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Magali Marro, MD1, Michel Mondina, MD1, Dominique Stoll, MD1, and Ludovic de Gabory, MD, PhD1

No sponsorships or competing interests have been disclosed for this article.

Abstract

Objective. Until now, there has been no validated and specific questionnaire in French allowing the assessment of nasal obstruction and its consequences on quality of life. The aim of this study was to validate the French translation and sociocultural adaptation of the Nasal Obstruction Symptom Evaluation (NOSE) and Rhinosinusitis Quality of Life Survey (RhinoQOL) self-questionnaires.

Study Design. Prospective instrument validation study.

Setting. French tertiary referral center.

Subjects and Methods. The questionnaires were translated into French and then translated back into English. The final version was administered twice to an asymptomatic control population (n = 50) and once to a population with symptomatic septal deviation (n = 50). The psychometric properties (reliability, reproducibility, validity, responsiveness) were assessed by test-retest procedure, internal consistency, correlation intra- and interscores, and response sensitivity between both populations.

Results. There was no statistical difference in both responses obtained from the control population after the test-retest procedure. Internal consistency was 0.86 for the NOSE and 0.57, 0.67, and 0.83 for the scores of the RhinoQOL (frequency, bothersomeness, and impact, respectively). There was always a strong correlation between all NOSE variables and RhinoQOL scores ($r > 0.40; P < 10^{-3}$). Effect size showed a high sensitivity to change.

Conclusion. The French versions of both questionnaires appear to be as reliable, valid, and sensitive to change as the English versions. Their association was strong, allowing assessment of nasal obstruction in all its dimensions.

Keywords

quality of life, instrument, validation, septoplasty, nasal obstruction

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Nasal obstruction is a common symptom in everyday otorhinolaryngological practice. Regardless of the etiology or the treatment used, the assessment of the results on respiratory comfort remains a matter of debate because there is a poor correlation between objective and subjective measures.1-4

Health-related quality-of-life (QOL) questionnaires are among the most recent and innovative methodologies for assessing chronic diseases. They were developed either for general applications or to assess a specific disease, function, or symptom. They must undergo psychometric validation to ensure their scientific validity.5 Many international guidelines have been published over the past few years regarding the sociocultural adaptation of questionnaires to different languages and cultures.6-8 Any adaptation must include the translation of questionnaires into 1 or more languages and their validation to ensure intercultural relevance and conceptual equivalence with the original questionnaire(s).

In rhinological practice, numerous questionnaires are available in English.9 Only the SF-36 and Sinonasal Outcome Test–16 (SNOT-16) are usable in French populations, but one is a generic questionnaire, and the other does not take nasal obstruction into account.10,11 To our knowledge, there is currently no QOL questionnaire that is specific to nasal obstruction and could be used in a French-speaking population. The Nasal Obstruction Symptom Evaluation (NOSE) questionnaire is specific to nasal obstruction...
and allows for pre- and posttreatment assessments. However, it does not explore the different ways in which QOL can be altered because of nasal obstruction. The Rhinosinusitis Quality of Life Survey (RhinoQOL) questionnaire is aimed at patients with chronic rhinosinusitis. It seems complementary to the previous one because of its analysis of rhinologic signs other than nasal obstruction and its ability to assess their impact on the different areas of diurnal and nocturnal QOL.

The aim of our study was to carry out the translation and cultural adaptation into French of the NOSE and RhinoQOL self-questionnaires and to check their conceptual equivalence to have instruments that are valid, reliable, and sensitive to change for managing nasal obstruction in a French-speaking population.

**Methods**

A prospective instrument validation study was approved by the institutional review board at the University Hospital of Bordeaux (France). Data collection was carried out by 2 of the authors (MM and MM) using Excel version 5.1 software (Microsoft Corp, Redmond, Washington).

**Subjects**

Two paired populations were constituted. The first comprised 50 controls who were seen for nonrhinologic complaints in the otolaryngology department of the University Hospital of Bordeaux (France). They were older than age 18 years, able to speak and read French, had no history or current nasal sinus disease, and had not taken any form of corticosteroids for more than 4 weeks. They were from various professional fields (4 company executives; 20 manufacture workers; 21 physicians who were not ear, nose, and throat [ENT] doctors or paramedical professionals; and 5 retirees). The second population was assembled prospectively in the same department. It included 50 consecutive patients presenting nasal obstruction due to a symptomatic septal deviation. These patients were able to speak and read French, exhibited permanent and persistent symptoms despite 1 or several medical treatments, had no prior rhinologic surgery, and had not taken any form of corticosteroids for more than 4 weeks. Patients seen in our department for revision septoplasty, septorhinoplasty, septrhinoplasty combined with a surgical procedure on the sinuses, septal perforation, nasal valve collapse, adenoid hypertrophy, or sleep apnea syndrome or patients with inflammatory or infectious sinus disease, a history of tumor, radiotherapy, or trauma of the facial skeleton were excluded, as were pregnant women. The enrollment period was July 1, 2009, to December 23, 2009. Both populations were paired by age, gender, body mass index (BMI), tobacco intake, and allergies (Table 1).

