



Introducing Nasal Obstruction Symptom Evaluation (NOSE) scale in clinical practice in Serbia: validation and cross-cultural adaptation

Uvođenje *Nasal Obstruction Symptom Evaluation* (NOSE) skale u kliničku praksu u Srbiji: validacija i kros-kulturalna adaptacija

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Abstract

Background/Aim. The Nasal Obstruction Symptom Evaluation (NOSE) scale is widely used in clinical practice for assessment of quality of life in patients with nasal obstruction. It has been validated in several countries up to date. The aim of this study was to validate and cross-culturally adapt the NOSE scale for Serbian population. **Methods.** The Serbian version of the NOSE scale (NOSE-s) was prepared through forward and backward translation, committee review, and pretesting. Validation process was carried out on 50 patients diagnosed with the nasal septal deviation (the study group) and 50 ear, nose and throat (ENT) patients with other non-rhinological diagnosis (the control group). **Results.** The NOSE-s instrument demonstrated good reliability (Cronbach α coefficient 0.81). Stability and reliability of the NOSE-s questionnaire were confirmed by test-retest procedure showing no statistically significant difference in obtained responses (Goodman-Kruskal gamma coefficient 0.83). Item and total scores were significantly higher in the study group than in the control group indicating the very good inter-group discrimination ($p < 0.001$). Inter-item and item-total correlations were similar to the original NOSE instrument. Three months after septoplasty, a mean NOSE-s score in patients was 19.2 ± 12.8 . Calculated standardized response mean of 1.7 showed high sensitivity to change. **Conclusion.** The Serbian version of the NOSE scale is simple, valid and reliable instrument for estimating the nasal obstruction. Therefore, it can be recommended for application in rhinological practice and research in Serbian speaking population.

Key words:

nasal obstruction; quality of life; surveys and questionnaires; translations; serbia.

Apstrakt

Uvod/Cilj. *Nasal Obstruction Symptom Evaluation* (NOSE) skala se koristi u kliničkoj praksi za procenu kvaliteta života bolesnika sa nazalnom opstrukcijom. Do sada je validirana u nekoliko zemalja. Cilj ove studije je bio da se validira i kulturalno adaptira NOSE skala za korišćenje u srpskoj populaciji. **Metode.** Srpska verzija NOSE scale (NOSE-s) je pripremana na sledeći način: prevodom na srpski jezik, potom povratnim prevodom na engleski jezik, komisijskim pregledom prevoda i pretestiranjem skale. Proces validacije sproveden je u grupi od 50 bolesnika sa postavljenom dijagnozom devijacije nosne pregrade (studijaska grupa) i među 50 bolesnika koji su se lečili na Klinici za uho, grlo i nos, kod kojih je postavljena dijagnoza nekog drugog ne-rinološkog problema (kontrolna grupa). **Rezultati.** NOSE-s instrument je pokazao dobru pouzdanost (Cronbach α coefficient 0.81). Stablnost i pouzdanost NOSE-s upitnika su potvrđeni test-retest procedurom pokazujući da nema statistički značajne razlike u dobijenim odgovorima (*Goodman-Kruskal gamma coefficient* 0.83). Skor pojedinačnih pitanja, kao i ukupan zbir su bili viši u studijskoj grupi bolesnika nego u kontrolnoj grupi, pokazujući da postoji razlika između grupa ($p < 0.001$). Međusobna veza između pojedinačnih pitanja i pojedinačnog pitanja i ukupnog zbira je bila sličnih vrednosti kao i kod originalne skale. Tri meseca nakon septoplastike prosečan NOSE-s skor je bio 19.2 ± 12.8 . Izračunata je i vrednost *standardized response mean* (1.7) koja je pokazala visoku senzitivnost upitnika na promenu. **Zaključak.** Srpska verzija NOSE skale je jednostavna za korišćenje, validna i pouzdana za procenu nosne opstrukcije. Zbog toga je preporučujemo za upotrebu u svakodnevnoj rinološkoj praksi kao i u budućim kliničkim istraživanjima u populaciji koja govori srpski jezik.

