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French translation and validation of the Sinus and Nasal Quality of Life Survey (SN-5) in children.

Running title: French adaptation of the SN-5 score

ORIGINAL CONTRIBUTION

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ABSTRACT

Purpose: Chronic rhinosinusitis (CRS) is a frequent, quality-of-life (QOL) impairing disease in pediatrics. The SN-5 is a reliable, sensitive and reproducible QOL questionnaire, validated in English for evaluation of CRS disease-specific QOL in children. This study aims to adapt and validate the French version of this test.

Methods: The SN-5 score was adapted into French language through a forward-backwards translation process, and validated through a monocentric prospective controlled study. Inclusion criteria were 2 to 12 years of age, CRS symptoms for at least 12 weeks, or absence of sino-nasal symptom for controls. Reproducibility was assessed through Spearman's correlation between initial answers and a re-test conducted 15 days later. Internal consistency was measured through Cronbach's alpha, construct validity through Spearman's correlation between items, discriminative ability through Mann-Whitney tests.

Results: 40 patients and 37 controls filled the score between November 2019 and March 2020. Retest was returned by 35 patients and 35 controls. Mean cases age was 8.5 ± 2.6 years old. 26 patients had primary CRS, 10 had cystic fibrosis, 4 had ciliary dyskinesia. All had diffuse disease. Mean SN-5 overall score was $3.63 / 7 \pm 6.4$ for CRS patients and $1.89/7 \pm 0.9$ for controls ($p < 0.001$). Test-retest coefficient was 0.84 (0.70-0.92; $p < 0.001$), Cronbach's alpha was 0.83 for CRS patient. Item per item construct validity was good to excellent.

Conclusions: The French version of the SN-5 showed good statistical properties, with good test-retest reliability, internal consistency, structural validity and discriminative ability between CRS and control patients.

Key words: Sinusitis, Quality of life, Nasal polyps, Surveys and Questionnaires, Chronic disease, Paediatrics

1. INTRODUCTION

The main objective of chronic rhinosinusitis' (CRS) treatment is to improve quality of life, which is a subjective perception of one's health [1], bearing in mind that the treatment may itself negatively impact quality of life (for example repeated daily nasal wash).

Health-Related Quality of life (HR-QOL) tools are necessary to adequately quantify the impact of diseases on children's lives [2,3]. There are several issues specific to paediatric patients, as reported by the recommendations from the ISPOR Taskforce [4,5]: age-based Patient Reported Outcome (PRO) administration, paediatric-specific instruments, proxy usage when required, and cross-cultural considerations.

The impact of diseases on quality of life can be assessed by either disease-specific or generic PRO's, like the PedsQL[6]. Generic PRO's are designed for the general HR-QOL, and procure the possibility of comparing the impact on QOL of different diseases [2]. However, they are much less sensitive to small changes or the impact of interventions for disease-specific issues than specific PRO's [3,7]. Thus, disease-specific PRO's are also more susceptible to show differences between competing therapies [8].

Only one CRS-specific HR-QOL questionnaire has been validated in English for children from 2 to 12 years of age: the Sinus and Nasal Quality of Life Survey (SN-5)⁹. It is a reliable, sensitive, and reproducible test, widely used in the international literature to assess the quality of life of children with CRS [10-16]. It has been adapted and validated in Brazilian Portuguese [17].

The aim of this study was to translate, adapt and validate the SN-5 to French in a paediatric population.

2. MATERIALS AND METHODS

We conducted a prospective study in a paediatric otolaryngology tertiary-care centre between November 2019 and June 2020. In this study, CRS was defined by two or more of the three major following items: (i) symptoms during more than 12 weeks (purulent discharge, nasal obstruction, facial pain and/or cough); (ii) nasal endoscopy (mucosal oedema, purulent discharge and/or polyposis); (iii) CT-scan (sinus or ostiomeatal complex mucosal anomalies) [18,19].

2.1. The SN-5 score:

The test comprises of five items which assess five domains of sino-nasal QOL: sinus infection, nasal obstruction, allergy symptoms, emotional distress, and activity limitations. Each item is rated from 1 to 7 and the total SN-5 score is the average of all five items. Overall QOL is assessed by a visual analog scale (VAS), scored from 0 to 10.

2.2. Cross-cultural adaptation:

Adaptation into French language was conducted through a forward-backwards translation process [20]. SN-5 score was first translated from the original English version by two native French-speaking practitioners, and the two versions were harmonized. The result was then translated back to English by a native English-speaking practitioner blinded from the original version. The result of the reverse translation was then compared to the original version, and all participants adjusted together the final French version of the score (Figure 1).

