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# *Cross-cultural adaptation and validation of the NOSE scale in European Portuguese*

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# CROSS-CULTURAL ADAPTATION AND VALIDATION OF THE NOSE SCALE IN EUROPEAN PORTUGUESE

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**Abstract**

*Introduction:* Nasal airway obstruction is a common presenting symptom in otolaryngology. Nasal obstruction symptom evaluation (NOSE) scale is a fast, easy-to-complete and disease-specific instrument, used to assess the quality of life in patients with nasal obstruction before and after treatment outcomes. However, this scale is not available in European Portuguese. This study aimed to culturally adapt the NOSE scale to European Portuguese (NOSE-pt) through a cross-cultural adaptation and validation.

*Methods:* A prospective observational study was conducted in 57 patients with nasal obstruction symptoms, preoperatively and 3 months after surgery. Guidelines for the cross-cultural adaptation and validation process were followed. Collected data were analyzed to determine internal consistency, sensitivity to change, reliability and validity.

*Results:* NOSE-pt scale proved to be a valid and reliable instrument, with adequate internal consistency (Cronbach´s alpha = 0.88), sensitivity to change (effect size = 0.987) and good intraclass correlation coefficient (r = 0.803).

*Conclusion:* Cross-cultural adaptation process demonstrated that NOSE-pt scale is a reliable, valid, easy-to-use, self-administered and symptom-specific questionnaire. For these reasons, its application is recommended.

**Keywords:** nasal airway obstruction; NOSE scale; validation studies; European Portuguese.

## Introduction

Nasal airway obstruction is a common presenting symptom in otolaryngology that can range from a mild annoyance to a life-threatening condition that affects breathing during wakefulness and sleep (Hsia et al., 2014). It is defined as a feeling of blockage or insufficient air flow through the nose (Bezerra et al., 2012) and a source of significant patient discomfort and financial burden (Chandra et al., 2009; Stewart et al., 2004a).

Nasal obstruction prevalence in urban and rural dwellers is 26.7% and 24.1%, respectively (Jessen and Malm, 1997), and nose septal deviation is considered the main trigger of nasal obstruction (Sipila and Suonpaa, 1997), with its definitive treatment consisting of a septoplasty. There are also several inflammatory and anatomic contributors for nasal obstruction (Moche and Palmer, 2012). So, the potential for multiple contributing causes and factors requires a challenging evaluation.

Numerous tools, like computed tomography (CT) or quality of life questionnaires, have been used to assess nasal obstruction and to predict the clinical outcome of patients following surgical correction. However, there is a weak correlation between them (Kahveci et al., 2012; Stewart and Smith, 2005). Several studies have accessed patients' subjective outcome after septoplasty, most of them retrospectively, and prospective ones have used non-validated instruments (Arunachalam et al., 2001; Dinis and Haider, 2002; Samad et al., 1992; Siegel et al., 2000; Stewart et al., 1996). Stewart et al (2004) developed the Nasal Obstruction Symptom Evaluation Scale (NOSE) with wide medical acceptance (Stewart et al., 2004b).

The NOSE scale is a disease-specific tool designed to assess: 1) the patient's quality of life with nasal obstruction (Benninger and Senior, 1997; Gliklich and Metson, 1995; Juniper and Guyatt, 1991; Piccirillo et al., 2002; Rhee et al., 2003) and 2) the outcome measurements of an intervention in nasal obstruction in different types of research studies (Fokkens et al., 2007). The NOSE is a fast and easy to complete scale. It consists of 5-point Likert Scale questions resulting in a sum score (ranging from 0 to 20) that is multiplied by 5 to scale to a total score of 0 to 100. Due to the wording of the items, higher scores mean greater nasal obstruction.

The NOSE scale has been linguistically translated and culturally adapted, which allows maintaining the content validity towards to be used in different countries and cultural backgrounds. This cross-cultural adaptation and validation has been done in various countries, such as Spain (Larrosa et al., 2015), China (Dong et al., 2014), Greece (Lachanas et al., 2014), Brazil (Bezerra et al., 2011) and used in different outcome studies (Kahveci et al., 2012; Mondina et al., 2012; Most, 2006). There is only one study in Portuguese patients confirming the effectiveness of septoplasty in patients with nasal

obstruction, when the NOSE scale was used (Alves et al., 2010). In this way, the present study aims the cross-cultural adaptation and validation of the NOSE scale in European Portuguese.

## Materials and methods

*Study design*

A prospective cohort study, consisting of a cross-cultural adaptation process of the original NOSE instrument, was conducted at the Faculdade de Medicina da Universidade de Coimbra. This study was approved by the Ethics committee (CE 132/2018). Written informed consent was obtained from all patients. Only normal cognitive function and reading skilled patients' data were included.

