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Clinical Evaluation of a Polish Translation and Cross-Cultural Adaptation of the Nasal Obstruction Symptom Evaluation (NOSE) Scale

Authors' Contribution:
Study Design A
Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
Literature Search F
Funds Collection G

ABCDEF 1,2 **Justyna Dąbrowska-Bień**
ADE 1,2 **Henryk Skarżyński**
ACDEF 1,2 **Elżbieta Gos**
BDE 1,2 **Iwonna Gwizdalska**
BDE 1,2 **Katarzyna Bożena Łazeczka**
ADEF 1,2,3,4 **Piotr Henryk Skarżyński**

1 Institute of Physiology and Pathology of Hearing, Warsaw, Poland
2 World Hearing Center, Kajetany, Poland
3 Department of Heart Failure and Cardiac Rehabilitation, 2nd Faculty, Medical University of Warsaw, Warsaw, Poland
4 Institute of Sensory Organs, Kajetany, Poland

Corresponding Author: Piotr Henryk Skarżyński, e-mail: p.skarzynski@ifps.org.pl
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Background: Nasal obstruction is the most common rhinologic complaint in ear, nose, and throat (ENT) clinical practice and septal deviation is the leading cause. The Nasal Obstruction Symptom Evaluation (NOSE) scale is a brief, self-administered questionnaire that has been widely used to assess symptoms and quality of life related to nasal obstruction, and is commonly used in clinical outcome studies. The aim of this study was to undertake a clinical evaluation of a Polish translation and cross-cultural modification of the NOSE scale for nasal obstruction.





Material/Methods: A controlled clinical validation study was conducted in a tertiary referral center. The Polish version of the NOSE scale was developed according to cross-cultural adaptation guidelines. The psychometric properties of the Polish version of the NOSE scale (internal consistency, reproducibility, validity, responsiveness, interpretability) were assessed in 51 patients with nasal obstruction and 51 controls matched according to gender and age.

Results: Internal consistency of the Polish version of the NOSE scale was 0.80 as assessed by Cronbach's alpha, and an intraclass correlation of the reproducibility was 0.98. Construct inter-item and item-total correlations confirmed validity. Correlation confirmed appropriate criterion validity with a visual analog scale (VAS) and discriminant validity was confirmed between patients and controls. Responsiveness and interpretability were also confirmed.

Conclusions: The Polish version of the NOSE scale is a brief and reproducible clinical evaluation tool for use in clinical practice in Polish-speaking patients with nasal obstruction.

MeSH Keywords: **Nasal Obstruction • Psychometrics • Quality of Life • Validation Studies**

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Background

Nasal obstruction is the most common complaint in rhinologic ear, nose, and throat (ENT) clinical practice, and septal deviation is considered to be the main cause [1]. A 'blocked nose' is the symptom reported by 60% of allergic rhinitis sufferers [2]. The prevalence of nasal congestion in rhinosinusitis is between 66–70% [3,4], and it is also the most severe symptom of nasal polyposis, which occurs in between 2–4% of the general population [5,6].

Several diagnostic tools have been used to investigate nasal obstruction and to predict which patients are most likely to have satisfactory clinical outcome following surgery, including computed tomography (CT), rhinomanometry, acoustic rhinometry, and quality of life questionnaires, but with poor correlation between objective and subjective methods [7,8]. Health-related quality of life questionnaires are among the most recent tools for assessing changes in of symptoms, the impact of disease on the quality of life and effectiveness of the treatment of chronic diseases. These questionnaires were developed either for gauging general health status or assessing a specific clinical problem. In the rhinologic field, there are several questionnaires in English, including the Sino-Nasal Outcome Test-22 (SNOT-22), the Nasal Symptom Questionnaire (NSQ), the Rhinoplasty Outcome Evaluation (ROE), and the Fairley Nasal Questionnaire (FNQ), but none of the disease-specific questionnaires exist in the Polish language. Therefore there is an immediate need for a validated Polish language questionnaire for patients with nasal obstruction.