2.3. Population:

Inclusion criteria were as follow:

- ages 2 to 12 years
- patients with CRS symptoms at the time of evaluation
- or control cases with neither sino-nasal symptom during evaluation nor history of CRS

Specific exclusion criteria were:

- primary diagnosis of obstructive sleep apnoea syndrome caused by tonsillar hyperplasia
- intellectual disability, cognitive impairment, or developmental delay
- child's family unable to read and understand French

2.4. Data collection:

The following data were collected: patients age, sex, the type of sino-nasal disease and the presence or absence of polyps, SN-5 score and VAS submitted twice to all patients and controls. The re-test was submitted at least 15 days after the initial test.

2.5. Statistical analysis

Test-retest reliability was assessed with a two-tailed Spearman rank correlation of the overall score and of each item. Spearman rank correlation was used to determine construct validity by testing intercorrelations between the overall and items' scores (calculations were made on the first of both test). Cronbach's alpha was calculated for internal consistency and was considered good between 0.7 and 0.9 and excellent over 0.9 (calculations were made on the first of both test). The ability to discriminate between cases and controls was evaluated using a Mann-Whitney test and a ROC curve was established. For all statistical tests, p-values < 0.05 were considered significant.

2.6. Ethical considerations:

This prospective study has been approved by the institutional review board "CPP Ouest V" under the validation number 2019-A00387-50 and has been registered on the ClinicalTrials database ID NCT04117646. Informed consent, written and oral, was obtained from the participants and their parents.

3. RESULTS

3.1. Population

40 patients and 37 controls were included between November 2019 and June 2020 and completed at least one test. Of those, 35 patients and 35 controls returned a re-test. There were 23 (58%) males and 17 (42%) females in the patient group and 22 (59%) males and 15 (41%) females in the control group. Patient mean age in the CRS group was 8.5 ± 2.6 years old (range: 2 - 12) vs 7.4 ± 2.7 (range: 2 - 12) in the control group ($p=0.08$), detail is reported in Figure 2.

3.2. Conditions

CRS was found to be secondary in 14 (35%) patients (10 cystic fibrosis, and 4 ciliary dyskinesia) and primary in 26 (65%) patients. CRS without nasal polyps (CRSsNP) was diagnosed in 23 (58%) patients (of those 4 had ciliary dyskinesia) and CRS with nasal polyps (CRSwNP) in 17 (42%) patients (of those 10 had cystic fibrosis).

3.3. Statistical results

The overall SN-5 score was $3.63/7 \pm 6.4$ for CRS patients (range: 1 - 6.4), and $1.89/7 \pm 0.9$ for controls (range: 1 - 4.6), $p<0.001$. Item per item comparison was also statistically significant (Table 1). Visual analogue scale mean value was $5.9/10 \pm 2.0$ for CRS patients (range: 2 - 10), and $8.3/10 \pm 2.0$ for controls (range: 3 - 10, $p<0.001$).

The test-retest reliability coefficient was $r = 0.91$ (95% confidence interval: 0.86 - 0.94; $p < 0.001$) for the overall population (CRS and control patients) and $r = 0.84$ (95% confidence interval: 0.70 - 0.92; $p < 0.001$) for the CRS patients. Item per item test-retest reliability ranged from 0.79 to 0.91 ($p<0.001$ for all items) (Table 1).

Internal consistency was good, with Cronbach's alpha coefficient reaching 0.89 for the overall population and 0.83 for CRS patients.

Item per item's construct validity coefficient was good to excellent, as shown in Table 2.

ROC-curve analysis showed a maximum area under curve with a threshold of 2.2 (Se = 88.6% and Sp = 74.2%). Two points of interest were identified: thresholds of 2/7, which has a very high sensitivity rate (Se 88.6%, Sp 70.1%), and 3/7 which has a high specificity (Se 65.7% Sp 93.6%) (Figure 3).

3.4. Subgroup analysis

Concerning subpopulations analysis, there was a statistically significant difference between CRSwNP (mean SN-5 score of 2.9 ± 1.2 (range: 1 - 4.2)) and CRSsNP patients (mean SN-5 score of 4.1 ± 1.4 (range: 1.2 - 6.4, $p=0.014$)). Considering VAS, the mean VAS score was 6.5 ± 2.2 (range: 3 - 10) in the CRSwNP group compared to 5.4 ± 2.1 (range: 2 - 10, $p=0.17$) in the CRSsNP group.