*Cross-cultural adaptation process*

Cross-cultural adaptation to Portugal was performed, in the same way as the study of Bezerra et al. (Bezerra et al., 2011), according to the accepted general guidelines and using standard techniques (Beaton et al., 2000; Boynton and Greenhalgh, 2004). The first stage is the forward translation of the original NOSE scale, made by two translators (a bilingual European Portuguese-native otolaryngologist and a bilingual Portuguese-native professional translator without medical background). The two translators, a recording observer and an expert committee checked for semantic, idiomatic and conceptual issues, resulting in a refined Portuguese translated version. Blind to the original English version of the NOSE scale, two professional English-native translators without medical background, translated the Portuguese version back into English (source language). Again, two translators, a recording observer and an expert committee synthesized the translation results in an English back translated version that was compared to the original English version of the NOSE scale. After checking for semantic, idiomatic and conceptual issues, a final version of the questionnaire was created (see **Figure 1**). In this phase of the study, 57 patients (32 females and 25 males) who reported nasal obstruction symptoms with scheduled elective surgery were prospectively enrolled.

The exclusion criteria considered were age below 18 years, previous nasal surgery, immunodeficiency, primary ciliary dyskinesia, vasculitis, recent treatment for any infection (in the last 15 days) and recent use of endonasal spray medication.

*Validation*

Patients answered autonomously the translated questionnaire while discussing the wording and the meaning of each topic with the senior clinician.

*Methods and Statistical Analysis*

The internal consistency of the NOSE-pt scale was estimated by Cronbach´s alpha and corrected inter-item correlations. The reliability of the internal consistency was considered acceptable if Cronbach´s alpha was 0.70 or higher (Stewart et al., 2004b). Corrected inter-item correlations were established using the Spearman correlations.

*Test-retest reliability (reproducibility)*

To assess test-retest reliability, a second NOSE-pt questionnaire was administered to 38 subjects from the patient group, 2 weeks after the first one. No considerable changes were expected to take place in subjects' nasal condition in this period. The test-retest reliability was calculated using Goodman-Kruskal gamma (correlation strength was considered strong for values greater than 0.5, moderate for values ranging between 0.3 and 0.5 and weak for values less than 0.3).

*Construct validity*

Similarly to the original study of Stewart et al., in the absence of an objective gold standard to measure nasal obstruction, the construct's validity was assessed with a Spearman correlation test, comparing items from the NOSE-pt questionnaire with the SNOT22 scale (Stewart et al., 2004b).

*Discriminant validity*

Discriminant validity was assessed by comparing the total scores between two different groups (pre and postoperative groups) using the Mann-Whitney U test, with an alpha set at 0.05.

*Response sensitivity*

The sensitivity to change (response sensitivity) was estimated by calculating the effect size 3 months post-surgical intervention. This value was compared with the published standard values. According to the study of Stewart et al., values around 0.2, 0.5 and 0.8 were considered of low, moderate and high sensitivity to change, respectively (Stewart et al., 2004b).

*Agreement between NOSE measures (before and after surgery)*

To assess a bias between the mean differences, and to estimate an agreement interval, within which 95% of the differences of the second measure, compared to the first one fall (Giavarina, 2015), a Bland-Altman graph was used.

*Statistical analysis*

An alpha of 0.05 was considered statistically significant for statistical tests. Data analysis and statistical tests were performed using the Statistical Package for Social Sciences (SPSS; IBM Corp., Chicago, IL, USA), version 23.0.

## Results

Fifty-seven patients were included in this study, and all completed the European Portuguese version of the NOSE scale (**Figure 1**), created after a cross-cultural adaptation and translation of the original one. However, to assess the changes occurred between pre and 3 months post-surgery, only 52 patients were considered (55.8% female), with an average age of 42.9±12.6 (range 20-71) years.

*Internal consistency*

The Cronbach´s alpha values obtained for NOSE-pt total score were, α=0.88 (for preoperative group) and α=0.80 (for postoperative group), which means that the internal consistency reliability was considered good.

The corrected inter-item correlations are displayed in **Table 1**. The analysis of inter-item correlations showed that all items had significant correlation coefficient with each other except for the “Trouble sleeping” item (r=-0.212 for the correlation between “Trouble sleeping” and “nasal congestion”; r=0.156 between “Trouble sleeping” and “nasal obstruction”; r=0.148 between “Trouble sleeping” and “Trouble breathing through my nose” and r=0.182 between “Trouble sleeping” and “Unable to get enough air through my nose during exercise or exertion”).

*Test-retest reliability*

The test-retest reliability (N=38) was good with a Goodman-Kruskal gamma of 0.574 ($p<0.01$).

