

Adaptation and validation of the Spanish version of the Nasal Obstruction Symptom Evaluation (NOSE) Scale^{*,#}

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Rhinology 53: 176-180, 2015

DOI:10.4193/Rhino14.137

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***Received for publication:**

June 3, 2014

Accepted: October 18, 2014

Abstract

Background: The Nasal Obstruction Symptom Evaluation (NOSE) scale is a symptom-specific, self-completed questionnaire for assessing quality of life related to nasal obstruction or its treatment in patients with septal deviation. The aim of this study was to validate the Spanish adaptation of the NOSE, thus allowing comparison across studies and international multicenter projects.

Methodology: Multicenter prospective instrument validation study. Guidelines for the cross-cultural adaptation process from the original English language scale into a Spanish language version were followed. The psychometric properties (reproducibility, reliability, validity, responsiveness) of the Spanish version ("NOSE-e" for "NOSE-español") were assessed in 58 consecutive patients undergoing septoplasty (both before and 3 months after surgery) and 58 matched asymptomatic controls.

Results: Test-retest reliability and internal consistency reliability were adequate. The NOSE-e demonstrated satisfactory construct validity. Positive correlations between the NOSE-e scores and the score of a visual analog scale measuring the subjective sensation of nasal obstruction were found. The instrument showed excellent between-groups discrimination and high response sensitivity to change.

Conclusions: The Spanish version of the NOSE (NOSE-e) is a valid tool for measuring the subjective severity of nasal obstruction, and its use is recommended.

Keywords: nasal obstruction, septoplasty, quality of life, questionnaire, validation

Introduction

The Nasal Obstruction Symptom Evaluation (NOSE) instrument is a symptom-specific, self-completed questionnaire for assessing the impact of nasal obstruction or its treatment in patients with septal deviation. Five obstruction-related items, including nasal congestion or stuffiness, nasal blockage or obstruction, trouble breathing through the nose, trouble sleeping, and unable to get enough air through the nose during exercise or exertion, are scored using a 5-point Likert scale: not a problem, very mild problem, moderate problem, fairly bad problem, and severe problem. By multiplying the raw score by 5, results can be

easily scaled to a total score of 0 to 100 (0 means no problems with nasal obstruction; 100 means the most severe problem). Developed and validated by Stewart et al. ⁽¹⁾, NOSE has become a valuable tool for outcome research in rhinology ⁽²⁻⁹⁾. It has been used in prospective trials to evaluate outcomes in septoplasty ⁽³⁻⁵⁾, other interventions, such as functional rhinoplasty ^(6,7), and radiofrequency turbinate reduction ⁽⁸⁾. With increased numbers of multinational and multicultural research projects, the need to adapt health status measures for use in other than the source language has grown rapidly. Portuguese ⁽¹⁰⁾, French ⁽¹¹⁾, Italian ⁽¹²⁾ and Chinese ⁽¹³⁾ adaptations

[#]The copyright of the English version of the NOSE Scale belongs to American Academy of Otolaryngology-Head and Neck Surgery Foundation 2003

of this brief, easy to complete, reliable and responsive survey have been validated to date. To our knowledge, no Spanish version of the NOSE is available at present although, with 329 million speakers, it is one of the three most widely spoken languages in the world with Chinese (1.213 billion) and English (328 million) ⁽¹⁴⁾. Given the high prevalence of nasal obstruction caused by septal deviation, ^(15,16) the need for uniform data collection efforts in cross-national studies, and the desire to avoid the selection bias that may be associated with studies that must exclude all patients who were unable to complete an English form, a translation, cultural adaptation, and validation process of the Spanish version of the NOSE is needed ⁽¹⁷⁾. The aim of this study is to validate the Spanish cross-cultural adaptation of the NOSE instrument.

Materials and methods

This multicenter prospective instrument validation study was approved by the ethics committee at each of the participating institutions. All study participants agreed and signed consent forms. Data collection was carried out by the same author (FL).