Cystic fibrosis patients had a significantly lower SN-5 score 2.5 ± 1.1 (range: 1 - 4) compared to other patients 3.9 ± 1.4 (range: 1-6, $p<0.01$). Patients with ciliary dyskinesia had mean SN-5 score of $4.1/7 \pm 1.4$ (range: 2 - 5.8), and VAS of 5.2 ± 2.1 (range: 3- 8). Patient younger or older than 7 years of age had similar results (Table 3).

4. DISCUSSION

CRS is a frequent disease characterized by the association of chronic objective and subjective symptoms which impact the quality of life [19,21]. Paediatric patients are particularly difficult to diagnose and follow-up, as subjective symptoms can be difficult to express for a child and because the symptoms are often intricately intertwined with other factors [22]. Moreover, CRS symptoms vary over time due to episodes of acute infections or seasonal allergies [23].

The French version of the SN-5 showed good statistical properties, with good test-retest reliability, internal consistency, structural validity and discriminative ability between CRS and control patients. In comparison to the native English version, the SN-5 score was comparable (3.6 ± 1.4 vs 3.9 ± 0.9), the Cronbach's alpha was 0.83 vs 0.62, and global score test-retest reliability was 0.84 vs 0.71 [9].

Although patients included in our study were older than those in Kay et al [9]. (8.5 vs 4.9 years old), age was not found to have an impact on the responses to the SN-5 questionnaire, probably due to the fact that SN-5 relies on the hetero-assessment of symptoms which do not vary with age. Indeed, even if children as young as 8 years old are able to complete self-reported questionnaires [6], hetero-assessment questionnaires by parents which focus on physical problems tend to be reliable throughout childhood [3,24]. Although the impact on QOL may be underestimated [25], parental evaluation is reliable and thus, enables repeated use over a long period of time facilitating follow-up instead of prematurely switching to a self-evaluation questionnaire.

Although there is no validated QOL questionnaire for > 12 years old children with CRS, the adult SNOT-22 questionnaire, which has been translated and adapted to French [26,27], has already been successfully used in this population [28]. Further research should be undertaken to statistically assess which of the SNOT-22 or SN-5 is best in this age-group and if certain adjustments are required.

Interesting results were found when analysing CRS sub-groups, as both CRSwNP and more specifically cystic fibrosis patients had significantly lower SN-5 scores than other CRS patients ($p = 0.014$ and $p < 0.01$). This may be explained by the fact, especially in cystic fibrosis patients which represented the majority of our CRSwNP group, that the importance of nasal symptoms is scaled down compared to other respiratory or digestive symptoms. We do not however have enough patients in our study to further comment on these results.

Finally, our ROC-curve analysis reported the best sensitivity and specificity ratio for a threshold of 2.2 (Se = 88.6% and Sp = 74.2%). On a practical note, we were able to identify a threshold of 3/7 with a high specificity rate (93.6%) to help diagnose CRS, with acceptable sensitivity (65.7%). For screening purposes, we

recommend to use the threshold of 2/7, which has a very high sensitivity rate (88.6%) and an acceptable specificity rate (70.1%). This is especially true when screening cystic fibrosis patients who may have lower QOL scores than other CRS patients. We recommend that patients with one SN-5 test $\geq 3/7$ or two consecutive tests $\geq 2/7$ (excluding acute sino-nasal infections) be referred to a paediatric otolaryngologist.

5. CONCLUSION

The French version of the SN-5 score was found to have good statistical properties, and may therefore be used in the clinic and for research activities. This score may be used by specialised paediatric otolaryngologists to help assess CRS management during follow-up. It may also be used by non-specialised otolaryngologists, paediatricians or general practitioners to help diagnose CRS in the child, which is a disease sometimes difficult to identify.

6. DECLARATIONS

Availability of data and material: data can be found at:

<https://www.openicpsr.org/openicpsr/project/130361/version/V1/view>

The authors declare that there is no conflict of interest

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Ethics approval: This prospective study has been approved by the institutional review board “CPP Ouest V” under the validation number 2019-A00387-50

Consent: Informed consent, written and oral, was obtained from the participants and their parents.

