CROSS-CULTURAL ADAPTATION AND VALIDATION OF NASAL OBSTRUCTION SYMPTOM EVALUATION QUESTIONNAIRE IN SLOVENIAN LANGUAGE

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ABSTRACT

Objectives. Nasal obstruction is highly subjective perception with numerous efforts being made towards objective measuring. Many instruments in quality of life studies encompass subjective symptom of nasal obstruction, but only NOSE has been properly validated and is easy to use in every day practice.

Methods. Multicenter prospective instrument validation and cross-cultural adaptation cohort study was conducted on patients with deviated nasal septum, with or without inferior turbinate hypertrophy, to develop the Slovenian version of NOSE questionnaire. A cross-cultural adaptation of the original questionnaire was done in five steps, producing Slovenian NOSE-si, used on a pilot group to confirm the quality of adapted tools and, afterwards, on the main study and control group. Symptoms were lasting for more than 12 months and all had an indication for septal surgery. A control group was selected from a pool of healthy subjects, self-assessed as having no rhinological complaints.

Results. NOSE-si was used on 116 patients (58 from the study group vs. 58 from the control group). High degree of internal consistency - Cronbach’s α 0.971 and reliability after retesting - Goodman-Kruskal gamma coefficient 0.984 was proven. Responsiveness was confirmed in the surgery subgroup with standardized response mean (SRM) 2.76 (p<0.001).

Conclusions. The study produced a valid Slovenian version of NOSE questionnaire through rigorous and well defined five-phase effort to maintain scientifically comparable QoL instrument, and may be used by clinicians and researchers.

IZVLEČEK

Ključne besede: nosna obstrukcija, kakovost življenja, medkulturna prilagoditev vprašalnikov

Uvod. Zamašenost nosu je pogost simptom pri boleznih nosu in obnosnih votlin. Veliko poskusov objektivizacije zamašenosti nosu ni prineslo zadovoljivih rezultatov. Obstaja več vprašalnikov o kakovosti življenja, ki zajemajo tudi zamašenost nosu. Vprašalnik NOSE je validiran, torej globalko primerljiv, zanesljiv in odziven ter dovolj enostaven za vsakodnevno uporabo.

Metode. Študija je multcentrni preiskovalni instrument validation and cross-cultural adaptation cohort study, which was conducted on patients with deviated nasal septum, with or without inferior turbinate hypertrophy, to develop the Slovenian version of NOSE questionnaire. A cross-cultural adaptation of the original questionnaire was done in five steps, producing Slovenian NOSE-si, used on a pilot group to confirm the quality of adapted tools and, afterwards, on the main study and control group. Symptoms were lasting for more than 12 months and all had an indication for septal surgery. A control group was selected from a pool of healthy subjects, self-assessed as having no rhinological complaints.

Rezultati. NOSE-si je izpolnilo 116 bolnikov (58 v študijski skupini in 58 v kontrolni skupini). Dokazali smo visoko stopnjo notranje skladnosti - Cronbach’s α 0.971 in zanesljivost po retestiranju - Goodman-Kruskal gamma koeficient 0.984. Odzivnost smo dokazali na kirurški skupini bolnikov, 12 mesecov. Posamezniki brez subjektivnih težav z zamašenostjo nosu so sestavljali kontrolno skupino.

Zaključki. Študija smo z jasno definiranimi metodske postopki uspešno prilagodili in potrdili vprašalnik NOSE-si. Vprašalnik je na voljo uporabi v kliničnem in raziskovalnem delu.

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1 INTRODUCTION

Blocked nose or nasal obstruction is a frequently encountered nasal symptom (1). Nasal obstruction is defined as a discomfort, manifested as a feeling of insufficient airflow through the nose (2). The prevalence of nasal obstruction has been estimated at 26.2% (3). It is often a complex clinical problem, involving mucosal, structural, and even psychological factors. The perception itself is subjective, with many efforts being made towards objective measuring (4). Etiology of nasal obstruction can vary, from deviation of the nasal septum, turbinate hypertrophy, adenoid hypertrophy to mucosal congestion or nasal masses (5). To evaluate the effectiveness of surgical treatment or change in quality of life (QoL), an instrument called Nasal Obstruction Symptom Evaluation (NOSE) was developed and validated (6). NOSE questionnaire is not the only QoL instrument used by researchers in rhinology. Some of them are not fulfilling the definition of health-related quality of life instrument (HRQL), as Chronic Sinusitis Survey (CSS) or even Sinonasal Outcome Score 22 (SNOT-22). Some instruments do not evaluate only nasal obstruction, like Allergy Outcome Score (AOS) (7). Subjective symptoms like nasal obstruction remain important in quantifying an aspect of disease not detected by objective testing, and are representing real burden for the patient (8). Standardized questionnaires allow researchers to produce comparable data from disease specific QoL studies (9). Nevertheless, true equivalence between the original and adapted questionnaires can be achieved only through cross-cultural adaptation (CCA). CCA is a delicate process, but it is faster than creating a new questionnaire, and is assumed to produce an equivalent instrument (10). The process of CCA must be rigorous enough and should involve well-defined steps with the initial translation, synthesis, back translation, expert committee review and pretesting (10-12). The aim of our study was to create a Slovenian Nasal Obstruction Symptom Evaluation (NOSE-si) with a high degree of equivalence with the original NOSE questionnaire, using the proposed strategy (12).

