

SLOVENIAN CROSS-CULTURAL ADAPTATION AND VALIDATION OF HEALTH-RELATED QUALITY OF LIFE MEASURES FOR CHRONIC OTITIS MEDIA (COMQ-12), VERTIGO (DHI, NVI) AND TINNITUS (THI)

MEDKULTURNA PRILAGODITEV IN POTRDITEV SLOVENSКИH RAZLIČIC VPRAŠALNIKOV ZA OCENO KRONIČNEGA VNETHA SREDNJEGA UŠESA (COMQ-12), VRTOGLAVICE (DHI, NVI) IN TINNITUSA (THI)

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Received: Jan 20, 2020

Accepted: Apr 2, 2020

Original scientific article

ABSTRACT

Keywords:

quality of life, surveys and questionnaires, tinnitus, vertigo, otitis media, dizziness

Purpose: To provide physicians and patients with the tools needed to evaluate patients' problems and health-related quality of life by cross-culturally adapting and validating the Chronic Otitis Media Questionnaire 12 (COMQ-12), the Dizziness Handicap Inventory (DHI), the Neuropsychological Vertigo Inventory (NVI) and the Tinnitus Handicap Inventory (THI).

Materials and methods: COMQ-12, DHI, NVI and THI were translated into the Slovenian language and completed by patients treated at our department for chronic otitis media, vertigo or tinnitus. The control group for each questionnaire consisted of healthy volunteers. Internal consistency, test-retest reliability, discriminant validity, diagnostic accuracy and cut-off value were determined for each questionnaire.

Results: Test-retest reliability was excellent for DHI (ICC A=0.946) and NVI (p=0.315, ICC A=0.975), good to excellent for COMQ-12 (p=0.680, ICC A=0.858) and satisfactory for THI (p=0.120). Discriminant validity was confirmed for each questionnaire (p>0.05) using the Mann-Whitney U test (COMQ-12, DHI, THI) or the Welch t-test (NVI). COMQ-12 had acceptable (α=0.796) and DHI (α=0.910), NVI (α=0.950) and THI (α=0.924) perfect internal consistency. COMQ-12 and DHI had excellent, NVI acceptable and THI perfect diagnostic accuracy (AUC=0.987, AUC=0.999, AUC=0.781 and AUC=1.000 respectively). Cut-off values determined by Youden's index were 7, 7, 9 and 56 for COMQ-12, THI, DHI and NVI, respectively.

Conclusion: Slovenian COMQ-12, DHI, NVI and THI are a valid and accurate tool for the diagnosis and measurement of health-related quality of life in patients with chronic otitis media, vertigo and tinnitus. They could aid general practitioners, occupational health specialists, neurologists and otorhinolaryngologists.

IZVLEČEK

Ključne besede:

kakovost življenja, ankete in vprašalniki, tinitus, vrtočlavica, vnetje srednjega ušesa, nestabilnost

Namen: Orodja za oceno težav bolnikov s kroničnimi vnetji srednjega ušesa, težav z ravnotežjem in tinitusom ter vpliv slednjih na kakovost življenja v slovenščini ne obstajajo. S projektom smo jih želeli zagotoviti zdravnikom in bolnikom s temi težavami. Vrzel bi zapolnili z medkulturno prilagoditvijo in potrditvijo vprašalnika o kroničnem vnetju srednjega ušesa (COMQ-12), vrtočlavici (DHI), nevropsiholoških vplivih vrtočlavice (NVI) in o obremenjenosti zaradi tinitusa (THI).

Metode: Vprašalniki so bili prevedeni iz angleščine v slovenščino skladno s priporočili. COMQ-12 so izpolnili bolniki s kroničnim vnetjem srednjega ušesa, DHI in NVI z vrtočlavico in THI s tinitusom. Kontrolno skupino za vsak vprašalnik so sestavljali zdravi prostovoljci. Vsakemu vprašalniku je bila določena stopnja notranje skladnosti, zanesljivost pri ponovnem testiranju, diskriminantna validnost, diagnostična natančnost in mejna vrednost.