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Table 1: Item per item descriptive statistics, test-retest Spearman rank correlation, and Cronbach’s alpha change if individual question is dropped

| Scale | SN-5 score CRS (n=40) | SN-5 score controls (n=37) | p† | CRS Test-retest reliability (n=35) | Total population test-retest reliability (n=70) | Cronbach’s alpha‡ (cases + controls) |
|-------------------------|-----------------------|----------------------------|---------|------------------------------------|---|--------------------------------------|
| Q1: nasal obstruction | 4.3 ± 1.8 | 2.1 ±1.4 | <0.0001 | 0.79*** | 0.90*** | -0.03 |
| Q2: sinus infection | 5.1 ±1.8 | 2.2 ±1.6 | <0.0001 | 0.79*** | 0.91*** | -0.02 |
| Q3: allergy symptoms | 3.4 ±2.0 | 1.6 ±1.2 | <0.0001 | 0.83*** | 0.80*** | -0.002 |
| Q4: emotional distress | 3.3 ±2.1 | 1.6 ±1.3 | <0.001 | 0.84*** | 0.80*** | -0.017 |
| Q5: activity limitation | 2.1 ±1.5 | 1.3 ±0.9 | <0.001 | 0.91*** | 0.84*** | 0.005 |
| Visual analog scale | 5.9 ±2.0 | 8.3 ±2.0 | <0.0001 | 0.84*** | 0.91*** | N/A |
| SN-5 score | 3.6 ±1.4 | 1.8 ±0.9 | <0.0001 | 0.85*** | 0.91*** | N/A |

Scores are shown by mean ± standard deviation. ***p <0,001

† Mann-Whitney comparison between patient and control groups. ‡ Native Cronbach’s alpha is 0.89, change in the value is shown if the individual question were to be dropped.

Table 2. Construct validity: Spearman rank correlation of items of the French SN-5 score for cases

| Scale | Q1 | Q2 | Q3 | Q4 | Q5 | VAS |
|------------|---------|----------|---------|----------|----------|----------|
| Q1 | 1 | | | | | |
| Q2 | 0.34* | 1 | | | | |
| Q3 | 0.48** | 0.07 | 1 | | | |
| Q4 | 0.5** | 0.73*** | 0.25 | 1 | | |
| Q5 | 0.22 | 0.42* | 0.21 | 0.52** | 1 | |
| VAS | -0.48** | -0.50*** | -0.31 | -0.55*** | -0.70*** | 1 |
| SN-5 score | 0.77*** | 0.68*** | 0.58*** | 0.57*** | 0.61*** | -0.68*** |

Correlation coefficients calculated using Spearman rank correlation, between each question and between the questions and the Visual Analog Scale (VAS) and overall SN-5 score.

* p <0.05; ** <0.01; ***<0.001

Table 3. Subgroups comparison

| | ≤ 7 years of age | > 7 years of age | p |
|----------------------|--------------------------------|--------------------------------|--------|
| Number of patients | 13 | 22 | |
| Q1 score mean | 4.1±1.7 | 4.4±1.9 | 0.5 |
| Q2 score mean | 4.8±1.6 | 5.3±1.9 | 0.2 |
| Q3 score mean | 3.1±2.0 | 3.4±2.1 | 0.7 |
| Q4 score mean | 3.0±2.1 | 3.5±2.2 | 0.5 |
| Q5 score mean | 2.0±1.5 | 2.2±1.6 | 0.8 |
| VAS score mean | 6.2±1.8 | 5.6±2.1 | 0.4 |
| SN-5 score mean | 3.4±1.3 | 3.8±1.4 | 0.3 |
| Internal consistency | 0.88 (95% lower limit 0.76) | 0.85 (95% lower limit 0.75) | |
| | CRSwNP | CRSsNP | |
| Number of patients | 23 | 17 | |
| Q1 score mean | 3.7±1.8 | 4.5±1.9 | 0.2 |
| Q2 score mean | 4.4±2.0 | 5.3±1.7 | 0.2 |
| Q3 score mean | 1.9±1.4 | 4.3±1.8 | <0.001 |
| Q4 score mean | 2.6±1.8 | 3.7±2.2 | 0.1 |
| Q5 score mean | 1.71±1.1 | 2.5±1.7 | 0.2 |
| VAS score mean | 6.53±2.2 | 5.4±2.1 | 0.2 |
| SN-5 score mean | 2.9±1.2 | 4.1±1.4 | 0.01 |
| | Cystic fibrosis patients | Other CRS patients | |
| Number of patients | 10 | 30 | |
| Q1 score mean | 3.2±1.8 | 4.5±1.8 | 0.05 |
| Q2 score mean | 4.1±2.0 | 5.2±1.8 | 0.1 |
| Q3 score mean | 1.4±0.84 | 4.0±1.9 | <0.001 |
| Q4 score mean | 2.3±1.6 | 3.5±2.2 | 0.1 |
| Q5 score mean | 1.6±0.84 | 2.3±1.7 | 0.3 |
| VAS score mean | 7.1±1.85 | 5.3±2.1 | 0.1 |
| SN-5 score mean | 2.5±1.1 | 3.9±1.4 | <0.01 |