Ključne reči:

nos, opstrukcija; kvalitet života; ankete i upitnici; prevođenje; srbija.

Introduction

The sensation of blockage or insufficient airflow through the nose is one of the most common reasons why patients seek medical help from an otorhinolaryngologist^{1,2}. Among numerous conditions that may manifest with nasal obstruction (adenoidal hyperplasia, (non)allergic rhinitis, chronic rhinosinusitis, nasal polyposis, turbinate hypertrophy), nasal septal deviation is a frequent diagnosis^{3,4}. Recent epidemiological studies reported that 10,000–95,000 septoplasties are performed in developed countries every year^{1,5}. However, objective assessment of nasal obstruction is controversial, and generally accepted measurement tool is still lacking⁶. Hence, patients' subjective evaluation of symptom severity stayed valuable source of information. Consequently, health-related-quality-of-life (HRQoL) instruments that estimate patients' health status and symptom severity are considered reliable and valid health-related measurement tools⁷.

The nasal obstruction symptom evaluation (NOSE) scale is the HRQoL questionnaire specifically designed to assess quality of life in patients with nasal obstruction. This instrument consists of five obstruction-related questions that evaluate severity of complaints experienced during the last month. The NOSE instrument uses 5-point Likert scale scoring system for each item (not a problem, very mild problem, moderate problem, fairly bad problem, and severe problem). The raw score is then multiplied by 5 so that the total score ranges from 0 (no problem with nasal obstruction) to 100 (the most severe problem with nasal obstruction). The NOSE scale has been confirmed as a valid, reliable and sensitive to change in patient's clinical status⁶. The original version of the NOSE scale was primarily applied to test patients prior to and after septoplasty. Additionally, its application is recommended for comparison of the effects of different treatment modalities (medical vs. surgical, different surgical techniques) as well as for evaluation of symptom severity between different groups of patients (eg. patients with and without nasal polyposis)⁶. Furthermore, the NOSE scale has been more widely used, for example, to evaluate the outcomes after nasal valve surgery, functional rhinoplasty, and radiofrequency turbinate reduction^{8–10}.

The NOSE scale has been accepted and validated in a few countries up to date^{11–19}. The aim of the current study was to translate, culturally adapt, and validate NOSE scale for Serbian population.

Methods

Study design

The validation of the Serbian version of the NOSE (NOSE-s) instrument was designed as a prospective instrument-validation study. Consent to perform cross-cultural adaptation of the NOSE instrument into Serbian language was obtained from the author of the original version of the scale.

Ethical approval

The study was approved by the Ethics Committee of the School of Medicine, No. 29/V-1. All procedures performed in the study involving human participants were in accordance with the ethical standards of the institutional and national research committees and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Cross-cultural adaptation process

Standard techniques for cross-cultural adaptation and validation of HRQoL instruments were applied^{20–22}. Two independent Serbian native-speakers with an academic knowledge of English performed forward translations. Both translated versions were reconciled into a single version by an expert committee. Subsequently, two persons performed independent back translations of this version of the questionnaire. The first person was an English native speaker with a medical education, who was also fluent in Serbian language. Another person was a bilingual speaker, the English teacher whose first language is Serbian. None of the back translators had insight into the original scale. These versions were further adjusted into a single version. The expert board reviewed all reports once again and created the pre-final version of the scale. This version was pretested on a group of 30 randomly selected patients. Each patient completed the pre-final version of the NOSE-s scale. According to technique suggested by Reichenheim and Moraes²³, meaning of each question was explored by asking patients to rephrase them. Proper understanding and approval of the instrument was surveyed by achieving more than 90 percent of understanding²³. Thus, the final version of the NOSE-s scale was created.

Sample size

Patient selection was carried out at the Department of Diagnostic Radiology, Faculty of Dental Medicine, University of Belgrade, due to high frequency of patients and in order to better represent general population. Patients were consecutively gathered for the study group (n = 50) and the control group (n = 50), respectively. The size of each group was calculated using a general rule of thumb, which is a common procedure to determine sample size for psychometric validation of questionnaires^{6,11–13,20}. This rule recommends inclusion of 10 subjects per each item of the instrument²⁰.

