10.1515/sjph-2017-0003 Zdr Varst 2017; 56(1): 18-23

Urbančič J, Soklič Košak T, Jenko K, Božanić Urbančič N, Hudoklin P, Delakorda M, Juvanec A, Zupančič Urbančič K, Vadnjal J, Gluvajić D.
Cross-cultural adaptation and validation of nasal obstruction symptom evaluation questionnaire in Slovenian language. Zdr Varst 2017; 56(1): 18-23

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

MEDKULTURNA PRILAGODITEV IN VALIDACIJA VPRAŠALNIKA NOSE O OCENI ZAMAŠENOSTI NOSU V SLOVENŠČINI

Jure URBANČIČ[1*], Tanja SOKLIČ KOŠAK[1], Klemen JENKO[1], Nina BOŽANIĆ URBANČIČ[1], Peter HUDOKLIN[2], Matej DELAKORDA[3], Ajda JUVANEC[4], Katarina ZUPANČIČ URBANČIČ[5], Jana VADNJAL[6], Daša GLUVAJIĆ[1]

[1]University Medical Centre Ljubljana, Department of Otorhinolaryngology and Cervicofacial Surgery, Zaloška 2, 1000 Ljubljana, Slovenia
[2]Novo mesto General Hospital, Department of Otorhinolaryngology, Šmihelska cesta 1, 8000 Novo mesto, Slovenia
[3]Celje General Hospital, Department of Otorhinolaryngology, Oblakova 5, 3000 Celje, Slovenia
[4]Community Health Centre dr. Adolfa Drolca Maribor, Ulica talcev 9, 2000 Maribor, Slovenia
[5]Kemofarmacija d.d., Cesta na Brdo 100, 1000 Ljubljana, Slovenia
[6]Zavod Zdravje d.o.o, Ulica padlih borcev 22, 6258 Prestranek, Slovenia

Received: Dec 16, 2015
Accepted: May 26, 2016

Original scientific article

ABSTRACT

Keywords:
nasal obstruction, quality of life instruments, cross-cultural adaptation of questionnaires

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, vprašalniki o kakovosti 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 kvaliteti življenja, ki zajemajo tudi zamašenost nosu. Vprašalnik NOSE je validiran, torej globalno primerljiv, zanesljiv in odziven ter dovolj enostaven za vsakodnevno uporabo.*

***Metode**. Študija je multicentrična, prospektivna, validacijska, kohortna, z medkulturno prilagoditvijo vprašalnika o kakovosti življenja. S petstopenjsko medkulturno adaptacijo je nastala slovenska različica vprašalnika - NOSE-si. Validacijo smo opravili pri bolnikih z deviacijo nosnega pretina s hipertrofičnimi spodnjimi nosnimi školjkami ali brez njih, z indikacijo za operacijo nosnega pretina in simptomi, daljšimi od 12 mesecev. Posamezniki brez subjektivnih težav z zamašenostjo nosu so sestavljali kontrolno skupino.*

***Rezultati**. NOSE-si je izpolnilo 116 bolnikov (58 v študijski skupini in 58 v kontrolni skupini). Dokazali smo visoko stopnjo notranje skladnosti s Cronbachovim koeficientom a 0,971. Zanesljivost pri ponovnem testiranju smo dokazali z Goodman-Kruskal gama koeficientom 0,984. Odzivnost smo dokazali na kirurški skupini bolnikov pred intervencijo in po njej s standardno mediano odziva 2,76 ($p<0,001$).*

***Zaključki**. V študiji smo z jasno definiranim petstopenjskim postopkom uspešno prilagodili in potrdili vprašalnik NOSE-si. Vprašalnik je na voljo uporabi v kliničnem in raziskovalnem delu.*

***Corresponding author:** Tel: ++ 386 41 726 079; E-mail: jure.urbancic@kclj.si

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 it 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).

	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 during exercise or exertion	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	15 (25.7%)	27 (46.6%)	
Female	43 (74.3%)	31 (53.4%)	0.004‡
Age (y)	37.8 (± 13.92)	40.1 (± 14.43)	0.452*
Body mass index (BMI)	25.21 (± 4.19)	22.85 (± 3.86)	0.003*
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).

Table 4. NOSE-si correlation (inter-item and item-total correlation; original NOSE field names are used).

