Validation of a modified Oral Health Impact Profile scale (OHIP-14) in patients with oral mucosa lesions or periodontal disease

Walidacja zmodyfikowanego wskaźnika profilu zdrowia jamy ustnej (OHIP-14) u pacjentów z chorobami błony śluzowej jamy ustnej lub periodontopatiami

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Abstract

Background. Now that healthcare systems have helped successfully extend the human lifespan, the next challenge is to improve the patient's quality of life (QOL), in particular health-related quality of life (HRQOL). A proper HRQOL assessment requires using reliable instruments that are well-adapted to the population.

Objectives. The objective of this study was to validate a modified Polish version of the Oral Health Impact Profile scale (OHIP-14) for patients with oral mucosa lesions or periodontal disease.

Material and methods. The sample consisted of 180 adults seeking highly specialized treatment at the Periodontology Department of the University Dental Clinic in Kraków, Poland. The main modification made to OHIP-14 was the inclusion of subquestions regarding the teeth (subscale 1), oral mucosa and other soft tissues (subscale 2), and dentures (subscale 3).

Results. The Cronbach's alpha values were excellent for all 3 subscales (subscale 1: $a = 0.924$; subscale 2: $a = 0.937$; subscale 3: $a = 0.936$). In the case of subscale 1, the Kaiser criterion showed a model with 3 factors ("psychological and social limitations"; "physical limitations"; "functional limitations"), which together explained 67.1% of the variance, in the case of subscale 2 – a model with 1 factor, and in the case of subscale 3 – a 2-factor model ("social interactions limitations"; "basic activities disorder and personal discomfort").

Conclusions. Statistical testing demonstrated that a modified OHIP-14 questionnaire is a reliable tool for evaluating QOL in patients with periodontal or oral mucosa diseases.

Key words: oral health, periodontal disease, validation, health-related quality of life

Słowa kluczowe: zdrowie jamy ustnej, choroby przyzębia, walidacja, jakość życia związana ze zdrowiem fizycznym

Introduction

Now that healthcare systems have helped successfully extend the human lifespan, the next challenge is to improve the patient's quality of life (QOL), in particular health-related quality of life (HRQOL). This goal accords with the World Health Organization's own definition of health, namely that "health is a state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity".[1] The HRQOL assessment is based on the patient's own subjective evaluation and may significantly improve the patient's treatment (by improving compliancy and the physician–patient communication, and helping to focus more on the patient's needs, expectations and satisfaction),[2,3] but, at the same time, may also indicate suitable ways of improving the healthcare system itself.[4] This is especially important in the case of chronic diseases,[5] which may require regular medical appointments, longer treatment, some sacrifices, and changes in the patient's habits, which often need to be maintained for the rest of their life. A proper HRQOL assessment requires using reliable instruments that are well-adapted to the population. Many of these have already been developed to evaluate oral health-related quality of life (OHRQOL) in adults, e.g., Oral Health Impact Profile (OHIP-49,[6] OHIP-14[7]), Geriatric Oral Health Assessment Index (GOHAI),[8] Liverpool Oral Rehabilitation Questionnaire (LORQ),[9,10] and Chronic Oral Mucosal Diseases Questionnaire (COMDQ).[11]

The original English version of OHIP-14 was developed from OHIP-49 and validated by Slade.[7] Since then, this instrument has been applied in many different languages, e.g., German,[12] Italian,[13] Greek,[14] Turkish,[15] Japanese,[16] Vietnamese,[17] and Polish.[18] The original OHIP-14 is a self-administered questionnaire consisting of 14 items divided into 7 dimensions: functional limitation (items 1 and 2), physical pain (items 3 and 4), psychological discomfort (items 5 and 6), physical disability (items 7 and 8), psychological disability (items 9 and 10), social disability (items 11 and 12), and handicap (items 13 and 14). The respondents answer questions regarding the frequency of the factors that have impacted their QOL in the last 12 months and their responses are recorded on a 5-point Likert scale: never – 0; hardly ever – 1; occasionally – 2; fairly often – 3; very often – 4.

The aim of this study was to validate a modified Polish version of OHIP-14 in a population of patients with mucosal lesions or periodontal disease in order to make this scale applicable to this group.