**Methods**

The English versions of the NOSE and RhinoQOL questionnaires were translated independently by 2 bilingual translators whose mother tongue is French (version 1). Following this, both versions were compared and discussed until a consensus version was reached (version 2). Next, the second version was translated into English by Dr. Ray Cooke, who is the senior reviewer of English texts in our university (version 3). This version was compared with the original English questionnaires to check that they had the same semantic value and to establish the final version of the questionnaire (version 4, online appendix 1).

To determine baseline values and to assess reliability for both questionnaire scores on the control population, a test-retest procedure was performed. The final version was sent to each control by postal mail or e-mail to avoid any influence due to the presence of a practitioner. Retest reliability was assessed by asking controls to complete the form twice, with a 2-week interval. During this procedure, the acceptability and understanding of the final version were tested to allow correction of any misunderstandings.

To determine values of scores on the symptomatic population, both questionnaires were filled out by the patients undergoing septoplasty the day prior to surgery. The questionnaire was always completed by the patient alone so as to avoid any third-party influence in interpreting the questions or in the quality of the responses.

All statistical analyses were performed using the Stata 1.5 software (Société d’Science, Paris, France, www.adscience.fr). The values observed in the 2 populations were not in line with a normal distribution. To determine the reproducibility of the questionnaires, the mean scores obtained in the test-retest phase for the control population were compared using the Wilcoxon nonparametric test. To assess reliability (precision of the measures), the internal consistency of both instruments was assessed by calculating Cronbach α coefficient for each score. The homogeneity of each score in the measurement of nasal obstruction was considered satisfactory when α ≥ 0.80. Construct validity of both questionnaires was assessed with the Spearman correlation test, allowing for intrascore comparisons among patients. For the NOSE questionnaire, the various responses obtained for each item were first correlated with each other and then with the overall questionnaire score. Regarding the RhinoQOL, the frequency, bothersomeness, and impact scores were compared with each other. Following this, the scores of both questionnaires were compared with each other in the 2 populations, thereby enabling us to test the relationship between the NOSE and the RhinoQOL in the measurement of nasal obstruction, as well as the strength of their association. The statistically significant

<table>
<thead>
<tr>
<th>Table 1. Characteristics of Both Populations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population</td>
</tr>
<tr>
<td>-------------</td>
</tr>
<tr>
<td>Age, y</td>
</tr>
<tr>
<td>Gender, male/female, No.</td>
</tr>
<tr>
<td>Body mass index</td>
</tr>
<tr>
<td>Smokers, %</td>
</tr>
<tr>
<td>Allergies, %</td>
</tr>
</tbody>
</table>

Abbreviation: NS, no statistical significance.
coefficients revealed a high-intensity relationship between frequency and bothersomeness scores ($r = 0.636; P < 10^{-5}$), frequency and impact scores ($r = 0.412; P < 10^{-5}$), and bothersomeness and impact scores ($r = 0.449; P < 10^{-5}$).

In the control population, the NOSE score significantly correlated with the frequency score ($r = 0.661; P < 10^{-5}$), bothersomeness score ($r = 0.492; P = .00029$), and impact on QOL score ($r = 0.598; P < 10^{-5}$). Within the patient population, the NOSE score significantly correlated with the bothersomeness score ($r = 0.481; P = .00041$) and impact score ($r = 0.469; P < .0006$) but not with the frequency score ($r = 0.299; P < .035$).

### Sensitivity to Change

A highly significant statistical difference was noted in the means obtained for each NOSE questionnaire item among the 2 populations ($P < 10^{-5}$). As for the RhinoQOL questionnaire, the means of each frequency score item were statistically different for nasal obstruction ($P < 10^{-5}$) and anterior/posterior rhinorrhea ($P < 10^{-5}$) but not for facial pain or pressure. Similarly, the mean scores of each bothersomeness item were statistically different for nasal obstruction ($P < 10^{-5}$) and posterior rhinorrhea ($P < 10^{-5}$) but not for facial pain. On the other hand, all the impact score items were altered in a statistically significant fashion in patients as compared with controls. This score showed that the main patient complaints were nose-related embarrassment, fatigue, sleep alteration, its diurnal impact, and clouding of thought ($P < 10^{-5}$).