Before clinical use, health-related quality of life questionnaires should undergo psychometric validation. Evidence-based medical practice requires the use of validated, reliable, and accurate instruments for clinical diagnosis. Currently, several guidelines are used to describe how to cross-culturally adapt questionnaires from one language and culture to another, with the aim of achieving equivalence between the original and the modified clinical tool [9–11].

The Nasal Obstruction Symptom Evaluation (NOSE) scale is a health-related quality of life questionnaire for patients with nasal obstruction, which was developed by Stewart et al. in 2004, and has since been translated into many languages and clinically validated [12–17]. In our clinical practice, we have chosen this questionnaire because it is brief, easy to complete for the patient, specific for nasal obstruction, and is used with the permission of the author. Also, the NOSE scale can be further applied for outcome analysis after septoplasty [18], functional rhinoplasty [19] or turbino-plasty [20].

Therefore, the aim of this study was to undertake a clinical evaluation of a Polish translation and cross-cultural modification

of the NOSE scale for nasal obstruction. To our knowledge, there is currently no health-related quality of life questionnaire that is specific for nasal obstruction and which can be used in a Polish-speaking population.

Material and Methods

Ethical statement

The study protocol, informed consent form, and patient information brochure were approved by the Institutional Ethics Committee (approval number: IFPS: KB/19/2016) and were in accordance with the World Medical Association Declaration of Helsinki. Each patient gave informed written consent to participate in the study.

Patients recruited to the study group and control group

Two groups of volunteers were recruited for this study. The first group included patients with nasal obstruction due to symptomatic nasal septal deviation and included 51 consecutive patients with nasal septal deformity undergoing septoplasty. This study group included 12 women and 39 men aged between 18–62 years (mean, 35.06±11.45 years).

The control group consisted of 51 patients without rhinologic complaints or Eustachian tube dysfunction recruited from the Otolologic Outpatient Clinic. Only one patient who met the study inclusion criteria refused to participate in the study. The control group included 12 women and 39 men aged between 18–62 years (mean, 35.63±12.74 years). The controls were selected to match the patients according to gender and age. The study enrolment period was from 1st March 2017, to 30th June 2017.

For the study group of 51 patients with nasal obstruction, the inclusion criteria included the following: age ≥18 years; septal deviation associated with symptoms of chronic nasal obstruction; symptoms that were present for at least three months; and persistent symptoms after a four-week trial of medical management (including topical nasal steroids, topical or oral decongestants, or an oral antihistamine/decongestant combination). Exclusion criteria for the study included the following: a diagnosis of sino-nasal malignancy; radiation therapy to the head and neck; previous surgery (septoplasty, sinus surgery, rhinoplasty, or turbino-plasty); a history or clinical evidence of chronic sinusitis using the criteria from the European Position Paper on Rhinosinusitis and Nasal Polyps 2012 (<http://ep3os.org/EPOS2012.pdf>); adenoid hypertrophy; sleep apnea syndrome; septal perforation; craniofacial syndrome; acute nasal trauma or fracture in the previous three months; nasal septal collapse; sarcoidosis; Wegener's granulomatosis; uncontrolled asthma; pregnancy; and inability to understand and sign the consent form.

The inclusion criteria for the control group were age ≥ 18 years, and a signed informed consent to take part in the clinical study. The exclusion criteria included any history of nasal or sinus disease, the use of oral or intranasal steroids in the previous four weeks, and a previous history of previous nasal or sinus surgery.

Patients from the study group completed the Nasal Obstruction Symptom Evaluation (NOSE) questionnaire three times, two weeks before surgery, one day before surgery, and at three months following surgery. The control group completed the NOSE questionnaire once.

Surgical septoplasty performed in the study group

The surgical procedure used for the 51 patients in the study group was septoplasty via a hemi-transfixion incision according to the Cottle cartilage-sparing procedure, which was performed by one of two senior surgeons in the study (JDB or EW). The postoperative instructions were the same for all patients.

The study authors closely followed the methods used by Stewart et al. [21], in the development and validation of the original version of the NOSE scale, and a summary visual analog scale (VAS) was also used. The study participants were asked to mark on a horizontal line how difficult it was to breathe through the nose. The line was 100 mm long with three verbal descriptors (or word anchors): 'none' (on the left); 'medium' (in the center); and 'severe' (on the right). The mark made by the participants was converted into a number from 0 to 10. The higher the numerical rating, the more severe were the symptoms of nasal obstruction and difficulty in breathing through the nose.