Rezultati: Zanesljivost pri ponovnem testiranju je bila odlična za DHI (ICCA = 0,946) in NVI (p = 0,315, ICCA = 0,975), dobra do odlična za COMQ-12 (p = 0,680, ICCA = 0,858) in zadovoljiva za THI (p = 0,120). Diskriminantna validnost je bila potrjena (p > 0,05) za vsak vprašalnik bodisi z uporabo testa Mann-Whitney U (COMQ-12, DHI, THI) bodisi z Welchovim t-testom (NVI). COMQ-12 je imel sprejemljivo (α = 796), DHI (α = 0,910), NVI (α = 0,950) in THI (α = 0,924) pa popolno notranjo skladnost. COMQ-12 in DHI sta imela odlično (0,987 in 0,999), NVI sprejemljivo (0,781) in THI popolno (1,000) diagnostično natančnost glede na vrednost površine pod krivuljo ROC. Mejne vrednosti so bile določene objektivno z Youdonovim indeksom (J) in so znašale 7 za COMQ-12 (J = 0,90) in THI (J = 1,00), 9 za DHI (J = 0,95) in 56 za NVI (J = 0,43).

Zaključek: Slovenske različice vprašalnikov COMQ-12, DHI, NVI in THI so medkulturno prilagojene, potrjene in uporabne kot pomembna merila za oceno z zdravjem povezane kakovosti življenja. Hkrati so tudi natančen diagnostični pripomoček pri bolnikih s kroničnim vnetjem srednjega ušesa, vrtočlavico ali tinitusom, ki bo v pomoč zdravnikom specialistom družinske medicine, specialistom medicine dela, prometa in športa, nevrologom ter otorinolaringologom.

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1 INTRODUCTION

Patient-reported health-related quality-of-life (HRQoL) questionnaires are an indispensable tool for general practitioners, occupational health specialists and physicians of other medical specialisations when approaching a variety of medical conditions. They provide subjective information about the patient's health status, and complement the objective findings of clinical examination or diagnostic procedures (1-3). They also play an important role in assessing treatment efficacy in many otorhinolaryngologic diseases (4).

Chronic otitis media (COM), dizziness and tinnitus are common diseases and symptoms that can have a great impact on HRQoL. Different questionnaires are therefore available in various languages to assess it. Moreover, as there is a common overlap of COM, dizziness and tinnitus-associated complaints in a single patient, it is appropriate to provide multiple questionnaires to assess these complaints. COMQ-12, DHI, NVI and THI are useful questionnaires to determine physical, cognitive, socio-economic and emotional neuropsychological influences of the disease on HRQoL (5-8).

When modifying a questionnaire from an original to the desired target language, a thorough process of cross-cultural adaptation and validation is required, rather than a simple translation (9). It appears that this process may present a certain obstacle as, to the best of our knowledge, no such questionnaires for patients with COM, dizziness and tinnitus have yet been produced in the Slovenian language.

There is therefore a desire to provide such questionnaires to physicians dealing with patients with COM, dizziness and tinnitus in Slovenia. For that reason, the purpose of our study was to cross-culturally adapt and validate Chronic Otitis Media Questionnaire 12 (COMQ-12), the Dizziness Handicap Inventory (DHI), the Neuropsychological Vertigo Inventory (NVI) and the Tinnitus Handicap Inventory (THI) into the Slovenian language for the first time. Furthermore, Slovenian versions of COMQ-12, DHI, NVI and THI would contribute to a further comparison of populations divided by culture or language.

1.1 Chronic Otitis Media

COM can be defined as at least three months of persistent middle ear inflammation with an associated permanent tympanic membrane defect. While inconsistent definitions of COM make the analysis of epidemiological data difficult, assessments of the burden presented by otitis media have been made. It is a leading reason why patients visit a doctor and are prescribed medication, and it places the brunt of the burden on developing countries (10). In some countries, the cost of treating ear infections is higher than the minimum monthly wage (11). The population of

developed industrialised countries, including Slovenia, is the least at risk (10). COM causes disabling hearing loss, impedes speech development and involvement in education, and makes it more difficult to find and retain employment in jobs that require high levels of qualification (12). Additionally, patients with COM are affected by ear discharge, ear discomfort, balance disorders, tinnitus and mental disorders, all of which lead to poorer quality of life and higher levels of absenteeism (13, 14). HRQoL patient-reported questionnaires are therefore an important adjunct to the management of patients with COM (5).