Material and methods

Two hundred and thirty-two adult patients looking for treatment at the Periodontology Department in the University Dental Clinic in Kraków, Poland, between January 2017 and July 2018 were approached. Out of the 232 individuals, 180 agreed to participate in the study (a response rate of 77.6%). The study comprised a modified short Polish version of Oral Health Impact Profile (mOHIP-14-pl) and was part of a larger questionnaire-based study that included a clinical examination. The cross-cultural adaptation process of the English version of OHIP-14 was carried out according to the suggested guidelines.[19] The original questionnaire was translated into Polish by 2 persons with advanced English language skills, then the back-translation was performed and the review committee agreed on the final Polish version.

In this study, the authors used their own modified version of the standard OHIP-14 (Table 1) that features 2 adjustments. The first involved asking about the same items separately in relation to the teeth (subscale 1), oral mucosa and other soft tissues, e.g., gingiva or tongue (subscale 2), and dentures (subscale 3). The purpose of this modification was to explore the differences in the respondents' opinions, which could influence the clinical approach. The second adjustment concerned the inclusion of 2 additional answers: "I don't know", because some of the respondents found it difficult to determine the proper frequency of a given factor, and "not applicable", which was useful in the questions regarding the teeth in edentulous patients or dentures in patients who do not use any of them. Two supplementary answers were thus recorded: "I don't know" – 5 and "not applicable"– 6.

Each of the enrolled subjects was provided with detailed information about the study. All the participants gave their written informed consent. The exclusion criterion was only lack of consent. The study was approved by the Ethics Committee of the Jagiellonian University Medical College in Kraków, Poland (No. 122.6120.354.2016).

The data was analyzed using the IBM SPSS Statistics for Windows, v. 24 (IBM Inc., Armonk, USA). The reliability analysis based on Cronbach's alpha test was performed to evaluate the internal consistency of the scales. Additionally, to check if the reliability of the scale could be improved by excluding any items, Cronbach's alpha for the scale without this item was estimated. The factor analysis was used to make an initial decision about the number of underlying factors contributing to a set of responses. The varimax rotation was used to simplify the structure, with each item loading on as few dimensions as possible. The number of factors chosen was based on the inspection of the scree plot and the Kaiser criterion with an eigenvalue ≤1.[20] Eigenvalues show the degree of variance of all factors, explained by the factor with greater eigenvalues, accounting for more of the variance. The level of significance was set at $p < 0.05$ for all analyses.

Table 1. Authors' modified, Polish version of Oral Health Impact Profile (mOHIP-14-pl)

Original dimension	Question No.	Item	Subscale
Functional limitation	1.	Have you had trouble pronouncing any words because of problems with your:	A. teeth? B. oral mucosa? C. denture?
	2.	Have you felt that your sense of taste has worsened because of problems with your:	A. teeth? B. oral mucosa? C. denture?
Physical pain	3.	Have you had painful aching in your mouth because of problems with your:	A. teeth? B. oral mucosa? C. denture?
	4.	Have you found it uncomfortable to eat any foods because of problems with your:	A. teeth? B. oral mucosa? C. denture?
Psychological discomfort	5.	Have you been self-conscious because of your:	A. teeth? B. oral mucosa? C. denture?
	6.	Have you felt tense because of problems with your:	A. teeth? B. oral mucosa? C. denture?
Physical disability	7.	Has your diet been unsatisfactory because of problems with your:	A. teeth? B. oral mucosa? C. denture?
	8.	Have you had to interrupt meals because of problems with your:	A. teeth? B. oral mucosa? C. denture?
Psychological disability	9.	Have you found it difficult to relax because of problems with your:	A. teeth? B. oral mucosa? C. denture?
	10.	Have you been a bit embarrassed because of problems with your:	A. teeth? B. oral mucosa? C. denture?
Social disability	11.	Have you been a bit irritable with other people because of problems with your:	A. teeth? B. oral mucosa? C. denture?
	12.	Have you had difficulty doing your usual jobs because of problems with your:	A. teeth? B. oral mucosa? C. denture?
Handicap	13.	Have you felt that life in general is less satisfying because of problems with your:	A. teeth? B. oral mucosa? C. denture?
	14.	Have you been totally unable to function because of problems with your:	A. teeth? B. oral mucosa? C. denture?