The original English instrument was not designed to be used on an individual patient or predict the outcome of intervention, but it can evaluate nasal obstruction in any disease, not only in rhinitis or rhinosinusitis (7).

2 METHODS

2.1 Study Design

A multicenter prospective instrument validation and CCA cohort study were conducted according to published methods and guidelines (6, 11, 13), in four phases (Table 1). The first phase started on 1st December, 2014. Patients meeting the inclusion criteria (nasal obstruction due to deviated nasal septum, with or without inferior turbinate hypertrophy, with symptoms lasting more than 12 months and indication for septal surgery) were enrolled consecutively at University Clinical Centre Ljubljana - the Department of Otorhinolaryngology, General Hospital Novo mesto - Ear, Nose and Throat Department (ENT), General Hospital Celje - ENT Department, Community Health Centre Maribor - ENT Outpatient Clinic. The enrollment ended on 1st June, 2015.

Exclusion criteria were: a) a prior surgery in the nose or paranasal sinuses; b) allergic rhinitis; c) pregnancy; d) hyperplastic rhinitis as a single entity; e) chronic rhinosinusitis according to EPOS guidelines (14); f) age less than 18; g) perforation of the nasal septum; h) craniofacial syndromes or tumors of the nose or paranasal sinuses; i) sarcoidosis or granulomatosis of the nose; j) bronchial asthma, adenoid hypertrophy; k) recent trauma of the nose - up until 2 years from the event; l) being unable to communicate in or understand Slovenian language.

A control group was selected from a pool of healthy subjects, self-assessed as having no rhinological complaints. All patients agreed and signed a written consent form.

Table 1. Cross-cultural adaptation (phases and steps leading to adapted and validated QoL tool).

| Phase I | Cross-cultural adaptation of the original NOSE questionnaire in five steps, according to emerging guidelines (7, 15). |
|---------|------------------------------------------------------------------------------------------------------------------|
| Step I  | Two experts in rhinology blinded one to another translated the original NOSE questionnaire. |
| Step II | A third expert reviewed both translations and created a new version. |
| Step III| A fourth expert reviewed it, blinded to both initial versions. |
| Step IV | The latest version was sent to a translator with no medical background to form and backtranslate. |
| Step V  | A board of experts (3 rhinologists, 1 audiologist, 3 general ENT consultants, 1 family medicine practitioner, 1 ENT specialist in training, 1 non-medical translation consultant) reviewed results and synthesized the final version of NOSE-si. It was proofread, and the final report was created. |

Phase II The pilot phase consisted of submitting NOSE-si to a limited number (n=33) of patients in the study group and control group. Patient and expert comments with results were reevaluated by an expert committee and a preliminary statistical analysis was done to compare the pilot version of NOSE-si to the original tool and other CCA processed NOSE questionnaires (13, 16).

Since high degree of internal consistency reliability was found, the expert committee accepted NOSE-si as the final version.
Phase III Both the study and control group were enrolled. Retesting was scheduled 7-14 days after the initial testing for the study group and controls (90 patients). Patients had to fill out the same questionnaire and send it back to the researchers.

Phase IV The postintervention test in the study group (90 days after surgery - submucosal resection of nasal septum).

A group of patients fulfilling the outpatient follow up date by the end of the study was selected for the postintervention test (Table 1) as phase IV. All patients had septoplasty in local or general anesthesia as indicated primarily by each involved author. Details of surgery were not recorded as this was not the goal of the study. Authors were encouraged not to change their standard diagnostic or operative technique, but they were not blinded to the preinterventional score.

2.2 The Questionnaire
The NOSE questionnaire is structurally composed of five items, namely: 1) nasal congestion or stuffiness; 2) nasal blockage or obstruction; 3) trouble breathing through my nose; 4) trouble sleeping; 5) unable to get enough air through my nose during exercise or exertion (6). All items are scored using the 5-point Likert scale with the range from 0 to 4 (Table 2). Results are scaled to the total range from 0 (no nasal obstruction) to 100 (the most severe nasal obstruction) by multiplying the row score by 5.