The total mean ± SD and median (interquartile range) scores of each questionnaire of the patient population are presented in Table 4. There was a highly significant statistical difference among these means for each questionnaire between the control and patient populations ($P < 10^{-5}$). The effect size was 1.46 for the NOSE score and 0.9, 0.7, and 1.1 for the frequency, bothersomeness, and impact scores of the RhinoQOL questionnaire, respectively. This indicates moderate sensitivity for the bothersomeness score and very high sensitivity to change for all other scores.

With regard to scores over 100, the MCID for the NOSE was between 5 and 7.5, whereas the mean score deviation between the 2 populations was 43 points. Similarly, the MCIDs for the RhinoQOL ranged from 3.4 to 5.1 for the frequency score, whereas the mean deviation between populations was 21.12 points; MCIDs were between 4 and 6 for the bothersomeness and impact scores, with mean deviations of 18.8 and 25.25 points, respectively.

### Discussion

The methodology used in our study had been previously and effectively used by other research teams. Increasing data appear to suggest that the simple process of translation-retranslation produces questionnaires that are similar to the original version. However, some teams have observed major cultural differences within populations that were supposedly comparable. Furthermore, score values of asymptomatic control populations were not known according to the country and were used directly on patient populations. On the other hand, all the impact score items were altered in a statistically significant fashion in patients as compared with controls. This score showed that the main patient complaints were nose-related embarrassment, fatigue, sleep alteration, its diurnal impact, and clouding of thought ($P < 10^{-5}$).

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The reliability of a questionnaire is its ability to find similar results in the presence of stable characteristics when measured repetitively over time. Reliability is defined by internal consistency and reproducibility. The reliability of a questionnaire is one of the most reliable and best validated properties of the instrument: reliability, validity, and sensitivity to change. Regarding the NOSE and the RhinoQOL, our results do not appear to differ from those obtained by the authors who validated these 2 questionnaires. The synergistic use of the questionnaires does not appear to weaken their validity or include redundant items in the analysis of nasal obstruction and its impact. The authors who created the NOSE questionnaire indeed proposed to associate it with a more generic instrument. The RhinoQOL questionnaire investigates issues not already covered by QOL. Nasal obstruction was the main complaint dealt with by QOL. Nasal obstruction was the main complaint presented in the population where it was developed, and septoplasty was the operative comparison, before and following septoplasty, and thus confirming the ability to measure nasal obstruction itself. The combination of both questionnaires appeared to result in high-level correlations of the different scores, thus justifying their concomitant management. To our knowledge, no study to date has combined these 2 questionnaires. The synergistic use of the questionnaires does not appear to weaken their validity or include redundant items in the analysis of nasal obstruction and its impact. The authors who created the NOSE questionnaire indeed proposed to associate it with a more generic instrument. The RhinoQOL questionnaire investigates issues not already covered by QOL. Nasal obstruction was the main complaint dealt with by QOL. Nasal obstruction was the main complaint presented in the population where it was developed, and septoplasty was the operative comparison, before and following septoplasty, and thus confirming the ability to measure nasal obstruction itself. The combination of both questionnaires appeared to result in high-level correlations of the different scores, thus justifying their concomitant management. To our knowledge, no study to date has combined these 2 questionnaires.

Validity concerns the aptitude of a questionnaire to measure what it is supposed to measure. There are several ways to demonstrate validity. Item-item correlations, correlations between each item, and the total NOSE score always demonstrated a strong relationship that was sometimes slightly higher than that reported by the authors of the English version, thus confirming the validity of the French version. This was also the case for the RhinoQOL. However, the correlation values were lower than those reported by Atlas et al, most likely because our study population did not present chronic sinusitis but rather a morphological syndrome. The combination of both questionnaires appeared to result in high-level correlations of the different scores, thus justifying their concomitant and complementary use in assessing nasal obstruction management. To our knowledge, no study to date has combined these 2 questionnaires. The synergistic use of the questionnaires does not appear to weaken their validity or include redundant items in the analysis of nasal obstruction and its impact. The authors who created the NOSE questionnaire indeed proposed to associate it with a more generic instrument. The RhinoQOL questionnaire investigates issues not already covered by QOL. Nasal obstruction was the main complaint presented in the population where it was developed, and septoplasty was the operative comparison, before and following septoplasty, and thus confirming the ability to measure nasal obstruction itself. The combination of both questionnaires appeared to result in high-level correlations of the different scores, thus justifying their concomitant management. To our knowledge, no study to date has combined these 2 questionnaires.