Translation of the NOSE scale questionnaire

The cross-cultural adaptation of the NOSE questionnaire was conducted according to previously published guidelines [9–11]. Firstly, permission was obtained from the NOSE author, MG Stewart, to use the NOSE questionnaire [21]. The NOSE questionnaire was translated into Polish by two bilingual translators, whose primary language was Polish. An expert committee of two senior ear, nose, and throat (ENT) consultants, one methodologist, and one English translator compared and discussed both versions until a preliminary translated version was agreed. The Polish translation and modified version of the NOSE questionnaire (NOSE-POL) was initially given to a test group of 15 patients to check for clarity and patient understanding. Some patients reported difficulties in distinguishing between symptoms such as 'nasal congestion' versus 'stuffiness,' and 'nasal blockage' versus 'obstruction.' Following the feedback from the patient test group, an expert committee compiled the final version of the Polish modification of the NOSE questionnaire, the

NOSE-POL. The NOSE-POL was then translated back into English by two translators whose, primary language was English, and compared with the original version of the questionnaire. There were no differences in meaning between the two versions.

Psychometric and statistical analysis

Internal consistency was assessed by calculating Cronbach's α coefficient. According to the criteria of Nunnally and Bernstein [22], internal consistency was considered good when Cronbach's α coefficient was >0.70 . To determine the reproducibility of the revised NOSE-POL questionnaire and scale, intraclass correlation (ICC) was used, with a positive rating considered to be >0.70 [23]. The limits of agreement were assessed according to the method of Bland and Altman [24], and 95% scores were expected to be within these identified agreement limits. The expert panel assessed content validity. Construct validity was assessed using Spearman's correlation coefficient, both between the items and the global score, with a positive correlation coefficient being >0.40 [21]. In the absence of an objective 'gold standard' with regard to nasal patency, the correlation between the NOSE-POL total score and the VAS score was calculated to assess criterion validity, with a strong correlation assumed to be a Rho >0.70 [25].

Discriminant validity was tested by comparing the global NOSE-POL score of the patient group with the control group. The predefined hypothesis was that patients would have higher global NOSE-POL scores than the controls. A Mann-Whitney test was used, and the statistical significance threshold was $P < 0.05$. Responsiveness was assessed by calculating the effect size, or the mean change in test-retest score divided by the standard deviation (SD) of this score. According to Cohen's criteria, an effect size was considered small if <0.2 , medium if 0.5 , or large if >0.8 [26]. Also, paired sample t-tests were used to compare the global NOSE score before and after treatment. The study hypothesis was that the global NOSE-POL score before septoplasty would be greater than after septoplasty. Interpretability was determined by examining the distribution of scores and the normative values for the patient group. Baseline and ceiling effects were considered to be absent if $<15\%$ of the respondents achieved the lowest or highest possible score, respectively [27].

The study sample size was calculated using the power of 0.80 , an alpha level $=0.05$, and a correlation coefficient of 0.40 , as an outcome of construct validity [13,21]. The required sample size was $N=46$, but it was extended by 10% because of possible refusal to participate or patient drop out before the study ended. Therefore, the study included 51 subjects in each group. Also, the sample size for a validation study is recommended to be a minimum of 50 persons, and when comparing groups (patients and controls), a minimum of 50 persons per subgroup has also been recommended [26].