1.2 COMQ-12

At least five patient-reported HRQoL questionnaires are available to assess the quality of life of COM patients. COMQ-12, and ZCMEI-21 are upgrades of CES, COMOT-15, COM-5. COMQ-12 is shorter than ZCMEI-21 (14, 15). Chronic Otitis Media Questionnaire 12 (COMQ-12) contains 12 questions: seven related to the severity of symptoms, two to the impact of the disease on lifestyle, two to the impact on healthcare and one general question. Each answer is given a score of 0-5 points (14). A total score is also determined for persons without COM. Additionally, if the total score is ≤ 5 , surgical treatment should be reconsidered (16). The original English version has so far been translated into Turkish (5), Portuguese (17), Indian (18), Serbian (19) and Dutch (20, 21), etc.

1.3 Vertigo

Vertigo is defined as the perception of rotation or movement of an individual or objects in space. Patients often confuse it with symptoms of dizziness or visual or balance disturbance (7). In addition to the normal functioning of the vestibular apparatus, normal balance requires good vision and proprioception and good functioning of the central nervous system, which is where the integration of signals from these systems takes place. Damage to any of these structures can cause vertigo. Dizziness, impaired balance, vision, emotions, memory and self-perception may be associated with vertigo depending on the location of the dysfunction of the vestibular system. Understandably, patients often experience vertigo, dizziness and unsteadiness at the same time (rarely each of these symptoms individually). About 50% of people experience vertigo, 40% unsteadiness and 35% dizziness in one year (22). Vertigo and dizziness are also risk factors for falls, especially in the elderly (23). These problems lead to loss of an employment in 20% and reduction of work efficiency and social life impairment in 50% of cases (24). Vertigo and dizziness can therefore severely reduce quality of life and represent a major public health problem. For that reason, it is crucial to evaluate a patient's problems by means of patient-reported HRQoL questionnaires.

1.4 DHI

The DHI is a reference questionnaire (25) most commonly used to evaluate vertigo-associated problems (7). It has been developed to evaluate problems with balance, since the results of vestibulometry (e.g. caloric test) are often inconsistent with the clinical findings (26, 27). The DHI consists of 25 questions, 7 of which are related to physical, 9 to emotional and 9 to the functional influences of vertigo. The patient answers each question with “yes” (4 points), “sometimes” (2 points) or “no” (0 points). A higher total score means that vertigo has a more severe impact on the patient’s quality of life. Four questions directly evaluate issues specific to the problems associated with benign paroxysmal positional vertigo (27). DHI has been translated into Swedish (28), Chinese (29), Dutch (30), Turkish (31), Italian (32), German (33), Spanish (34), Greek (6), etc.

1.5 NVI

The NVI was developed in response to the absence of questionnaires that evaluate vertigo-related cognitive problems. It tests attention, memory, emotion, vision, motor skills, and spatial and time perception. It is therefore designed to assess patient-reported, vertigo-associated neuropsychological problems. The NVI has so far been made available in English and French (35). The French version consists of 28 and the English of 32 questions, containing 4 distractors (7, 35). The answer to each question is scored using the Likert scale (7). The English version without distractors was used to cross-culturally adapt and validate the Slovenian NVI.

1.6 Tinnitus

Tinnitus is the perception of sound without a known external stimulus (36). In 8-17% of people, it occurs as temporary simple ringing after exposure to noise and it is rarely permanent (37). Its incidence increases with age and is present in 15% of people over the age of 65 (36, 37). In most cases, people do not seek medical attention because of tinnitus, as it does not significantly impact their daily life. However, it does have a significant impact on quality of life in some (36), and leads to hyperacusis, impaired cognitive ability, anhedonia, anxiety, depression and insomnia. Suicidality resulting from severe tinnitus has also been reported (37). Tinnitus can therefore interfere with daily activities (38) and affects the quality of life of certain personality types more significantly (38). The degree of tinnitus impairment also depends on tinnitus awareness throughout the day, the loudness and variability of the tinnitus, education, and additional physical symptoms (39). Although tinnitus can be determined audiometrically, patient-reported HRQoL questionnaires present an indispensable tool for evaluating tinnitus (40, 41).

