some small corrections were made in the questionnaire according to the patients' suggestions.

Test–retest study

The test–retest reliability was carried out in a separate sample of 48 patients with CRS with/without nasal polyps. The SNOT-22 questionnaire was employed twice during routine visits of the patient, by two different physicians. The retest examination was carried out after 10–20 days; the patients' answers were obtained by letter or by a second visit to one of the physicians.

Control study

The SNOT-22 scores were calculated in the general population subjects without sinonasal disease. 137 subjects who participated in the study were recruited among members of the medical staff, hospital staff and residents, and among students of the University. Patients with ear diseases from the in-patient department were included as well. The volunteers were asked whether they suffered from rhinitis or CRS with/without sinonasal polyps, and whether they were using nasal medication. In case of a positive answer to any of these questions, the subjects were excluded from further examination.

"Surgery" study

36 patients of the study group underwent endonasal surgical treatment. The "surgery" study group patients were examined twice: at baseline and 3 months after the surgery.

Statistical analysis

We analyzed the internal consistency and test–retest reliability of the Lithuanian version of the 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. The minimum acceptable value is 0.7. The test and retest reproducibility measures the stability of an instrument along time after repetitive tests, and it is evaluated by the use of the questionnaire in different occasions, examining the correlation among the scores. The test and retest correlation must be at least 0.7 [12].

The validity of the measures is the capacity the questionnaire has to reflect differences between known groups, using the Mann–Whitney test. We analyzed the capacity of the questionnaire to produce different scores between the group of patients with CRS with/without nasal polyps and the group of volunteers without sinonasal disease [13]. To test the limiting score on which the sensitivity and specificity curves cross in identifying patients with CRS with/without nasal polyps, receiver operating characteristic (ROC) curve analysis was used. Graphical trade-off between false-negative (sensitivity) and false-positive (specificity) rates for every possible cutoff was presented. The test accuracy was calculated to explain the proportion of true results (both true positives and true negatives) in the study sample.

Responsiveness is the capacity of the questionnaire to detect clinical changes over time. The pre- and post-operative scores were compared using the paired t test. Responsiveness can also be assessed measuring the magnitude of the effect, which is the mean value of the score variation divided by the standard deviation of the initial values. 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 [12].

Clinical interpretability: interpretability is a key challenge for researchers interested in the measurement of HRQoL. Instruments such as the SNOT-22 do not always produce intuitively meaningful data, and this complicates the interpretation of the clinical importance of differences within groups and individuals. One method of facilitating this is to calculate the smallest change in scores that a group of patients can detect as a real improvement: the 'minimally important difference' (MID). This defines a difference in score that is clinically significant, as opposed to statistically significant, which is more commonly reported [14].

The post-operative questionnaires contained a patient-reported transition rating scale comparing pre- and post-operative health (1 = 'much better', 2 = 'a little better', 3 = 'about the same', 4 = 'a little worse', 5 = 'much worse'). The mean change in the SNOT-22 scores for patients in each of the transition rating categories was calculated, then the MID was defined as the change in

score for those who reported their symptoms to be 'a little better' minus the mean change score for those who reported that their symptoms were 'about the same'.

All statistical analyses were performed using SPSS 20 statistical software, produced by IBM.

For statistical purposes, values of $p < 0.05$ were considered significant results.

Results

Pilot study

The study included 34 patients, 15 of which were women (44.1 %), and 19 were men (55.9 %). All the patients were diagnosed with CRS with/without polyps. The mean age was 43.21 ± 16.83 years (range 20–75 years). There was only one patient who suggested changing 1 question from "Need to blow nose" to "Wish to blow nose", and we accepted this change. Five patients could not find the section of five most important symptoms, and therefore we decided to bold this part of the table.

Test–retest study

A total of 72 persons with CRS with/without nasal polyps were included in this part of the study. The criteria for exclusion from test–retest were as follows: change in treatment, and acute change of symptoms due to common cold/influenza during the period between completing the test–retest (26 persons). Eight persons were not available for retest examination of the questionnaire the second time. In four cases, more than 50 % of the questionnaire slots were unfilled, and thus they were excluded from the study. Test–retest was accepted for 34 patients.

The mean age of the test–retest study sample was 44.0 years (range 20–80 years); 32.4 % of subjects were females, and 68.6 % were males. The mean time between the initial test and the subsequent retest was 15.64 days (range 13–21). The mean SNOT-22 sum score was 44.52 (range 11–99) in the initial test, and 46.44 (range 7–101) in the retest.