Comparisons between mean items' mean score is calculated with Mann-Whitney's test. Internal consistency is measured with Cronbach's alpha. Test-retest coefficient is calculated with Pearson's correlation. *CRSwNP* : Chronic Rhinosinusitis with nasal polyps. *CRSsNP* : Chronic Rhinosinusitis without nasal polyps

INSTRUCTIONS : Parents, aidez-nous s'il vous plaît à évaluer le retentissement des problèmes de nez et de sinus de votre enfant sur sa qualité de vie en cochant une seule case par question. Merci.

INFECTION SINUSIENNE : écoulement nasal ou par l'arrière dans la gorge, mauvaise haleine, toux pendant la journée, maux de tête, douleur faciale continue ou pulsatile. Est-ce que cela a été un problème pour votre enfant au cours des 4 dernières semaines ?

- Jamais Exceptionnellement Parfois Presque tout le temps
 Rarement Souvent Tout le temps

OBSTRUCTION NASALE : nez bouché ou encombré, congestion nasale, diminution ou perte de l'odorat, difficulté à respirer la bouche fermée. Est-ce que cela a été un problème pour votre enfant au cours des 4 dernières semaines ?

- Jamais Exceptionnellement Parfois Presque tout le temps
 Rarement Souvent Tout le temps

SYMPTÔMES ALLERGIQUES : éternuements, nez ou yeux qui grattent, besoin de se frotter le nez ou les yeux, yeux qui larmoient. Est-ce que cela a été un problème pour votre enfant au cours des 4 dernières semaines ?

- Jamais Exceptionnellement Parfois Presque tout le temps
 Rarement Souvent Tout le temps

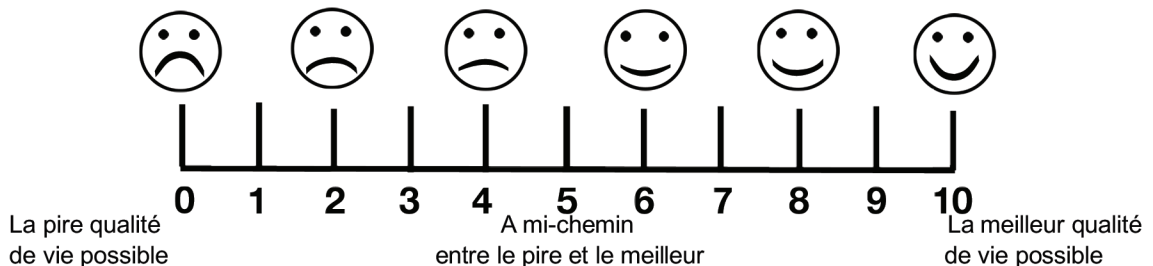
RETENTISSEMENT EMOTIONNEL : irritabilité, frustration, tristesse, agitation ou trouble du sommeil à cause de ses problèmes de nez ou de sinus. Est-ce que cela a été un problème pour votre enfant au cours des 4 dernières semaines ?

- Jamais Exceptionnellement Parfois Presque tout le temps
 Rarement Souvent Tout le temps

LIMITATION DES ACTIVITES : absentéisme scolaire, retentissement sur les activités périscolaires, réduction du temps consacré à la famille et aux amis à cause de ses problèmes de nez ou de sinus. Est-ce que cela a été un problème pour votre enfant au cours des 4 dernières semaines ?

- Jamais Exceptionnellement Parfois Presque tout le temps
 Rarement Souvent Tout le temps

AU TOTAL, Comment évalueriez-vous la qualité de vie de votre enfant compte-tenu de ses problèmes de nez ou de sinus ? (entourez un chiffre) _____



PARTIE MEDICALE :

- État de base (pré thérapeutique) Suivi à la semaine [] (post thérapeutique) État de base (pré opératoire) Suivi à la semaine [] (post opératoire) *Score de chacune des 5 questions (1-7)*