1.7 THI

The THI is useful for evaluating tinnitus and its impact on HRQoL. It comprises 25 questions and is expected to complement the DHI in clinical practice. Twelve questions evaluate functional, eight emotional and five catastrophic responses to tinnitus. The patient answers each question with “yes” (4 points), “sometimes” (2 points) or “no” (0 points), where the maximum score is 100. Scoring 78-100 points means that the tinnitus is catastrophic, 58-76 severe, 38-56 moderate, 18-36 mild and <18 light (42). The THI has been translated into Hungarian (43), Danish (44), Polish (45), Korean (46), Brazilian Portuguese (47), Turkish (48), Italian (49), Chinese (50, 51), French (52, 53), Hebrew (54), Russian (8), etc.

2 MATERIALS AND METHODS

2.1 Translation and Cross-Cultural Adaptation of Questionnaires

To enable replicability, the cross-cultural adaptation and validation processes are described according to the guidelines for translating and adapting hearing-related questionnaires for different languages and cultures by Hall et al. (9).

We conducted an initial review of the literature and were unable to locate any Slovenian versions of the COMQ-12, DHI, NVI or THI questionnaires. Permission to use the questionnaires was obtained from the authors of the original questionnaires. These authors were available for any additional questions regarding concepts or ambiguities behind the items. Literacy, population characteristics and the requirement for administrative help were evaluated for the target population. Template documents for recording the translation and adaptation process were created and the definition of concepts for each questionnaire item developed.

Two independent dual-language translators (native Slovenian speakers with a very good knowledge of English) were briefed on the questionnaires and their clinical concepts. They independently translated questionnaires into Slovenian (i.e. forward translation). The two translations were harmonised by two field experts to create a single translation.

Two independent dual-language translators (native English speakers with a very good knowledge of Slovenian) then independently translated the questionnaires back to the English language (i.e. back-translation). The two translations were reconciled by two field experts to create a single translation, which was then reviewed by the board of experts (one otosurgeon, one audiologist, two general otorhinolaryngology consultants, two otorhinolaryngology residents, one non-medical translation consultant).

This was followed by pilot testing with the target audience (20 patients for each questionnaire) to ensure that the questions were understood and culturally appropriate. The results of the pilot testing were reviewed and the translation finalised. The same board of experts formatted and proofread the finalised translation. The questionnaires were then given to patients with COM, dizziness or tinnitus and to healthy volunteers. These subjects were later included in the statistical analysis.

2.2 Subjects

Patients treated at our department for COM, vertigo or tinnitus completed the COMQ-12, DHI, NVI or THI after an otorhinolaryngological check-up and confirmation of the diagnosis. The control groups for each questionnaire consisted of healthy volunteers, i.e. medical staff and their acquaintances or relatives. Every subject gave informed consent.

2.3 Statistical Analysis

After the cross-cultural adaptation of all the questionnaires, the validation was performed using various statistical methods; these are thoroughly described in order to enable replicability. Data were analysed using Microsoft Excel for Mac (version 16 and later) and SPSS (Statistical Package for the Social Sciences, version 23, IBM Corp., Armonk, NY, USA).

Internal consistency, test-retest reliability, discriminant validity, diagnostic accuracy and cut-off value were determined for each questionnaire. Internal consistency was determined with Cronbach's alpha and diagnostic accuracy and cut-off values using ROC curve analysis and Youden's index (55). Test-retest reliabilities and discriminant validities were determined by means of various statistical tests and depending on the analysed data.

3 RESULTS

The Slovenian translations of the COMQ-12, DHI, NVI and THI are available from the authors upon request and from the institution's official website.

3.1 COMQ-12

COMQ-12 was completed by 20 (52.6%) male and 18 (47.7%) female patients ($P_{\text{COMQ-12}}$) with an average age of 52.02 ± 16.61 years (Mdn=55 years, Ra=18-87 years) and average score of 23.34 ± 10.47 (Mdn=22, Ra=4-51). The control group that completed COMQ-12 consisted of 10 (16.4%) male and 51 (83.6%) female volunteers with an average age of 37 ± 10.53 years (Mdn=35 years, Ra=41 years). They completed COMQ-12 twice within a two-day interval, hence test ($CT_{\text{COMQ-12}}$) and retest ($CRT_{\text{COMQ-12}}$). The

average score was 1.410 ± 3.111 (Mdn=0, Ra=20) for $CT_{\text{COMQ-12}}$ and 1.246 ± 2.248 (Mdn=0, Ra=9) for $CRT_{\text{COMQ-12}}$.