The study group was selected among patients who were clinically diagnosed with nasal septal deviation by an otolaryngologist and referred to the computed tomography (CT) examination of the nose and paranasal sinuses. All patients had symptoms of chronic nasal obstruction persisting 4 weeks after trial of medical therapy. Patients with the history of surgery (septoplasty, septorhinoplasty, septoplasty combined with a paranasal sinus surgery), craniofacial syndromes, facial bone trauma, adenoid hypertrophy, sleep apnea syndrome, acute or chronic sinusitis, sinonasal malignancy, radiotherapy of the head and neck, and uncontrolled asthma, were not included in the study.

Patients enrolled in the control group were referred to the CT examination of the head and neck by ear, nose and throat (ENT) specialist. These patients did not complain of any rhynological symptoms and had no nasal septal deviation, which was additionally confirmed by CT scans. None of these patients had developmental facial anomalies, history of facial trauma, and/or sinonasal malignancy.

Patients from both groups were sex and age matched. All participants were older than 18 years, and gave written informed consent for participation in the study.

The NOSE-s scale testing

In order to avoid possible investigator influence on patients' responses, the NOSE-s questionnaires were self-administrated. The time needed to complete the questionnaire was measured for each patient. The test-retest procedure was carried out among 30 randomly selected patients from the study group within two weeks. A total of 40 patients from the study group underwent septoplasty, while 10 patients refused surgical intervention. Three months after surgery, 33 patients completed the NOSE-s questionnaire again. The rest of seven patients were lost to follow-up.

Statistical analysis

Data were statistically analyzed by descriptive (mean, standard deviation, range, frequencies) and analytical methods. Internal consistency was assessed by Cronbach's alpha coefficient. The value higher than 0.81 was considered satisfactory²⁴. Test-retest reliability was evaluated by Goodman-Kruskal gamma coefficient. Discriminant validity between groups was evaluated by Mann-Whitney *U* test. Spearman's

coefficient (*r*) was used to correlate item-item and item-total score. The statistically significant degree of correlation was considered if the coefficient *r* was higher than or equal to 0.40. In order to evaluate response sensitivity of the questionnaire, standardized response mean was computed by dividing the mean score change by the standard deviation of the change. A value of approximately 0.2 demonstrated low sensitivity to change, while a value of 0.5 demonstrated a moderate sensitivity, and 0.8 demonstrated high sensitivity to change. A *p*-value < 0.05 was considered as significant. All statistical analyses were performed using SPSS Statistical Software 17.0 (SPSS, Inc., Chicago, IL).

Results

The final version of the NOSE-s scale is displayed in Table 1. The mean time required to fulfill the questionnaire was 2.5 ± 0.5 min and 2.0 ± 0.5 min for the study group and the control group, respectively.

The internal consistency analysis demonstrated good reliability of the NOSE-s questionnaire at the level of Cronbach's alpha coefficient of 0.81. The mean time between test-retest administrations was 11.4 days (5–14 days). The obtained value of Goodman-Kruskal gamma coefficient of 0.83 (*p* < 0.001) suggested a good test-retest reliability. Test reproducibility was presented by standardized response mean of 0.18, which confirmed low sensitivity to change after retesting.

Average scores for each item obtained in both groups are shown in Table 2. All values (single items and the total score) were significantly higher in patients from the study group when compared to the control group (*p* < 0.001), which demonstrated excellent inter-group discrimination.