Results

A group of 180 subjects (age: 24–82 years; mean age: 55 years; 40.6% men; details in Fig. 1 and Table 2) self-completed the modified Polish language version of the OHIP-14 questionnaire for all 3 subscales. The main disorders diagnosed in patients are presented in Table 3.
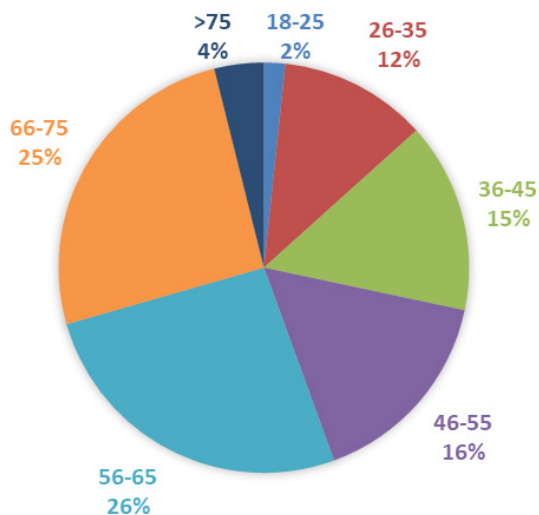

Fig. 1. Age structure of the respondents

Table 2. General diseases of the patients

General disease	n (%)
No general diseases	66 (36.7)
Any cardiovascular disease (including hypertension)	73 (40.6)
Hypertension	54 (30.0)
Diabetes mellitus	7 (3.9)
Osteoarticular diseases	32 (17.8)
Nervous system diseases (e.g., depression)	5 (2.8)
Any gastrointestinal diseases (including gastroesophageal reflux)	20 (11.1)
Gastroesophageal reflux	6 (3.3)
Respiratory diseases (asthma, chronic obstructive pulmonary disease)	6 (3.3)
Obesity	1 (0.6)
Lichen planus cutis	1 (0.6)
Other	52 (28.9)

The questionnaires with 1 and more "I don't know", "not applicable" and missing answers were excluded from the statistical analysis. One hundred and twenty-eight patients (71.1%) gave detailed answers to the questions regarding the teeth (subscale 1). In subscale 2, 134 respondents (74.4%) and in subscale 3, 82 patients (45.6%) were considered in the analysis. Ninety-three patients (51.7%) were fixed or removable prosthesis users.

Table 3. Disorders diagnosed in the patients

Disorders	n (%)
Gingivitis: dental biofilm-induced	56 (31.1)
Periodontitis	79 (43.9)
Periodontal abscesses and endodontic-periodontal lesions	1 (0.6)
Gingival recession	8 (4.4)
Oral mucosa diseases (oral lichen planus, leukoplakia, burning mouth syndrome, candidosis, xerostomia, geographic tongue, aphthous stomatitis, Sjögren's syndrome)	74 (41.1)
Neuralgia	1 (0.6)
Caries	7 (3.9)
Teeth to extraction	9 (5.0)
Temporomandibular joint disorders	4 (2.2)
Fetor ex ore	4 (2.2)
Prosthesis-related oral mucosa injuries	5 (2.8)
Defect after maxillectomy or mandibulectomy	4 (2.2)

The internal consistency assessed on the basis of Cronbach's alpha test was excellent for all 3 subscales (subscale 1: α = 0.924; subscale 2: α = 0.937; subscale 3: α = 0.936). Excluding items in each subscale did not significantly improve the Cronbach's alpha value, so the authors decided that all items were necessary in the scale.

The factor structure of the examined scales was explored using the factor analysis. Bartlett's test of sphericity (subscale 1: χ = 1102.7, df = 91, $p < 0.001$; subscale 2: χ = 1303.8, df = 91, $p < 0.001$; subscale 3: χ = 888.2, df = 91; $p < 0.001$) revealed significant correlations between the studied items, thereby enabling further analysis. The Kaiser–Meyer–Olkin (KMO) test for sampling adequacy (subscale 1: 0.907, $p < 0.001$; subscale 2: 0.897, $p < 0.001$; subscale 3: 0.882, $p < 0.001$) indicated that the items could be implemented as a scale and the factor analysis could be applied.