3.2 DHI and NVI

The DHI and NVI were each completed twice within a three-day interval by identical groups comprising 26 (43.3%) male and 34 (56.7%) female patients with an average age of 61.4 ± 13.8 years (Mdn=63.5 years, Ra=56 years). The average score was 49.67 ± 22.843 (Mdn=52, Ra=86) for first completion of the DHI (PT_{DHI}) and 47.00 ± 22.81 (Mdn=49, Ra=84) for the second completion (PRT_{DHI}). The average score was 65.07 ± 18.78 (Mdn=65, Ra=80) for first completion of the NVI (PT_{NVI}) and 64.52 ± 18.88 (Mdn=65, Ra=80) for the second completion (PRT_{NVI}). The DHI and NVI were completed by identical control groups comprising 28 (46.7%) male and 32 (53.5%) female volunteers with an average age of 46.6 ± 16.2 years (Mdn=45 years, Ra=51 years). The average score was 1.17 ± 2.395 (Mdn=0, Ra=10) for the DHI control group (C_{DHI}) and 47.68 ± 18.88 (Mdn=65, Ra=80) for the NVI control group (C_{NVI}).

3.3 THI

The THI was completed by 19 (31.7%) male and 41 (68.3%) female patients (P_{THI}) with an average age of 53.80 ± 13.7 years (Mdn=57 years, Ra=59 years) and an average score of 52.12 ± 23.50 (Mdn=51, Ra=88). The control group completed the THI twice over an interval of a few days. The THI was first completed by 19 (31.7%) male and 41 (68.3%) female volunteers with an average age of 37 ± 10.53 years (Mdn=35 years, Ra=41 years) as a test group (CT_{THI}). The retest group (CRT_{THI}) consisted of three male (23.1%) and ten female (76.9%) volunteers recruited from the CT_{THI} with an average age of 47.4 ± 13.5 years (Mdn=49 years, Ra=52 years) and average score of 0 ± 0 (Mdn=0, Ra=0).

3.4 Statistical Analysis

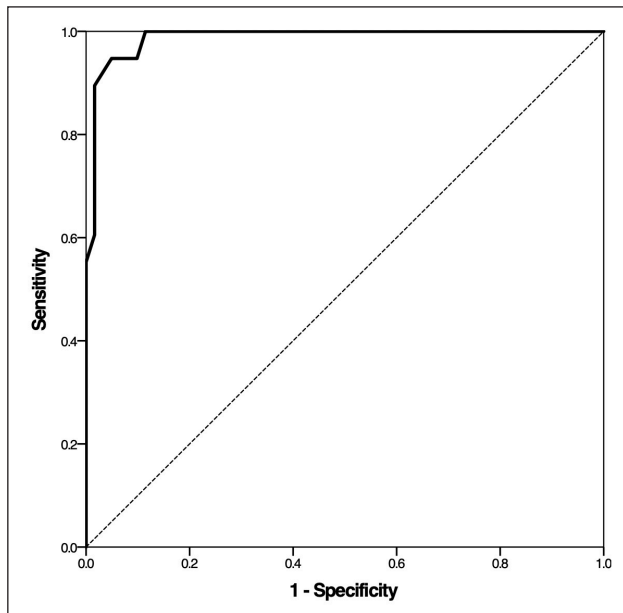
Test-retest reliability, discriminant validity, internal consistency, ROC curve analysis and cut-off value for each questionnaire are depicted in Table 1 and Figures 1, 2 and 3.

Table 1. Test-retest reliability, discriminant validity, internal consistency, cut-off value and Youden's index for the COMQ-12, DHI, NVI and THI.

	Test-retest reliability	Discriminant validity	α	A_{ROC}	Cut-off value	J
COMQ-12	$p=0.680^*$, $ICC_A=0.858$ (0.774-0.912)**	$p<0.0005$ †	0.796	0.987	7	0.90
DHI	$ICC_A=0.946$ (0.902-0.969)**	$p<0.0005$ †	0.910	0.999	9	0.95
NVI	$p=0.315$ ‡, $ICC_A=0.975$ (0.959-0.985)**	$p<0.0005$ ††	0.950	0.781	56	0.43
THI	$p=0.120^*$	$p<0.0005$ †	0.924	1.000	7	1.00