Cronbach's alpha was 0.89 at initial examination, and 0.93 at the retest examination; both values suggested good internal consistency within the SNOT-22. Pearson's correlation analysis was calculated for each item with a mean value of 0.72 ($p < 0.001$). Thus, a strong correlation was obtained between the scores of the initial test and the retest examination. For the six subscales, Pearson's correlations were as follows: physical—0.81, health—0.92, rhinological—0.81, ear/facial—0.63, sleep—0.85, and psychological—0.92. For the items "cough" and "waking up tired", the correlations were 0.77.

Control study

The control group included 115 volunteers—78 women (67.8 %), and 37 men (32.2 %). The mean age was 45.58 years ± 14.96, ranging from 22 to 80 years. The mean of total scores was 16.78 ± 16.1, median—12, and 95 % confidence interval of the mean values was 13.8–19.8. We compared the control group with the group of patients before surgery. The mean SNOT-22 score in the control group (16.78) was significantly lower, compared to the mean SNOT-22 score in CRS patients before surgery (52.43). The instrument was capable of differentiating between the studied groups, demonstrating its validity ($p < 0.0001$). The ROC test indicated that in the Lithuanian version of the SNOT-22, the total score of >29 was the optimal score (limiting value) distinguishing between patients and healthy controls (Fig. 1). When using the SNOT-22 limiting value (>29.0), classification accuracy of 92 % was detected. The sensitivity of the Lithuanian version of SNOT-22 was 91.7 %, and specificity 82.6 %.

Pre- and post-operative groups

The "treatment" group consisted of 36 patients—15 women (41.7 %), and 21 men (58.3 %) whose age ranged from 20 to 73 years (mean age 45.89 ± 16.21 years). The mean score at pre-operative examination was statistically significantly higher (52.43 ± 20.2) than that registered 3 months after the operation (22.52 ± 20.85) ($p < 0.0001$, $t = 9.26$). The statistically significant reduction in the post-operative scores demonstrated the responsiveness of the instrument. The magnitude of the effect of the surgery after 3 months was 1.48—which was considered high (>0.8).

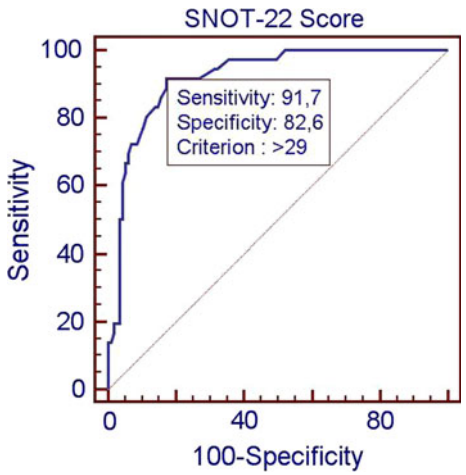

Fig. 1 The ROC test of Lithuanian version of the SNOT-22

Table 2 Total SNOT-22 scores of the groups

Group	*n*	Mean	SD
Initial test	34	44.52	19.55
Retest	34	46.44	22.28
Control	115	16.78	16.1
Pre-operative	36	52.43	20.2
Post-operative	36	22.52	20.85

n number of patients

SD standard deviation

Clinical interpretability

When calculating the MID using the method above, the MID was found to be 13.3. This means that changes smaller than 13 points in the SNOT-22 may not be seen as improvement or worsening for the patient.

The mean change in the SNOT-22 score increased significantly by category (one way between groups $F = 14.1$, $p < 0.0001$).

The characteristics of the total SNOT-22 scores of the groups are presented in Table 2.

Discussion

We found that the Lithuanian version of SNOT-22 is a valid outcome measuring tool for patients with sinonasal disease in the Lithuanian population.

It demonstrates good internal consistency, reliability, concurrent validity, and responsiveness to change. We have also defined the 'minimally important difference', which helps to interpret scores in the clinical setting.

Comparison with other measures

Nowadays, the use of HRQoL questionnaires in daily clinical practice is of primary importance. The evaluation of patients' HRQoL plays a significant role in understanding patients' disease and treatment outcomes. Since HRQoL questionnaires show how every single patient feels about his/her symptoms, they help to personalize the disease, and to better understand the patients' condition and his/her expectations with regard to treatment outcomes.