Inter-Item Correlation Matrix					
	Nasal congestion or stuffiness	**Nasal blockage or obstruction**	**Trouble breathing through my nose**	**Trouble sleeping**	**Unable to get enough air through my nose during exercise or exertion**
Nasal congestion or stuffiness	1.000	0.916	0.899	0.822	0.881
Nasal blockage or obstruction	0.916	1.000	0.909	0.844	0.887
Trouble breathing through my nose	0.899	0.909	1.000	0.851	0.875
Trouble sleeping	0.822	0.844	0.851	1.000	0.800
Unable to get enough air through my nose during exercise or exertion	0.881	0.887	0.875	0.800	1.000

Item-Total Statistics					
	Scale Mean if Item Deleted	**Scale Variance if Item Deleted**	**Corrected Item-Total Correlation**	**Squared Multiple Correlation**	**Cronbach's Alpha if Item Deleted**
Nasal congestion or stuffiness	6.02	32.208	0.929	0.875	0.961
Nasal blockage or obstruction	5.91	32.027	0.942	0.892	0.959
Trouble breathing through my nose	5.92	31.933	0.934	0.875	0.960
Trouble sleeping	6.09	32.800	0.864	0.755	0.971 0.965
Unable to get enough air through my nose during exercise or exertion	5.84	32.567	0.905	0.828	

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.

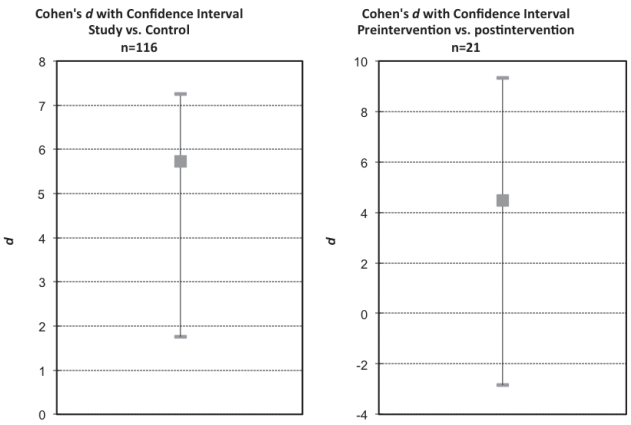

Figure 1. Effect size estimate (the left side showing large discrimination, the right side showing efficacy of intervention).

Responsiveness of the NOSE-si was confirmed on a group of patients with surgical intervention (n=21), comparing pretreatment NOSE-si score to postreatment NOSE-si score. Standardized response mean (SRM) was 2.76 ($p<0.001$) and is considered very large. As is efficacy of intervention, with effect size estimate (Cohen's d) of 4.58 (CI 0.95, -2.74-9.34), as seen in Figure 1.

The reproducibility of the questionnaire was confirmed with retesting, and compared to the baseline score (the initial/preintervention NOSE-si score in controls/study group, cumulative n=90, Table 1.), using Goodman-Kruskal gamma coefficient 0.984 ($p<0.001$), proving excellent reliability.

4 DISCUSSION

The subjective assessment of nasal obstruction requires validated survey instruments. In case when a linguistically native instrument is not available, the full process of CCA should be performed to acquire valid QoL questionnaires and scientifically comparable results. The process itself is a multistage effort to maintain comparable contents. The NOSE-si instrument was developed according to principles of good practice (15) and emerging guidelines (11). Internal consistence reliability, test-retest reliability, psychometric properties, validity and response sensitivity were very high. There is no sample size or power calculation for psychometric evaluation (6), and the general rule of thumb with 25 to 50 patients is considered adequate, therefore we opted for multicentric setup and higher sample size. Our study had one of the largest sample sizes found in literature (20–23). Our validation results were comparable with English-language validation by Stewart 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.

FUNDING

The study had no financial support.