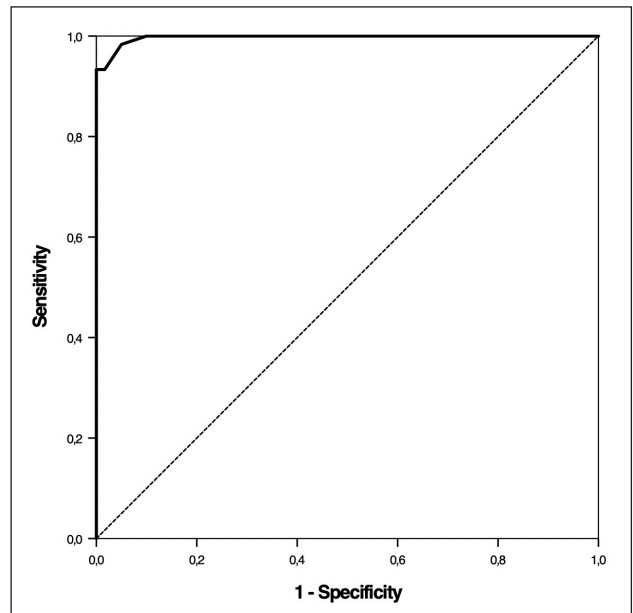
Legend: α , Cronbach's alpha; A_{ROC} , area under ROC curve; J, Youden's index; p, p-value; *, Wilcoxon signed-rank test; **, type A intraclass correlation coefficient estimates and their 95% confident intervals using an absolute agreement definition, based on single measures and two-way mixed effects (ICC_A); †, Mann-Whitney U test using an exact sampling distribution for U (Dineen & Blakesley, 1973); ‡, paired samples t-test; ††, Welch's t-test.

Commentary: statistical significance is $p<0.05$. As the minimum NVI score is 28, the cut-off value is higher compared to the other questionnaires.



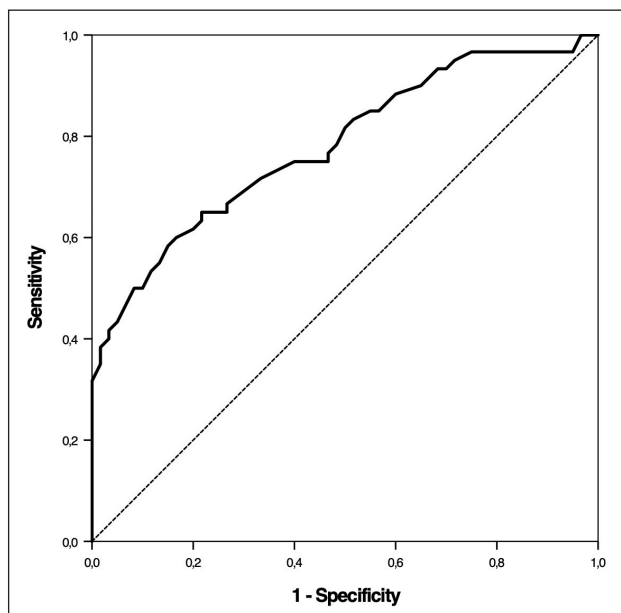
Commentary: The area under the ROC curve (0.987) signifies outstanding diagnostic accuracy. A threshold score of 7 was determined to distinguish between chronic otitis media and a healthy ear. The ROC curve was created by plotting $P_{COMQ-12}$ and $C_{COMQ-12}$.

Figure 1. COMQ-12 ROC curve.



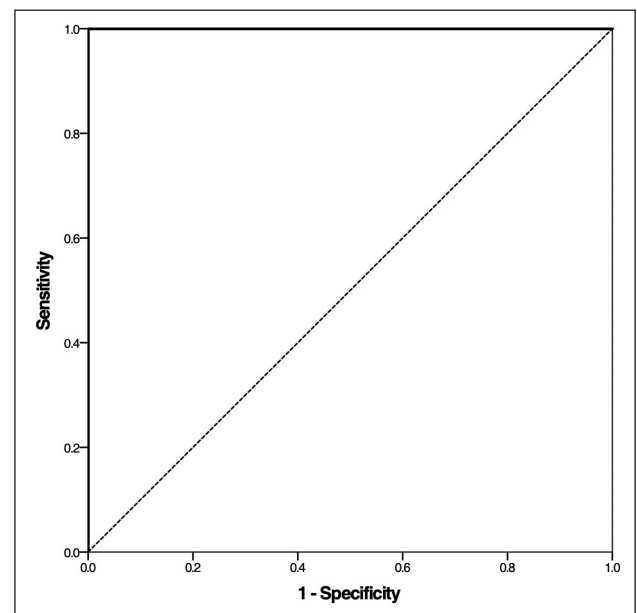
Commentary: The area under the ROC curve (0.999) signifies outstanding diagnostic accuracy. A threshold score of 9 was determined for the recognition of vertigo. The ROC curve was created by plotting P_{DHI} and C_{DHI} .