Subjects and setting

Patients with nasal septal deformity undergoing septoplasty were enrolled consecutively from a public, level 1, regional hospital and two private practice tertiary centers in Barcelona, Spain, between November 15, 2013 and February 26, 2014. Inclusion criteria were: age of at least 18 years; surgery indication for septoplasty (septal deviation, with or without inferior turbinate hypertrophy, consistent with presenting symptom of chronic nasal obstruction; symptoms lasting at least 3 months; and persistent symptoms after a 4-week trial of medical management with topical nasal steroids, topical or oral decongestants, or oral antihistamine-decongestant combinations). Exclusion criteria were sinonasal malignancy; radiation therapy to the head and neck; septoplasty performed with concurrent sinus surgery, aesthetic rhinoplasty, or as access to other sites; prior nasal surgery; chronic rhinosinusitis ⁽¹⁸⁾; septal perforation; craniofacial syndrome; acute nasal trauma or fracture in the past 3 months; nasal valve collapse; adenoid hypertrophy; sarcoidosis; granulomatosis of the nasal cavity; uncontrollable asthma; pregnancy; and illiteracy.

An asymptomatic control population was collected. This second population included a convenience sample of healthy volunteers from the participating institutions. Controls were selected consecutively to match patients (1:1 ratio) according to age (years) and gender.

Cross-cultural adaptation and validation processes

Guidelines for the cross-cultural adaptation process of the NOSE survey were followed ^(17,19). Two forward translations were made of the instrument from the original language (English) ⁽¹⁾ to the

target language (Spanish). Both translators had Spanish as their mother tongue. One of them was uninformed, a professional translator who had no medical background, while the other was an informed English philologist and teacher. Results of the translations were synthesized into one common translation. Two English first-language persons, naive to outcome measurement and without medical background, created two back translations working from the synthesized target version. One of them was a professional translator while the other was a bilingual graduate. A final version of the Spanish questionnaire (NOSE-e) for testing was then produced by an expert committee composed by 3 rhinologists, 1 methodologist and the translators and language professionals involved in the process (Figure 1). The original developer of the questionnaire ⁽¹⁾ was contacted during this part of the process.

For the validation process, patients completed the NOSE-e questionnaire before and 3 months after surgery. Controls completed the NOSE-e survey during the enrollment visit. The questionnaire was always completed by the subject alone to avoid any third-part influence in interpreting the questions. To assess test-retest reliability, patients and controls completed the NOSE-e questionnaire again about 7 to 15 days later. In addition, a 10 cm horizontal visual analog scale (VAS) measuring the subjective sensation of nasal obstruction "difficulty in breathing through your nose" was included with the NOSE-e instrument during the enrollment visit ⁽²⁰⁾.

All septoplasty patients were eligible. Procedures were performed under general anesthesia by 4 experienced surgeons (FL, JR, AA, MG) using Cottle technique. Concurrent turbinateplasty, if needed, was done through thermal ablation either by radiofrequency, molecular resonance or bipolar electrocautery.

Statistical methods

The demographic data were compared between the two groups, septoplasty patients and paired controls. The psychometric properties (reproducibility, reliability, validity, responsiveness) were assessed by test-retest procedure, internal consistency, correlation intra and interscores, and response sensitivity. To determine the reproducibility of the questionnaire, the mean total scores obtained in the test-retest were compared using the Goodman-Kruskal γ coefficient; a value of at least 0.70 was considered adequate test-retest reliability ⁽¹⁾. Cronbach's α coefficient was calculated to assess the internal consistency (reliability) of the instrument in all patients and controls. An α value of ≥ 0.80 was considered satisfactory ⁽¹¹⁾. Content validity was ensured during the dual translation process of the instrument. Construct validity was assessed with the Spearman correlation test. Responses obtained for each item were first correlated with each other and then with the overall questionnaire score. A

Escala de Evaluación de los Síntomas de Obstrucción Nasal (NOSE-e)

➔ **Para el paciente:** Le agradecería nos ayude a valorar el impacto de una obstrucción nasal en su calidad de vida **completando la siguiente encuesta.**

En el **ÚLTIMO MES**, ¿con qué intensidad se convirtieron las siguientes condiciones en un **problema** para usted?