In the case of subscale 1, the Kaiser criterion showed a model with 3 factors, which together explained 67.1% of the variance (Table 4). The 1st factor, accounting for 32.9% of the variance, represented psychological and social limitations. The highest factorial load was observed for the following items: 6, 10, 5, 11, 13, 14, and 12. The 2nd factor, constituting 22.0% of the variance, represented physical limitations. The items with a high factorial load were as follows: 3, 8, 9, 4, and 7. The 3rd factor, making up 12.2% of the variance, determined functional limitations. A high factorial load was observed for items 1 and 2.
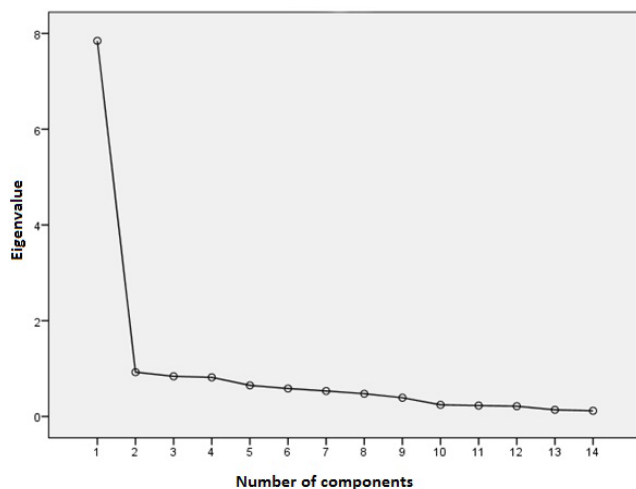
The Kaiser criterion for subscale 2 as well as the inspection of the scree plot produced a single-factor model (Fig. 2). This means that there are no other subscales for this scale.

In the case of subscale 3, the Kaiser criterion produced a model with 2 factors, which together explained 65.2% of the variance (Table 5). The 1st factor, accounting for 38.9% of the variance, referred to physical and psychological limitations that were particularly disruptive during social interactions. The highest factorial load was observed for the following

Table 4. Factor loadings in the rotated factor solution for subscale 1 (loadings below 0.3 are not displayed)

OHIP-14 item	Factor		
	psychological and social limitations	physical limitations	functional limitations
Item 6	0.893	–	–
Item 10	0.846	–	–
Item 5	0.825	–	–
Item 11	0.789	0.304	–
Item 13	0.615	0.389	–
Item 14	0.552	0.367	–
Item 12	0.519	0.431	–
Item 3	–	0.808	–
Item 8	0.316	0.803	–
Item 9	0.517	0.598	–
Item 4	0.366	0.540	0.368
Item 7	0.476	0.484	0.305
Item 1	–	–	0.919
Item 2	–	0.448	0.596
Variance explained	32.9%	22.0%	12.2%

OHIP – Oral Health Impact Profile.

Table 5. Factor loadings in the rotated factor solution for subscale 3 (loadings below 0.3 are not displayed)

OHIP-14 item	Factor	
	social interactions limitations	basic activities disorder and personal discomfort
Item 5	0.842	–
Item 4	0.842	–
Item 10	0.828	0.371
Item 6	0.813	0.372
Item 3	0.731	–
Item 8	0.684	0.394
Item 7	0.663	0.418
Item 9	0.510	0.465
Item 14	–	0.884
Item 12	–	0.826
Item 13	0.442	0.648
Item 11	0.616	0.621
Item 1	0.490	0.516
Item 2	0.326	0.442
Variance explained	38.9%	26.3%

Fig. 2. Scree plot for subscale 2

items: 5, 4, 10, 6, 3, 8, 7, and 9. The 2nd factor, accounting for 26.3% of the variance, comprised basic activities and personal comfort limitations. A high factorial load was observed for the following items: 14, 12, 13, 11, 1, and 2.

Discussion

An objective assessment of QOL requires the use of reliable tools. Reliability is tested using a standardized statistical process called validation. Its purpose is not only to create new reliable scales and questionnaires, but also to improve the already constructed ones. Validation should be conducted carefully and precisely for every surveyed population in view of linguistic differences and other factors related to age, disease, environment, etc.

To the authors' knowledge, this is the first study confirming the hypothetical factorial model of the OHIP-14 questionnaire in patients with periodontal disease and oral mucosa diseases. The assessment of QOL among such patients performed separately in relation to the teeth, oral mucosa and dentures showed a different structure of these scales. The factor analysis showed that using the same set of questions but in relation to distinct parts of the oral cavity raises the importance of different aspects of QOL. The factor structure of subscale 1 related to the teeth shows that the psychological and social, physical, and functional aspects of QOL should be treated separately. On the contrary, QOL for the oral mucosa subscale was shown to have only a 1-dimensional structure, suggesting that all aspects of QOL are mixed and strongly correlated. Subscale 3 is related to the denture usage and for this subscale, a 2-factor structure was found. In addition, those factors were different from the factors for subscale 1 – social relations were found to be most pronounced and other problems/aspects constituted the 2nd factor. These results suggest that oral health related to QOL, especially from the point of view of the periodontal patient, should be analyzed carefully, not only as a general oral health measure, but also in relation to the specific problems.