Table 1

The Serbian version of the Nasal Obstruction Symptom Evaluation (NOSE-s) scale

Over the past 1 month, how much of a problem were the following conditions for you? У последњих месец дана, колики проблем су Вам представљале следеће тегобе? Please circle the most correct response Молимо Вас да заокружите одговор који најбоље описује Ваше тегобе					
Symptom	Not a problem	Very mild problem	Moderate problem	Fairly bad problem	Severe problem
	Без тегоба	Веома благе тегобе	Средње изражене тегобе	Изражене тегобе	Веома изражене тегобе
1. Nasal congestion or stuffiness Осећај запушености носа	0	1	2	3	4
2. Nasal blockage or obstruction Осећај непроходности носа	0	1	2	3	4
3. Trouble breathing through my nose Отежано дисање кроз нос	0	1	2	3	4
4. Trouble sleeping Лош сан	0	1	2	3	4
5. Unable to get enough air through my nose during exercise or exertion Отежано дисање кроз нос приликом изражене физичке активности	0	1	2	3	4

Table 2

Comparison of item and total scores between groups (items presented as mean \pm standard deviation; range of patients' responses shown in parentheses)

Item	Study group mean \pm SD	Control group mean \pm SD	<i>p</i> -value	Skewness	Kurtosis
Nasal congestion	2.0 \pm 1.1 (0–4)	0.2 \pm 0.4 (0–2)	< 0.001	-0.176	-0.582
Nasal obstruction	1.8 \pm 1.1 (0–4)	0.1 \pm 0.4 (0–2)	< 0.001	-0.253	-0.607
Trouble breathing	1.6 \pm 1.2 (0–4)	0.1 \pm 0.1 (0–1)	< 0.001	0.026	-1.221
Trouble sleeping	0.9 \pm 1.1 (0–4)	0	< 0.001	1.207	0.884
Trouble breathing during exercise	2.5 \pm 1.3 (0–4)	0.2 \pm 0.5 (0–2)	< 0.001	-0.595	-0.717
Total raw score	8.9 \pm 4.4	0.6 \pm 0.8	< 0.001	–	–
Total score \times 5	44.3 \pm 22.3	2.9 \pm 3.9	< 0.001	–	–

SD – standard deviation.

Table 3

Inter-item and item-total correlations (Spearman's correlation coefficient)

Item	Nasal congestion	Nasal obstruction	Trouble breathing	Trouble sleeping	Trouble breathing during exercise
Nasal congestion					
Nasal obstruction	0.646				
Trouble breathing	0.368	0.611			
Trouble sleeping	0.170	0.310	0.466		
Trouble breathing during exercise	0.386	0.537	0.673	0.383	
Total score	0.653	0.776	0.852	0.571	0.811

Table 3 displays construct validity of the NOSE-s questionnaire assessed through inter-item and item-total correlation coefficients. The item “Nasal congestion or stuffiness” correlated significantly only with the item “Nasal blockage or obstruction” ($r = 0.646$). The item “Nasal blockage or obstruction” correlated significantly with all other items except with the “Trouble sleeping” ($r = 0.310$). Moreover, the item “Trouble breathing” was significantly associated with all but the first item (“Nasal congestion or stuffiness”) ($r = 0.368$). The fourth item (“Trouble sleeping”) correlated significantly with the “Trouble breathing” ($r = 0.466$) and not with other items. Finally, the item “Trouble breathing during exercise” was not significantly associated with items “Nasal congestion or stuffiness” ($r = 0.386$) and “Trouble sleeping” ($r = 0.383$). Additionally, each item correlated significantly with the total score.

Preoperative NOSE-s score of the patients that underwent septoplasty was 53.75 ± 16.8 . Three months after septoplasty, a mean NOSE-s score in patients was 19.2 ± 12.8 . Calculated standardized response mean of 1.7 showed high sensitivity to change.

Discussion

Development of an entirely new HRQoL instrument is a time consuming and expensive process. Instead, researchers often use previously validated and published instruments that are recognized as valuable tools for self-assessment of symptom severity. Achievement of the equivalence between the

original and the target version of the HRQoL instrument is an important and necessary step prior to application in a new population. This process requires translation, cross-cultural adaptation, and psychometric validation according to well-established principles^{20,22}. The entire process enables detection of the impact of a disease or patients' response to the applied therapy in a uniform way in each adopted version of the instrument. In addition, standardized questionnaires allow result comparison across studies. Moreover, thorough process of cultural adaptation enables inclusion of immigrant population in health studies, and omits a bias in quality of life studies²⁰.