REFERENCES

1. Jessen M, Malm L. The spontaneous course of nasal obstruction in patients with normal nasal airway resistance. Clin Otolaryngol 1991; 16: 302–4.
2. Eccles R, Jones AS. The effect of menthol on nasal resistance to air flow. J Laryngol Otol 1983; 97: 705–9.
3. Jessen M, Malm L. Definition, prevalence and development of nasal obstruction. Allergy 1997; 52: 3–6.
4. André RF, Vuyk HD, Ahmed A., Graamans K, Nolst Trenité GJ. Correlation between subjective and objective evaluation of the nasal airway: a systematic review of the highest level of evidence. Clin Otolaryngol 2009; 34: 518–25.
5. Kimelman P. The problem of nasal obstruction. Otolaryngol Clin North Am 1989; 22: 253–64.
6. Stewart MG, Witsell DL, Smith TL, Weaver EM, Yueh B, Hannley MT. Development and validation of the Nasal Obstruction Symptom Evaluation (NOSE) Scale. Otolaryngol Head Neck Surg 2004; 130: 157–63.
7. Van Oene CM, Van Reij EJF, Sprangers MG, Fokkens WJ. Quality-assessment of disease-specific quality of life questionnaires for rhinitis and rhinosinusitis: a systematic review. Allergy Eur J Allergy Clin Immunol 2007; 62: 1359–71.
8. Stewart MG, Smith TL. Objective versus subjective outcomes assessment in rhinology. Am J Rhinol 2005; 19: 529–37.
9. Hellings PW, Scadding G, Alobid I, Bachert C, Fokkens WJ, Gerth van Wijk R, et al. Executive summary of European Task Force document on diagnostic tools in rhinology. Rhinology 2012; 50: 339–52.
10. Epstein J, Santo RM, Guillemin F. A review of guidelines for cross-cultural adaptation of questionnaires could not bring out a consensus. J Clin Epidemiol 2014; 68: 435–41.
11. Epstein J, Osborne RH, Elsworth GR, Beaton DE, Guillemin F. Cross-cultural adaptation of the Health Education Impact Questionnaire: experimental study showed expert committee, not back-translation, added value. J Clin Epidemiol 2015; 68: 360–9.
12. Epstein J, Santo RM, Guillemin F. A review of guidelines for cross-cultural adaptation of questionnaires could not bring out a consensus. J Clin Epidemiol 2015; 68: 435–41.
13. Bezerra TFP, Padua FGM, Pilan RRM, Stewart MG, Voegels RL. Cross-cultural adaptation and validation of a quality of life questionnaire: the Nasal Obstruction Symptom Evaluation questionnaire. Rhinology 2011; 49: 227–31.
14. Lund VJ. Nasal polyps surgery versus medical management: European position paper on rhinosinusitis and nasal polyposis. Rhinology 2012; 50(Suppl 23): 1–298.
15. Wild D, Grove A, Martin M, Eremenco S, McElroy S, Verjee-Lorenz A, et al. Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) measures: report of the ISPOR Task Force for Translation and Cultural Adaptation. Value Heal 2005; 8: 94–104.
16. Lachanas VA, Tsiouvaka S, Tsea M, Hajiioannou JK, Skoulakis CE. Validation of the Nasal Obstruction Symptom Evaluation (NOSE) scale for Greek patients. Otolaryngol Head Neck Surg 2014; 151: 819-23.
17. Puhan M a, Bryant D, Guyatt GH, Heels-Ansdell D, Schünemann HJ. Internal consistency reliability is a poor predictor of responsiveness. Health Qual Life Outcomes 2005; 3: 33.
18. Lenhard W, Lenhard A. Calculation of effect sizes. Psychometrica. Available 1st January, 2014 from: http://www.psychometrica.de/effect_size.html.
19. Neill J. Psychology. Meta-Analysis. Research Metodology. Cohen's d v1.3. Available 22nd April, 2010 from: http://www.wilderdom.com/301/Cohensd.xls.
20. Marro M, Mondina M, Stoll D, de Gabory L. French validation of the NOSE and RhinoQOL questionnaires in the management of nasal obstruction. Otolaryngol Head Neck Surg 2011; 144: 988–93.
21. Mozzanica F, Urbani E, Atac M, Scottà G, Luciano K, Bulgheroni C, et al. Reliability and validity of the Italian nose obstruction symptom evaluation (I-NOSE) scale. Eur Arch Otorhinolaryngol 2013; 270: 3087-94.
22. Larrosa F, Roura J, Dura MJ, Guirao M, Alberti A, Alobid I. Adaptation and validation of the Spanish version of the Nasal Obstruction Symptom Evaluation (NOSE) Scale. Rhinology 2015; 53: 176–80.
23. Dong D, Zhao Y, Stewart MG, Sun L, Cheng H, Wang J, et al. Development of the Chinese nasal obstruction symptom evaluation (NOSE) questionnaire. Chin J Otorhinolaryngol Head Neck Surg 2014; 49: 20–6.
24. Rhee JS, Sullivan CD, Frank DO, Kimbell SJ, Garcia GJM. A systematic review of patient reported nasal obstruction scores: defining normative and symptomatic ranges in surgical patients. JAMA Facial Plast Surg 2014; 16: 219–32.
25. Mondina M, Marro M, Maurice S, Stoll D, De Gabory L. Assessment of nasal septoplasty using NOSE and RhinoQoL questionnaires. Eur Arch Otorhinolaryngol 2012; 269: 2189–95.
26. Wilson MA, Mobley SR. Extracorporeal septoplasty. Am Med Assoc 2013; 13: 85–90.
27. Manestar D, Braut T, Kujundžić M, Malvić G, Velepič M, Donadić Manestar I, et al. The effects of disclosure of sequential rhinomanometry scores on post-septoplasty subjective scores of nasal obstruction: a randomised controlled trial. Clin Otolaryngol 2012; 37: 176–80.