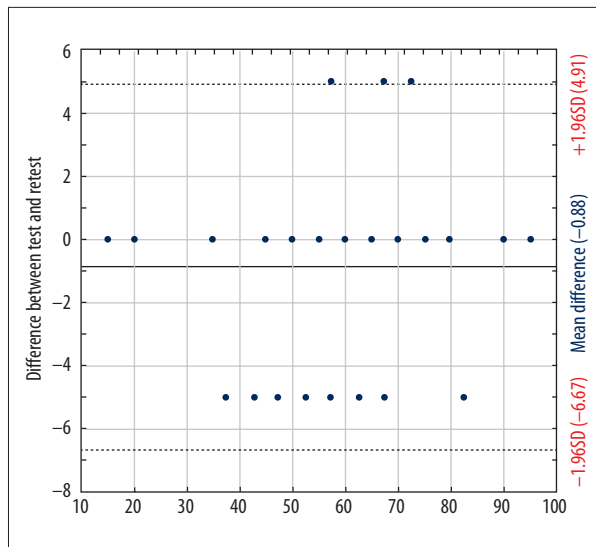


Figure 1. Bland-Altman plot of the test-retest agreement of the Polish adaptation of the Nasal Obstruction Symptom Evaluation (NOSE) scale.

Results

Internal consistency and reproducibility of the Polish adaptation of the Nasal Obstruction Symptom Evaluation (NOSE) scale

When used in the two patient groups in the study, the Polish adaptation of the Nasal Obstruction Symptom Evaluation (NOSE), the Cronbach's coefficient was $\alpha=0.80$, which fulfilled the criteria given by Nunnally and Bernstein [22]. None of the items reduced the internal consistency (if an item was deleted, Cronbach's α increased only from between 0.72 to -0.79). Reproducibility measured with ICC amounted to 0.98 obtaining positive rating [23]. The 95% limits of agreement were calculated to be from -6.67 to 4.91 points. Within these identified agreement limits were found 90.2% of the NOSE scores (Figure 1).

Validity

Content validity was assessed during the translation process by the expert panel. All items were deemed relevant and comprehensive for the construct to be measured. The evaluation of construct validity, correlations between the items, and the global score are shown in Table 1. All item total correlations were strong, and between items 1–3 (concerning congestion, obstruction, and trouble in breathing) correlations were strong or moderate. The associations between items 1 and 2, and items 4 and 5 were weaker.

Correlations with the visual analog scale (VAS) indicated highly satisfactory criteria validity. Correlations between the NOSE global score and VAS score were strong, $Rho=0.75$ ($P<0.001$) (before septoplasty) and were also strong after surgery, $Rho=0.71$ ($P<0.001$). Discriminant validity was also confirmed. Before septoplasty the patient mean NOSE scores were 62.35 ± 18.74 , and the control mean scores were 9.80 ± 10.77 ($U=30.0$) ($P<0.001$). The difference was statistically significant.

Responsiveness

The distribution of the NOSE-POL scores was normal before septoplasty and was also normal three months after surgery. The Kolmogorov–Smirnov test was used to assess normality, and the results were $K-S=0.08$ ($P>0.05$), and $K-S=0.12$ ($P>0.05$), respectively.

Before septoplasty the mean score was 62.35 ± 18.74 ; three months after surgery the mean score was 32.35 ± 14.30 ; $t(50)=13.29$ ($P<0.001$); Cohen's $d=1.86$. The test-retest difference was statistically significant. In accordance with expectations, higher scores were recorded before septoplasty when compared with scores three months after surgery. The effect size was large, showing that surgery significantly reduced symptoms of nasal obstruction and that the NOSE-POL was an instrument that could demonstrate the magnitude of change in symptoms following treatment.

Table 1. Inter-item and item – total correlations (Spearman's coefficient).

	NOSE2	NOSE3	NOSE4	NOSE5	Total score
NOSE1	0.77	0.65	0.40	0.37	0.79
NOSE2		0.53	0.36	0.30	0.74
NOSE3			0.50	0.52	0.80
NOSE4				0.44	0.77
NOSE5					0.66

All correlations were significant ($p<0.01$).

Table 2. Percentage of responses for each NOSE-POL item.