The NOSE scale was developed and validated in order to assess quality of life in patients with nasal obstruction⁶. In general, the main point of the NOSE scale is to evaluate nasal obstruction in any disease¹⁴. This questionnaire has been validated in several countries up to date^{11–19}. Given that the number of patients involved in these studies usually ranged from 100 to 116^{11, 13, 15, 18, 19}, our sample size can be considered as optimal when compared with previous studies.

All patients enrolled in the current study completed the NOSE-s scale without any difficulty, showing that it was not burdensome for them. The psychometric properties of the NOSE-s instrument are consistent with the original questionnaire confirming high reliability and validity of the instrument. Internal consistency of the NOSE-s scale was similar to values reported in previous studies that ranged from 0.74 to 0.97^{6, 11–19}.

Among five nasal obstruction related symptoms that NOSE scale evaluate, only trouble sleeping was close to one

end of the Likert's scale (Table 2). This result could be explained by consecutive patient sampling used in our study. Patients who were diagnosed with the nasal septal deviation and referred to the CT examination during sampling period were included in the study regardless of the obstruction severity. The predominance of patients with no or very mild sleeping trouble contributed to the low mean value of the item. If the study group contained more patients with severe nasal obstruction and thus severe sleeping trouble, it would certainly shift the mean score of the item 4 to the greater values.

Considering a short period (5 to 14 days) during which test-retest was made, significant changes in a clinical status of patients were not expected. Given that underlying patient's status did not change during this period and the fact that scores of the scale remained constant, our results demonstrated that the NOSE-s instrument measured a true state of the patient health. Calculation of standardized response mean confirmed our expectations and showed low sensitivity to change, suggesting good stability and reproducibility of the NOSE-s scale.

The comparison between the study group and the control group showed very good inter-group discrimination. Patients with a nasal septal deviation had scores significantly higher than controls. This indicates that the NOSE-s scale is a sensitive to detect the presence or absence of the nasal obstruction, which is consistent with the original NOSE instrument⁶ and other validation studies¹¹⁻¹⁹. Construct validity of the NOSE-s questionnaire was also in accordance with the original version of the instrument⁶ as with other validation studies too^{14, 15, 18}. All items correlated significantly with each other and with the total score, except the "trouble sleeping" with the "nasal congestion or stuffiness" and the "nasal blockage or obstruction". Additionally, our results demonstrated that the NOSE-s scale is also sensitive to detect change in the health status in patients treated with septoplasty.

The Serbian version of the NOSE instrument is the first validated rhinological scale that could be used in clinical studies on Serbian speaking territory. Additionally, there are nearly 3 million Serbs living abroad (1.2 million in the United States of America and Canada, half million in Germany, 300,000 in Austria, 207,000 in Australia and New Zealand, 12,000 in France and Sweden each) and about half a million labor migrants from Serbia in the European Union²⁵. Given

that some of them are not fluent in the language of the country they are living in, this questionnaire also allows them to be involved in clinical studies.

Although validity and reliability of the Serbian version of the NOSE scale was in accordance with the original NOSE scale, the lack of criterion validity testing could potentially limit our study. Another limitation refers to lack of multi trait multi method matrix approach. Questionnaires in our study were self-administrated in order to omit interviewer related bias and provide honest answers, as suggested in the literature^{26,27}. Since second turn testing by investigator was not performed, multi trait multi method matrix could not be made.

Conclusion

The equivalence between Serbian version and the original version of the NOSE scale was provided. Serbian speaking population gained culturally adapted and validated, feasible and intelligible questionnaire that is user-friendly both for patients and for health professionals. Patients found it understandable and not burdensome, while doctors considered it an important source of information with handy statistical data processing. An opportunity to use the already developed and validated NOSE-s instrument is created, which allows this important and frequently used HRQoL instrument to be applied in clinical practice and research. Additionally, the application of the NOSE-s scale would also enable comparison with the results obtained in studies conducted in other speaking areas and cultures.

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