In the present study, translation, cross-cultural adaptation, and validation of the SNOT-22 were performed. Until now, it has not been possible to measure CRS patients' HRQoL in the Lithuanian-speaking population because there has been no standardized questionnaire adapted. The SNOT-22 instrument has been chosen because of its extensively tested content, its concurrent and construct validity, and its wide use in research and clinical practice [5, 7, 8, 13, 15]. According to Morley and Sharp, the SNOT-20 and the SNOT-22 questionnaires are the first-choice HRQoL tools for patients with CRS. The original SNOT-20 questionnaire shows only modest reliability (0.59), whereas the SNOT-22 questionnaire shows good reliability (0.81) and has all four EPOS criteria, compared to only two in the SNOT-20 questionnaire.

The translation, cross-cultural adaptation, and validation of the Lithuanian version of the SNOT-22 questionnaire were comprehensive and systematic, and were carried out following the generally accepted methodology [11, 16].

The initial examination of the patients in the test–retest and the operation groups was performed in an interview form, giving the patients the possibility to clarify unclear points. The retest examination was completed by the patients independently if they could not come for the follow-up examination, which may be seen as a certain weakness of the present study. On the other hand, we avoided missed follow-up data, and preserved the set of our study group patients.

In the test–retest group, we found a good reliability score (0.72) and a good internal consistency score (Cronbach $\alpha = 0.89$ in the initial test patients' group, and Cronbach $\alpha = 0.93$ in the retest patients' group). These findings are very similar to those presented by other authors (Table 3).

The SNOT-22 questionnaire proved to be capable of differentiating between groups of patients with sinonasal diseases and individuals without nasal disease. The mean values of the scores of patients with CRS were significantly different from those of healthy individuals. Our clinical sample of healthy individuals had a mean SNOT-22 score of 16.78 points, while CRS patients had a mean SNOT-22 score of 52.43 $\pm$ 20.2 points. While the studies of Hopkins et al. [12] and Kosugi et al. [13] showed a little bit lower mean SNOT-22 scores for control group patients, we suppose that different mean scores were due to the differences

Table 3 SNOT-22 data of our study and other authors

	Lithuanian study	English study	Danish study	Brazilian study	Czech study	Swedish study
I.C.	0.89	0.91	0.83	0.93	0.85	0.91
Reliability	0.72	0.93	0.7	0.72	0.86	–
Responsiveness	1.48	0.81	–	1.57	–	–

in the demographic characteristics between the groups. The mean age in our control group was 45.58 years, while mean age of the control group in the study of Kosugi et al. was only 23.35 years. Like the aforementioned authors, we calculated median instead of mean score. The median score was 12 points in our study, compared to 7 points in the study of Hopkins et al. [12] and 10 points in the study of Kosugi et al. [13].

According to the results of the present study, the Lithuanian version of the SNOT-22 questionnaire is capable of measuring changes in patients' HRQoL after surgical treatment. We found the change between the pre-operative and post-operative mean SNOT-22 score to be 29.9 points. The magnitude of the effect of the surgery after 3 months was 1.48, and was considered to be high (>0.8). Similar results were obtained in the study of Kosugi et al. (the extent of the effect of surgery was 1.57 pts). Hopkins et al. in their study found the magnitude to be 0.81 pts. We think that the reason for this difference in magnitude between our study and the Brazilian study, compared to the English study, was due to the baseline scores. In the English study, the patient cohort was large, and the mean baseline score was 41.7 ± 19.7 points. In our study, the mean baseline score was 52.43 ± 20.2 pts. The mean baseline score was higher in the Brazilian study (62.39 ± 25.30 pts). The follow-up mean score was 23.09 points in the Brazilian study, 22.52 points—in the present study, and 25.5—points in the English study. Patients in our study and in the Brazilian study had more severe complains before surgery, yet after the surgery, the mean SNOT-22 scores were almost the same in all three cohorts.

In the present study, we calculated the MID for clinical interpretability. We found that a change in 13 points is not to be seen as improvement or worsening for a patient in the Lithuanian study. In our study, the MID was near the estimated value in the original SNOT-22 in English, which was 9 points, compared to 14 points in the Brazilian study.

Conclusion

The Lithuanian version of the SNOT-22 is a valid instrument for assessing patients with CRS. It demonstrated good internal consistency, reproducibility, validity, and responsiveness. It was found to be responsive to clinical change. The results of the present study demonstrated that the Lithuanian version of the SNOT-22 is a valid instrument for assessing CRS patients' HRQoL in the Lithuanian-speaking population.

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