Item	Responses				
	0	1	2	3	4
NOSE1	0.0	9.8	33.3	47.1	9.8
NOSE2	2.0	15.7	29.3	41.2	11.8
NOSE3	3.9	5.9	33.3	37.3	19.6
NOSE4	9.8	29.4	17.6	29.5	13.7
NOSE5	2.0	5.9	31.4	37.2	23.5

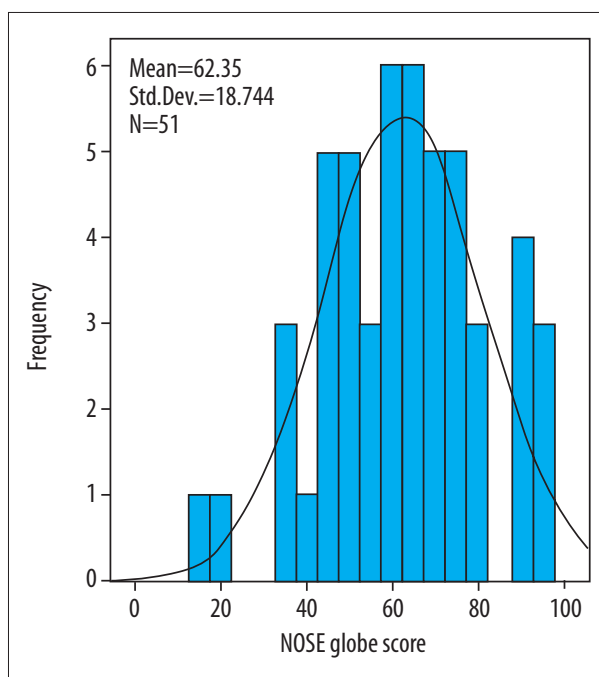


Figure 2. Distribution of scores of the Polish adaptation of the Nasal Obstruction Symptom Evaluation (NOSE) scale.

Interpretability

The frequency distribution for each NOSE-POL response item was examined (Table 2).

For no item was the percentage response for the lowest possible option greater than 15%. Only for two items (numbers 3 and 5) was there a possibility of the presence of a ceiling effect, or more than 15% of participants who chose the highest possible response option. The distribution of scores of the NOSE-POL is shown in Figure 2.

No patient obtained the lowest possible score (0 points) or the highest possible score (100 points). There was no clustering of patients at the extremes of the scale. When interpreting the NOSE-POL scores, it might be useful to note that adult patients

with nasal obstruction (before surgery) achieved mean scores of 62.35 ± 18.74 , median scores of 65, and mode $M_o=60$, lower quartile $Q_1=50$, and upper quartile $Q_3=75$. These values may be used as a benchmark for eligibility for surgery.

Discussion

Nasal obstruction is the most common rhinologic complaint in ear, nose, and throat (ENT) clinical practice and septal deviation is the main cause. There is perceived to be a need for a short, accurate, and easy to use method of patient evaluation of the symptoms of nasal obstruction in adults that can be used in a clinical practice in Poland. The Nasal Obstruction Symptom Evaluation (NOSE) scale, developed by Stewart et al. in 2004 [21] has been adapted into many languages, including Greek, Spanish, French, and Italian [12–14,16]. The NOSE questionnaire and scale is a well known and widely used reliable and valid patient evaluation method in rhinology. Cross-cultural adaptation of the NOSE scale makes it a valuable tool, which allows comparison of outcomes between medical institutions and facilitates multicenter studies. In the present study, the psychometric properties of the Polish version of the NOSE scale (NOSE-POL) were studied. Results showed good internal consistency, reproducibility, validity, responsiveness, and interpretability. Internal consistency measures the extent to which items in a scale are correlated, which is an important property for questionnaires that are intended to measure a single underlying concept on a multi-item scale. The internal consistency of the original English version of the NOSE scale was a Cronbach α of 0.79 [21], and in our study the NOSE-POL had a Cronbach α of 0.80, which indicates good homogeneity of the tool and corresponds well with the results of other studies in which the NOSE scale has been translated or modified [12,13,17].

Reproducibility is the degree to which a clinical tool yields stable scores over time, in stable individuals. This property of reproducibility was confirmed in our study by performing a test-retest, allowing an initial test and subsequent retest scores to be

correlated, which demonstrated an intraclass correlation coefficient (ICC) of 0.98, indicating excellent reproducibility, which was higher than in Stewart's study [21] but similar to the results of the Spanish validation of NOSE [12]. A Bland-Altman plot showed that 90.2% of the differences in scores were located between agreement thresholds, which is a slightly reduced finding than reported in the study by Lachanas et al. [14]. This difference in Bland-Altman plot findings in the present study might have been caused by more restricted limits of agreement used, which were from -6.67 to 4.91 points, whereas in the Greek validation of the modified NOSE [14] the limits were from -11.17 to 11.27 points.