Discriminatory validity is the ability of an instrument to distinguish between patient groups who have or do not have the disease being studied. It is assessed by comparing the scores obtained by populations presenting various diseases or by comparing the score of a diseased population with that of a disease-free population. This was the case in our 2 paired populations, as one presented the disease and the other did not. Their comparison showed a highly significant statistical difference for each item and each score in both questionnaires, thus confirming the ability to measure nasal obstruction itself and detect the presence or absence of the disease.

Sensitivity to change is the ability of an instrument to detect any significant change in the patient’s health, be it a small change. Although sensitivity analysis most often consists of seeking changes resulting from therapeutic action over a given period of time, there is no real consensus. The possibility, in

### Table 3. Correlation between All Items and among the 5 Nasal Obstruction Symptom Evaluation (NOSE) Items and the Total Questionnaire Scores (P < 10⁻³)

<table>
<thead>
<tr>
<th>NOSE Item</th>
<th>Stuffy Nose</th>
<th>Blocked Nose</th>
<th>Trouble Breathing</th>
<th>Trouble Sleeping</th>
<th>Trouble Breathing during Exercise</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blocked nose</td>
<td>0.48</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trouble breathing</td>
<td>0.515</td>
<td>0.663</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trouble sleeping</td>
<td>0.448</td>
<td>0.589</td>
<td></td>
<td>0.589</td>
<td></td>
</tr>
<tr>
<td>Trouble breathing during exercise</td>
<td>0.491</td>
<td>0.4</td>
<td>0.629</td>
<td>0.415</td>
<td></td>
</tr>
<tr>
<td>Total score</td>
<td>0.680</td>
<td>0.794</td>
<td>0.869</td>
<td>0.752</td>
<td>0.737</td>
</tr>
</tbody>
</table>

### Table 4. Outcomes of the NOSE and RhinoQOL Questionnaire Scores in the Symptomatic Population (n = 50) and Comparison with Scores Obtained in the Control Population (Wilcoxon Test)

<table>
<thead>
<tr>
<th>Score</th>
<th>Mean ± SD (Interquartile Range)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOSE</td>
<td>58.7 ± 25.1 (45.0-75.0)</td>
<td>&lt;10⁻⁵</td>
</tr>
<tr>
<td>RhinoQOL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequency</td>
<td>65.8 ± 17.0 (56.2-81.2)</td>
<td>&lt;10⁻⁵</td>
</tr>
<tr>
<td>Botherliness</td>
<td>69.6 ± 20.0 (60.0-83.3)</td>
<td></td>
</tr>
<tr>
<td>Impact</td>
<td>31.7 ± 20.0 (16.6-38.9)</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: NOSE, Nasal Obstruction Symptom Evaluation; RhinoQOL, Rhinosinusitis Quality of Life Survey.
our study, to compare the responses of the 2 homogeneous populations allowed us to assess the sensitivity to change of both questionnaires. The scores previously published for the control and patient populations with regard to both tests appear to be in line with those observed in our study.12,14 The highly significant statistical difference between both populations and effect size clearly show that sensitivity to change is high for the French version. Moreover, the MCID values in the French version of the NOSE ranged from 5 to 7.5 vs 3.9 to 5.9 for the English version. These MCIDs, which were higher in the French version regarding the detection of clinical changes, should be correlated with a mean score variation of 43 points between our 2 study populations, whereas the mean score was only 19.4 points in the English version.13 Mean score variations in the French RhinoQOL were 39, 48.9, and 55.3 for frequency, bothersomeness, and impact, respectively. MCIDs, however, were not calculated.14 They were lower in our study. The predominance or even exclusivity of nasal obstruction as a symptom in our population certainly accounts for this difference. Furthermore, the MCIDs that we obtained led to the establishment of a French-language testing tool that is extremely sensitive to change in this population.

Conclusion
We show that the French versions of the NOSE and RhinoQOL questionnaires are as reliable, valid, and sensitive to change as the English versions. These 2 questionnaires may be associated synergistically to measure nasal obstruction in all its dimensions. They can be used in either language to assess the efficacy of nasal obstruction management in international multicenter studies.

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Author Contributions
Magalie Marro, acquisition, analysis and interpretation of data, drafting; Michel Mondina, acquisition, analysis and interpretation of data; Dominique Stoll, concept and design, final approval; Ludovic de Gabory, concept and design, acquisition, analysis and interpretation of data, drafting, revision, final approval.

Disclosures
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Supplemental Material
Additional supporting information may be found at http://oto.sagepub.com/content/by/supplemental-data

References