*Construct validity*

Similarly, to the SNOT22 study (Gillett et al., 2009), the NOSE-pt questionnaire had a lower mean sum in the postoperative group in comparison with the preoperative score. In the SNOT22 study, this value went from 50.9±22.4 in the preoperative group to 21.6±15.3 in the postoperative group and, in our study, it went from 51.0±22.4 to 21.1±14.5. Also, the Pearson correlation between these two methods revealed a significant correlation between initial (preoperative group) NOSE sumscore and initial SNOT22 sumscore (r=0.785) and between NOSE final sumscore (postoperative group) and SNOT final sumscore (r=0.367).

*Discriminant validity*

The mean scores obtained from the pre and postoperative groups are shown in **Table 2**. The NOSE-pt scale showed an excellent between-groups discrimination with consistently lower values of total and single item scores for after surgery group (Mann-Whitney U test, $p < 0.05$).

*Response sensitivity*

The NOSE-pt scale had a high sensitivity to change with an effect size of 0.987.

*Agreement between NOSE measures (before and after surgery)*

As shown in **Figure 2**, the differences between the two NOSE measures were located between the agreement limits [mean value ± (1.96 x standard deviation)]. Moreover, there was no relationship between the differences of the two measures and their average.

## Discussion

Patient-reported outcome measures, can be applied when the instruments used are validated, even in the absence of globally accepted objective instruments (van Zijl et al., 2017). The NOSE scale is an accepted and validated instrument used to quantify the nasal obstruction-associated burden, with the advantage of being fast and easy to complete. In this study, the psychometric properties of the European Portuguese version of the original NOSE scale were studied and a cross-cultural adaptation and validation to the Portuguese language was made. The cross-cultural adaptation is a complex process which involves multiple translators to ensure that item content is maintained.

The final version (NOSE-pt), presented a high level of internal consistency ($\alpha=0.88$ for preoperative group and $\alpha=0.80$ for postoperative group), with an overall large size effect of 0.987 (which represents a high sensitivity to change). The test-retest reliability was good and item-level characteristics were maintained. All of these findings are consistent with the original English validation by Stewart et al. (Stewart et al., 2004b).

The internal consistency of the NOSE-pt Cronbach´s alpha score was 0.88 for preoperative group, which is within accepted ranges and comparable to other reported NOSE validation studies, for countries like Brazil (Bezerra et al., 2011), France (Marro et al., 2011), Italy (Mozzanica et al., 2013), Spain (Larrosa et al., 2015) and China (Dong et al., 2014), with Cronbach´s alpha ranging from 0.81 to 0.96. The Cronbach´s alpha for the postoperative group was 0.80.

The overall large size effect in our study was 0.987, which represents a high sensitivity to change and goes accordingly with data obtained by Stewart et al.(Stewart et

al., 2004b) in the original study, with an overall effect size of 2.65. This indicates that the instrument is suitable for measuring treatment outcome.

In our study, mean sumscores dropped from 64.5±28.9 before surgery to 18.5±15.6 following surgery, being comparable to that reported in the systematic review of Rhee et al. (Rhee et al., 2014). The authors reviewed the NOSE scores of patients with nasal airway obstruction after septorhinoplasty, with or without turbinate surgery, and found a mean pre and post-treatment score of 65 and 23, respectively. Our median decrease of 46 points after surgery, confirmed that the NOSE-pt could gauge clinically successful surgery in terms of nasal function improvement.

Test-retest reliability was used to confirm reproducibility, by the correlation between the initial test and subsequent retest scores. In our study, the test-retest reliability was good with a Goodman-Kruskal gamma of 0.574 ($p<0.01$), which goes accordingly with the findings of Bezerra et al. (Bezerra et al., 2011) (with a Goodmann Kruskal Gamma of 0.776) and in the original study (Stewart et al., 2004b) (with a Goodmann Kruskal Gamma of 0.702). Taken together, these data which support the idea that the NOSE-pt has a high stability and reproducibility over time.

Similarly to Brazilian NOSE validation, the inter-item correlation showed a low correlation between the item “trouble sleeping” and the other items (Bezerra et al., 2011). However, there was also a poor correlation between the item “unable to get enough air through my nose during exercise or exertion” and the other four items, specially the item “nasal congestion”, what was not observed in our study (Bezerra et al., 2011).

A potential shortcoming of the study is the fact that this was a single center study performed in an academic hospital, which may cause impaired generalizability or selection bias. In the original NOSE study, a multicenter study including four academic hospitals was used, and Larrosa et al. included both a tertiary and regional center with comparable results (Larrosa et al., 2015; Stewart et al., 2004b).

The NOSE-pt scale appears as a brief and easy-to-complete questionnaire, that should be used as a reliable tool to assess nasal obstruction-related quality of life and to measure the effectiveness of surgical interventions in patients with nasal obstruction in clinical trials.