Figure 2. DHI ROC curve.



Commentary: The area under the ROC curve (0.781) signifies acceptable diagnostic accuracy. A threshold score of 56 was determined for the recognition of vertigo. The ROC curve was created by plotting PT_{NVI} and C_{NVI} .

Figure 3. NVI ROC curve.



Commentary: The area under the ROC curve (1.000) signifies perfect diagnostic accuracy. A threshold score of 7 was determined for the recognition of tinnitus. The ROC curve was created by plotting P_{THI} and CT_{THI} .

Figure 4. THI ROC curve.

4 DISCUSSION

Each questionnaire had satisfactory test-retest reliability as determined by the intraclass correlation coefficient, the paired samples t-test or the Wilcoxon signed-rank test. Furthermore, the Slovenian COMQ-12 had good-to-excellent test-retest reliability, which was better than has been reported recently (18, 56). The Slovenian DHI had excellent test-retest reliability based on the intraclass correlation coefficient. This is consistent with other studies (32, 56). Since the NVI has only recently been developed, to the best of our knowledge no studies have yet been published regarding its test-retest reliability (35, 57). Instead, the Slovenian NVI possesses excellent test-retest reliability and contributes significantly to the current literature.

As in other studies, the discriminant validity was confirmed for the Slovenian COMQ-12, DHI and THI using the Mann-Whitney U test and for the Slovenian NVI using Welch t-test by determining $p > 0.05$ (5, 7, 53).

According to Cronbach's alpha, the Slovenian DHI, NVI and THI had perfect internal consistency, even higher compared to other studies (7, 8, 32). The Slovenian COMQ-12 had acceptable internal consistency.

To evaluate diagnostic accuracy and the cut-off value, the area under the ROC curve (AROC) and Youden's index were determined for each questionnaire. The Slovenian

COMQ-12 and DHI had excellent, NVI acceptable and THI perfect diagnostic accuracies according to A_{ROC} (58). There is no similar data published for DHI, NVI and THI in other languages regarding diagnostic accuracy and cut-off values by determining A_{ROC} and Youden's index.

5 CONCLUSION

The COMQ-12, DHI, NVI and THI questionnaires were cross-culturally adapted and validated in the Slovenian language for the first time. The questionnaires can be used in diagnosis or for evaluating the treatment outcome. It is therefore an efficient and essential tool for the comprehensive management of patients with chronic otitis media, dizziness and tinnitus. They are useful for general practitioners, occupational health specialists, neurologists and otorhinolaryngologists. In the future, the COMQ-12, DHI, NVI and THI questionnaires could also assist a physician in their choice of the most appropriate treatment modality, via their implementation to disease-management guidelines. However, further research is needed to substantiate the usefulness of these questionnaires for different types of chronic otitis media, vertigo and tinnitus. The relationships between the questionnaires and other diagnostic tests should also be considered. The Slovenian COMQ-12, DHI, NVI and THI could be used in research into new treatment efficacies

and into the impact of treatment on a patient's health-related quality of life. As we live in a digital era, the future lies in electronic questionnaires, which are easier to access and complete and aid the data analysis process.

ACKNOWLEDGEMENTS

John Phillips, Gary P. Jacobson, Emilia Lacroix and Craig W. Newman for permission to translate the original COMQ-12, DHI, NVI and THI, respectively.

CONFLICTS OF INTEREST

The authors declare that no conflicts of interest exist.

FUNDING

There is no financial interest or risk.

ETHICAL APPROVALS

Received from the Republic of Slovenia National Medical Ethics Committee (Nos 0120-146/2019/5, 0120-032/2016-2 and 21/6/15)

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