Content validity of the NOSE scale was previously demonstrated and reported by Stewart et al. [21], and has been confirmed in several previous cross-cultural adaptations. In our study, this important property of the instrument was assessed by experts during the translation process and received a positive rating from them. In the present study, we generated and tested the hypotheses concerning construct validity and criterion validity. The correlations between each item and between the items and the global score were mainly >0.40 , as expected. The correlations between the single summary visual analog scale (VAS) and the total NOSE score, pre-septoplasty, and post-septoplasty, were strong, which demonstrated good criteria validity and are comparable to the correlations documented in the Spanish and Italian validation studies [12,16].

The discriminant validity of the NOSE-POL scale was confirmed by comparing results obtained in patients and controls and was consistent with the predefined hypothesis. Other authors have also found excellent between-group discrimination using NOSE [12,17,21]. In line with other validation studies, the Polish NOSE demonstrated high responsiveness, indicating its suitability for measuring treatment outcomes. Mean scores dropped from 62.35 ± 18.74 before surgery to 32.35 ± 14.30 following surgery, which was comparable to the systematic review of Rhee and colleagues in which NOSE scores of patients with nasal airway obstruction after septorhinoplasty, with or without turbinate surgery, were reviewed [28]. The authors compiled scores and found a mean pretreatment score of 65 ± 22 , and a mean post-treatment score of 23 [28]. Also, these authors found that no individual study dropped below 30 points, suggesting that a change of at least 30 points may be considered a clinically meaningful measure of surgical success [28]. Our results confirmed that the Polish version of NOSE could gauge clinically successful surgery in terms of improvement in nasal function. In the NOSE-POL study, no patient obtained the lowest possible or highest possible score, which supported the high interpretability of this clinical patient assessment tool.

This study had several limitations. The study did not include a Polish questionnaire, validated in septoplasty patients, which

could measure the nasal patency-specific quality of life, so we had no 'gold standard' to compare with the results of the study. Instead, we chose to compare the results to a nasal patency VAS score, for which our predefined hypothesis was met. A further study limitation was that the selection of patients was not random, but consecutive patients scheduled for surgery in a single hospital were chosen for the study. However, to reduce possible bias and to make the study findings more generally applicable, patients were recruited from two different surgeons who performed the septoplasty procedures. Also, this was a single-center study conducted in a tertiary care hospital, and so there was potential for patient selection bias. However, in the original validation study of Stewart et al. [21], the NOSE questionnaire showed good clinical properties in a multicenter study with four academic hospitals, and Larrosa et al. [12] included both a tertiary and regional center and achieved comparable results.

Despite the study limitations, the results of the Polish translation and adaptation and validation of the NOSE scale support this questionnaire as a reliable tool for nasal-related quality of life and clinical assessment in populations of Polish patients complaining of nasal obstruction. The use of a patient-reported outcome instrument, in the absence of globally accepted objective measures, is reasonable when the instrument itself is validated. Until now there was no specific quality of life questionnaire for rhinitis, rhinosinusitis, or nasal obstruction that had been validated in the Polish language. NOSE is a validated, reliable, and globally accepted tool for assessing nasal obstruction and for measuring the effectiveness of nasal surgery. NOSE-POL makes it possible to measure the subjective perceptions of the patient regarding nasal airway obstruction, which is important because patient perceptions of disease severity are not always reflected in objective assessments of severity, such as anatomical imaging or peak flow measurement [7,8]. Disease-specific quality of life instruments, such as NOSE-POL, will be clinically useful to quantify aspects of diseases, such as nasal obstruction, which might not be detected by objective testing alone.

Conclusions

In Poland, the Nasal Obstruction Symptom Evaluation (NOSE) scale is the first adapted and validated questionnaire for assessing patient outcome following surgery for nasal obstruction in terms of quality of life. We recommend its use and encourage other specialists to use this brief but robust tool in clinical practice and to gather further evidence of its psychometric properties.

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Conflict of interest

None.