## Conclusion

The current findings support the reliability and validity of the NOSE-pt scale for measuring nasal obstruction and to assess clinical outcomes in clinical trials. This study proved that the cross-cultural adaptation and validation of the original NOSE scale was successfully performed and the psychometric properties of the NOSE-pt were adequate. In this way, the use of NOSE-pt in everyday practice and to assess patients' epidemiological, efficacy and outcomes in clinical trials is recommended.

## Conflict of interest

The authors declare that they have no conflict of interest.

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## Annexes

**Table 1.** Inter-item correlation matrix.

| | Nasal congestion | Nasal obstruction | Trouble breathing through my nose | Trouble sleeping | Unable to get enough air through my nose during exercise or exertion |
|---|---|---|---|---|---|
| **Nasal congestion** | - | - | - | - | - |
| **Nasal obstruction** | 0.496 | - | - | - | - |
| **Trouble breathing through my nose** | 0.430 | 0.491 | - | - | - |
| **Trouble sleeping** | -0.212 | 0.156 | 0.148 | - | - |
| **Unable to get enough air through my nose during exercise or exertion** | 0.579 | 0.581 | 0.431 | 0.182 | - |

**Table 2.** NOSE-pt scores in pre and postoperative groups.

| | **Preoperative (N=52)** | **Postoperative (N=52)** | **p value** |
|---|---|---|---|
| Nasal congestion | 3 (3) | 0 (1) | **<0.001** |
| Nasal obstruction | 4 (2) | 0 (1) | **<0.001** |
| Trouble breathing through my nose | 4 (2) | 1 (1) | **<0.001** |
| Trouble sleeping | 3 (3) | 0.5 (2) | **<0.001** |
| Unable to get enough air through my nose during exercise or exertion | 3 (4) | 0 (1) | **<0.001** |
| Total raw score | 12.9±5.8 | 3.7±3.1 | **<0.001** |
| Total score x 5 | 64.5±28.9 | 18.5±15.6 | **<0.001** |

Bold: $p<0.05$

Este questionário permite-nos entender melhor o impacto da obstrução nasal na sua qualidade de vida.
No último mês, qual a intensidade do problema perante as seguintes situações (coloque um círculo em redor da resposta mais correcta):

| | **Não é um problema** | **Problema ligeiro** | **Problema moderado** | **Problema grave** | **Problema muito grave** |
|---|---|---|---|---|---|
| **1.Congestão nasal ou nariz cheio** | **0** | **1** | **2** | **3** | **4** |
| **2. Obstrução ou bloqueio nasal** | **0** | **1** | **2** | **3** | **4** |
| **3. Dificuldade em respirar pelo nariz** | **0** | **1** | **2** | **3** | **4** |
| **4. Dificuldade em dormir** | **0** | **1** | **2** | **3** | **4** |
| **5. Incapaz de respirar pelo nariz durante o exercício físico** | **0** | **1** | **2** | **3** | **4** |

Notas administrativas:
Todas as 5 alíneas foram respondidas?
Multiplique os resultados por 20 para escala de 100 no máximo

**Figure 1.** European Portuguese version of the NOSE scale (NOSE-pt).

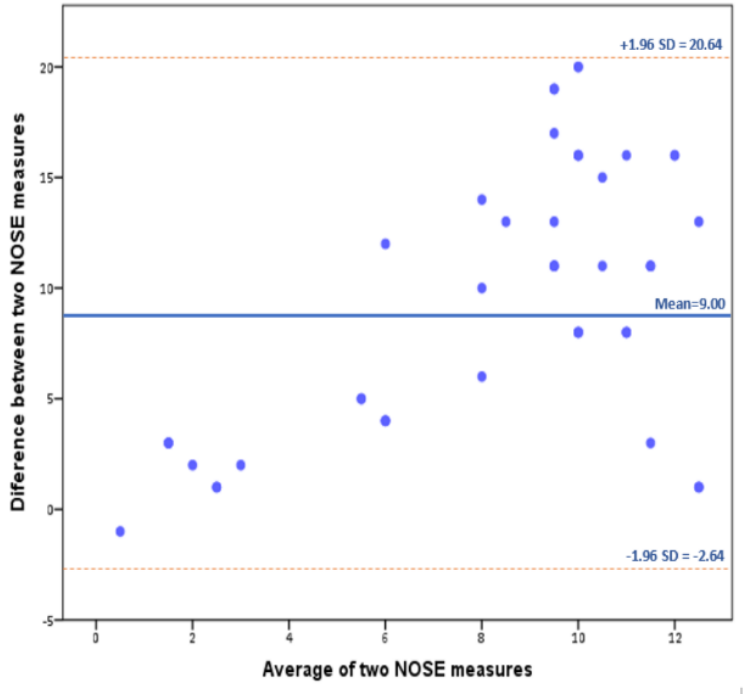


**Figure 2.** Bland-Altman plot.