Por favor **rodee** la respuesta correcta para usted

	<i>No es un problema</i>	<i>Un problema muy leve</i>	<i>Un problema moderado</i>	<i>Un problema bastante serio</i>	<i>Un problema grave</i>
1. Congestión nasal o sensación de nariz llena	0	1	2	3	4
2. Bloqueo u obstrucción nasal	0	1	2	3	4
3. Dificultad para respirar por la nariz	0	1	2	3	4
4. Dificultad para dormir	0	1	2	3	4
5. Incapacidad para ventilar lo suficiente por la nariz durante el ejercicio o esfuerzo físico	0	1	2	3	4

Figure 1. Spanish version of the NOSE (NOSE-e).

significant level of association was set as a coefficient of ≥ 0.40 ^(1,11). In addition, NOSE-e scores were correlated with the score of the VAS (Spearman correlation coefficient) to assess criterion validity. Discriminatory validity was estimated by comparing the NOSE-e total scores between patients undergoing septoplasty and controls, with the Mann-Whitney U test. Sensitivity was assessed by calculating the standardized response mean and effect size at 3 month after surgical intervention. For both measures, a value of approximately 0.2 represents low sensitivity to change, 0.5 represents moderate sensitivity, and 0.8 represents high sensitivity to change ⁽¹⁾.

It is estimated that 25 to 50 patients make an adequate sample size for psychometric validation ⁽¹⁷⁾. The statistical significance threshold retained for all tests was $p \leq 0.05$. Analysis was performed using the SPSS version 15.0 for Windows (SPSS Inc, Chicago, IL, USA).

Results

The Spanish version of NOSE (NOSE-e) was created after cross-cultural adaptation and translation of the original version (Figure 1).

Sixty-two consecutive patients aged 18-73 years who underwent septoplasty during the study period were invited to participate in the study. One patient declined to take part in the study. Three patients were lost to follow-up. Fifty-eight patients completed the study. Fifty-eight matched controls were selected from 86 healthy volunteers.

The mean ages of subjects in the patient and control groups were 43.9 ± 15.1 and 43.4 ± 13.2 , respectively. Twenty-two patients in the surgery group were female compared to 31 in

the control group. There were no differences in age and gender between the two groups ($p < 0.05$).

Sixty-two subjects (18 patients and 44 controls) completed the test-retest portion of the validation process. Internal consistency reliability, validity and responsiveness were analysed in all 58 patients and 58 controls.

Reproducibility and reliability

The reliability coefficient was adequate at $\gamma = 0.962$. Cronbach's correlation coefficient assessing the internal consistency was $\alpha = 0.955$.

Validity

Content validity was approved by the expert committee. The values of inter-item and between-item correlation coefficients and the total score are shown in Table 1. High-intensity relationship between the variables was shown. These values were all higher than or equal to 0.70, except for the correlation coefficient between "congestion" and "sleeping" (0.697). Statistical differences were highly significant ($p < 10^{-5}$) for all correlations. Criterion validity was also assessed by measuring the association of NOSE-e items and total score with VAS as shown in Table 2.

Sensitivity to change

The mean scores of the NOSE-e were 63.4 ± 19.3 in the patient group compared to 6.9 ± 9.8 in the control group. Significant statistical difference was noted in the means obtained for the NOSE-e questionnaire score among the 2 populations (Mann-Whitney U-test, $p < 0.001$). Therefore, the instrument demonstrated excellent discriminatory validity.

Table 1. Item-item and item-total correlations for the 5 item NOSE-e ($p < 10^{-5}$).

NOSE-e item	Congestion	Obstruction	Trouble breathing	Sleeping	Exercise
Congestion					
Obstruction	0.903				
Trouble breathing	0.904	0.939			
Sleeping	0.697	0.744	0.786		
Exercise	0.785	0.780	0.829	0.750	
Total score	0.928	0.946	0.967	0.865	0.901

Values shown are the Spearman correlation coefficient.

Table 2. Spearman correlation coefficients between the visual analog summary scale and NOSE-e (individual items and total score).

Item	Content	Coefficient
1	Congestion	0,876*
2	Obstruction	0,909*
3	Breathing	0,918*
4	Sleeping	0,787*
5	Exercise	0,863*
NOSE-e total score		0,946*

Abbreviations: NOSE-e, Nasal Obstruction Symptom Evaluation-español.