The statistical test used most frequently to assess the internal consistency of an instrument is Cronbach's alpha. In the present study, conducted among Polish adults suffering from periodontal or oral mucosa diseases, the Cronbach's alpha value was high for each subscale (subscale 1: $\alpha = 0.924$; subscale 2: $\alpha = 0.937$; subscale 3: $\alpha = 0.936$). Similar results were found for the validation of the Polish ($\alpha > 0.9$),[18] Turkish ($\alpha = 0.91$),[15] and Greek and Spanish ($\alpha = 0.90$)[14,21] version of the OHIP questionnaire. Excellent internal consistency was found in the German version of OHIP-49 ($\alpha = 0.96$).[12] Values above 0.7 show a factorial structure with good internal consistency, but according to Bland and Altman, for the clinical application, very high values of Cronbach's alpha are needed.[22] The desirable value is 0.95 and the minimum – 0.90.

The internal reliability of the original English version of the scale obtained by Slade, who recalibrated the original English version of OHIP-14 for a group of 1217 Australians,[7] was worse than in this study ($\alpha = 0.88$).

Periodontal patients often suffer from tooth mobility, displacement and loss. These problems may cause limitations in social interactions (fear of smiling and laughing, problems during eating related to mobile teeth and/or dentures, etc.), but also influence private life (fear of sudden tooth loss, tension, etc.). In periodontal patients, OHRQOL decreases[23–27] and is multidimensional. Oral rehabilitation as well as many factors related to treatment (e.g., the sort of denture, the frequency and regularity of follow-up appointments) can influence OHRQOL. McKenna et al. investigated the influence of prosthetic rehabilitation on OHRQOL in 2 groups of partially dentulous older people: group 1 was treated with removable partial dentures and group 2 – with fixed adhesive bridges.[28] The OHRQOL of the patients improved after oral rehabilitation in both groups. The improvement was greater in group 2 and was maintained at the same level for 24 months following the treatment. In group 1, the initial pace of improvement started to diminish after 6 months.

This study has some limitations. Firstly, it was conducted in a highly specialized university clinic, where many patients are referred because of the severity of their diseases, which may adversely influence the patients' HRQOL. Secondly, the majority of the respondents were elderly and their life experience, general diseases and social expectations may have affected the results. On this account, it is possible that the patients modified the answers to seem healthier or to emphasize their complaints and the severity of the disease. There is no doubt that the general health condition (such as insomnia or depression) can also influence the patient's responses.[29,30] It may be related to lowering the individual's acceptance level, some sacrifices or new habits in the case of chronic diseases, or with cognitive functions disorders in the case of mental diseases. Thirdly, the study population consisted not only of first-time patients, but also of regular patients. This means that some of the patients had undergone at least

the initial treatment (in some cases, also the long-term treatment), and that their awareness of their disease had changed and acute symptoms had been eliminated, which could influence subjective HRQOL.[23]

On the other hand, this study is innovative in the way HRQOL is assessed using a modified OHIP-14 questionnaire, in which this aspect is separately analyzed in relation to the teeth, oral mucosa and dentures. This may point out the dimensions that are especially affected in periodontal patients; in their case, the problem relates not only to the teeth and the surrounding tissues, but also to tooth loss and the necessity of prosthetic treatment. In the future, this innovative view of assessing the patient's HRQOL could be applied in clinical settings and influence the individual patient's treatment plan, compliancy and satisfaction.

Conclusions

Statistical testing showed the mOHIP-14-pl questionnaire to be a reliable tool for evaluating OHRQOL in patients with periodontal or oral mucosa diseases. The factor analysis confirmed 3 dimensions which should be considered regarding the teeth ("physical and social limitations", "physical limitations" and "functional limitations") and 2 dimensions regarding dentures ("social interactions limitations" and "basic activities disorder and personal discomfort"). Regarding oral mucosa, all standard dimensions should be taken into account. Very high values of Cronbach's alpha indicate that the questionnaire can be used in clinical settings.

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