Table 2. NOSE (the original questionnaire).

| Item                                      | Not a problem | Very mild problem | Moderate problem | Fairly bad problem | Severe problem |
|-------------------------------------------|---------------|-------------------|------------------|-------------------|---------------|
| Nasal congestion or stuffiness            | 0             | 1                 | 2                | 3                 | 4             |
| Nasal blockage or obstruction             | 0             | 1                 | 2                | 3                 | 4             |
| Trouble breathing through my nose         | 0             | 1                 | 2                | 3                 | 4             |
| Trouble sleeping                          | 0             | 1                 | 2                | 3                 | 4             |
| Unable to get enough air through my nose  | 0             | 1                 | 2                | 3                 | 4             |

2.3 Statistics
Cronbach’s α with inter-item and item-total correlation was used to estimate internal consistency reliability. Cronbach’s α 0.70 or higher was considered as acceptable internal consistency reliability (6). Content validity was confirmed during each CCA step. An expert review, harmonization, cognitive debriefing and a review of patients’ comments were done according to the study design. Mann-Whitney U test was used to confirm construct discriminant validity by comparing group discrimination (p<0.05).

Cohen’s d test was used to confirm convergent validity. The values of 0.2, 0.5, 0.8 represent low, moderate and high sensitivity, respectively. Standardized response mean (SRM) and effect size (ES) were used to assess sensitivity in the study group 90 days after intervention (surgery). Responsiveness was confirmed with standardized response mean in addition to previous Cronbach’s α (17). Test-retest reliability was assessed with Goodman Kruskal gamma.

Data analysis was carried out using the SPSS version 22 statistical software (SPSS Inc, Chicago, IL). Computation of effect sizes, SRM and Cohen’s d was done online (18, 19).

3 RESULTS
The study consisted of 116 patients with detailed data in Table 3.

Table 3. Clinical characteristics of study patients.

|                        | Study group (with complaints) (n=58) | Control group (no complaints) (n=58) | P value (study vs. control) |
|------------------------|-------------------------------------|-------------------------------------|-----------------------------|
| Sex                    | Male (25.7%)                        | Female (53.4%)                     | 0.004‡                      |
|                        | 15 (25.7%)                          | 27 (46.6%)                         |                             |
|                        | Female (74.3%)                      | 31 (53.4%)                         |                             |
| Age (y)                | 37.8 (± 13.92)                      | 40.1 (± 14.43)                     | 0.452*                      |
|                        | 25.21 (± 4.19)                      | 22.85 (± 3.86)                     | 0.003*                      |
| Body mass index (BMI)  | 25.21 (± 4.19)                      | 22.85 (± 3.86)                     |                             |
| Smokers                | 16 (27.6%)                          | 14 (24.1%)                         | 0.832‡                      |
| Mean NOSE-si score    | 70.52 (± 15.46)                     | 3.97 (± 5.9)                       | <0.001**                    |

* Independent samples Mann Whitney U test, ‡ Fisher’s Exact test, ***T-test
The internal consistency of NOSE-si was excellent with Cronbach’s α 0.971. Inter-item and item-total correlations are reported in Table 4. All items had a significant correlation with each other, thus confirming the instrument as a single unified construct. Above all, all individual items are measuring the exact same concept (r>0.800).

The study group had the mean rank of 87.50, and the control group had the mean rank of 29.50 (Mann Whitney U-test p<0.001). Cohen’s d test as effect size estimate was 5.73 (CI 0.95, 1.75-7.25) confirming the needed large discrimination between study groups and controls with a nearly perfect effect score.
et al. (6). The study design can explain the differences between groups when comparing basic demographic data, such as sex or BMI to some extent. Otherwise, these factors are not affecting the main goal of our study - the validation of QoL tool, with NOSE-si score comparison in distinct groups (Table 3). It should be emphasized that the study group may not represent the entire population of patients with nasal obstruction, as consecutive sampling was used. The study design (multicentric, referral centers) should broaden the base for sampling. We observed comparable scoring of the new instrument NOSE-si and published normative and symptomatic ranges (24). Our inclusion criteria were strict, all patients from study group fulfilled the criteria for a surgical intervention, as this is traditionally the main target group for the instrument (25). Having used broader criteria, the discrimination between groups would be less pronounced; but on the other hand, the study design would be less adherent to the original validation studies. The sample size for responsiveness is less than the declared minimum of 25. Given the rather vast statistical significance of the results, they may not be compromised. We were also unable to fully blind the surgeon to the preinterventional NOSE-si score, which could ideally influence the postinterventional score by following a more aggressive, still standard surgical technique (26). On the other hand, the NOSE score itself can be influenced by many other objective and subjective factors (27). We were trying to eliminate most of them by using the same simple and standard diagnostic and treatment protocols across the study. For the same reason, we opted not to use any additional objective measures, as they are not routinely used in participating centers.

5 CONCLUSIONS

The study produced a valid Slovenian version of NOSE questionnaire through rigorous and well-defined five-phase effort to maintain a scientifically comparable QoL instrument. It represents a proven excellent basic tool and may be used by clinicians and researchers as a reliable score of nasal patency related patient-reported quality of life measure.

6 LIMITATIONS OF THE STUDY

Our study had no limitations other than discussed in section 4.

CONFLICTS OF INTEREST

The authors declare that no conflicts of interest exist.
**ETHICAL APPROVAL**

Research has been performed in accordance with the Declaration of Helsinki. The study was approved by the Republic of Slovenia National Medical Ethic Committee by document number 114/04/14 dated 21th of April 2015.

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