*Correlations greater than 0.4

Mean NOSE-e score in patients at 3 month after septoplasty was 14.0 ± 17.3 . The standardized response mean and the effect size were 1.97 and 2.65, respectively. This indicates very high sensitivity to change.

Discussion

Cross-cultural adaptation and validation of the Spanish version of the NOSE survey were accomplished. To ensure equivalence between the original source and target version of the questionnaire, standard methodology was followed^(17,19). The NOSE-e instrument demonstrated good psychometric properties: reliability, validity, and sensitivity to change. These findings are

consistent with the original English-language validation.

An instrument is reliable if it is able to find similar results when the underlying patient's status does not change over time^(1,11). The reliability coefficient found in the present study was very good, with gamma = 0.962, thus confirming the reproducibility of the Spanish version. The internal consistency was also adequate, with Cronbach's α of 0.955. Results do not appear to differ from those obtained by the authors of the original version⁽¹⁾ whose coefficient α was 0.785. This confirms the measurement precision and high homogeneity of the questionnaire in both languages.

Validity is the aptitude of a questionnaire to measure what it is supposed to measure^(1,11). Item-item correlations, correlations between each item, and the total NOSE-e score demonstrated a strong relationship that was slightly higher than that reported by Stewart et al.⁽¹⁾, thus confirming the validity of the NOSE-e. It would be anticipated that similar results would be found in a well-translated instrument. We agree with Bezerra et al.⁽¹⁰⁾ who pointed previously that high inter-item correlation (> 0.7) could suggest there may be some redundancy of the items. Moreover, positive correlations between the NOSE-e scores and VAS were found in our study (0.94) thus confirming an adequate criterion validity^(1,12,13). As expected, items assessing obstruction correlated better than the item assessing sleeping difficulty⁽¹⁾.

The comparison of our paired populations (diseased population and disease-free population) showed a highly significant statistical difference, which confirms the instrument's ability to measure nasal obstruction and detect the presence or absence of the disease (discriminatory validity)⁽¹¹⁾ in a similar manner as the original version did⁽¹⁾. With the use of the appropriate version of the instrument, comparisons between groups known to differ in their health should result in similar values in each culture. However, cultural differences have been found within supposedly comparable populations⁽²¹⁾.

Sensitivity to change is the ability of an instrument to detect any significant change in the patient's health⁽¹¹⁾. The Spanish-language NOSE showed satisfactory sensitivity to change in the present study. The scores previously published appear to be in line with those observed in our study^(1,10,12,13), confirming the previous suggestion by Stewart et al.⁽¹⁾ that the brevity of the NOSE does not detract from its sensitivity. Long questionnaires are not necessarily more responsive to change than short ones^(10,22).

A potential limitation of this study could be the consecutive convenience sampling used. This sampling does not always produce the most accurate results due to a skewed representation, and we are aware that our study group might not represent the entire population of Spanish patients with nasal obstruction. Furthermore, it might be argued that the improvement of nasal obstruction was not confirmed with objective measures, ideally nasal resistance assessed by rhinomanometry. Nevertheless, we

believe that these limitations do not compromise the results obtained in the validation.

Therefore, the Spanish adaptation of the NOSE can be used to assess the efficacy of nasal obstruction management in patients with septal deviation in Spanish-speaking populations. Its use is recommended and will allow comparison across studies and international multicenter projects. Establishing normative values for the new version would be the next step.

In conclusion, the Spanish version of NOSE (NOSE-e) appears to be as reliable, valid, and sensitive to change as the English version, thus allowing assessment of the impact of nasal obstruction or its treatment on patients with septal deviation in Spain.

Acknowledgements

The authors would like to thank the staff from the participating

institutions and the patients and volunteers who accepted participation in this study.

Author contributions

FL: conception and design; acquisition and interpretation of data; drafting of the manuscript. JR: acquisition of data and critical revision of the manuscript. MJD: analysis and interpretation of data; drafting of the manuscript. MG: acquisition of data and critical revision of the manuscript. AA: acquisition of data and critical revision of the manuscript. IA: conception and design; critical revision of the manuscript.

Conflict of interest

The authors have no funding, financial relationships, or conflicts of interest to disclose.

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