ORIGINAL ARTICLE / ОРИГИНАЛНИ РАД

Psychometric properties of North Macedonian version of the Oral Health Impact Profile for Edentulous Subjects

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SUMMARY

Introduction/Objective Dental patient-reported outcome measures are very important in a disease-specific population such as edentulous subjects.

The aim of the study was to adapt the Oral Health Impact Profile for Edentulous Subjects (OHIP-EDENT) in the cultural environment of North Macedonia.

Methods This study adapted the original 19-item version of the OHIP-EDENT. After the forward–backward translation according to international standards, the OHIP-EDENT-MAC was psychometrically tested in 109 complete denture wearers.

Results The Cronbach's α coefficient of 0.892 confirmed good internal consistency. Test–retest reliability was confirmed by high intraclass correlation coefficient of the summary scores (0.986; 95% confidence interval 0.968–0.993). The concurrent validity was confirmed by the Spearman's rank correlation coefficient (r = -0.654) between the OHIP-EDENT-MAC summary scores and a single question which rated satisfaction with the existing removable dentures using a five-point scale (1 = unsatisfied, 5 = completely satisfied). Construct validity was confirmed by exploratory factor analysis. All item loadings were above 0.4. Items grouped in four factors (dimensions), which explained 66.25% of the variance, in both non-rotated and rotated matrices. Good responsiveness was confirmed in 33 participants after complete denture relining. Their OHIP Summary score (33.09 ± 11.61) decreased significantly (t = 7.68; df = 32; p < 0.001) after treatment (24.39 ± 8). The standardized effect size was 0.75, representing moderate to large effect.

Conclusion The OHIP-EDENT-MAC showed satisfactory psychometric properties providing evidence for its use in edentulous population of North Macedonia.

Keywords: OHIP-EDENT questionnaire; psychometrics; reliability; validity responsiveness; North Macedonia

INTRODUCTION

Edentulism is generally associated with ageing, although one can keep one's own teeth throughout whole life. The rate of edentulousness differs between cultures and countries with a trend to decline in rich countries due to investments and efforts in education on oral hygiene maintenance and other preventive measures. However, the prevalence of edentulousness is still large, mostly in less developed countries [1]. Moreover, the edentulism is not likely to be greatly reduced in the near future as the average lifespan is increasing and the population is generally growing older.

Oral health-related quality of life (OHRQoL) has become an important part of patients' well-being and an important issue in dentistry as it provides insight into a patient's view of dental problems or the provided therapy. Dental patient-reported outcome measures can be assessed by several psychometrically validated questionnaires, the Oral Health Impact Profile (OHIP) being one of the most frequently used.

The original 49-item OHIP was developed by Slade and Spencer in 1994, and the items were grouped (based on expert opinion) into seven domains: functional limitation, physical pain, physical limitation, psychological discomfort, social limitation, and disabilities (handicap) [2]. To reduce time consumption and incomplete answers of the 49-item OHIP questionnaire, a shorter version consisting of 14 items was developed from the original version. However, a disease-specific questionnaires are sometimes more appropriate. Therefore, many questionnaires for disease-specific patients have been developed in medicine and dentistry [3–7]. The OHIP-EDENT with 19 items has been developed for a disease-specific population suffering from tooth loss to enable measurement of the impact of edentulousness and interventions by conventional or implant-supported dentures in the edentulous population [7].

Each questionnaire has to be adapted before it can be used in other cultures and populations. The translation has to be performed according to accepted forward–backward process and the

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Table 1. North Macedonian version of the Oral Health Impact Profile for Edentulous Subjects (OHIP-EDENT) questionnaire

Ве молиме заокружете го соодветниот број на скала од 0 до 4 за секое прашање кое се однесува на проблеми со вашата протетска работа (вашата протеза)0 – никогаш; 1 – скоро никогаш; 2 – повремено; 3 – често; 4 – многу често

No.	OHIP-EDENT-MAC (NORTH MACEDONIA)
1.	Дали сте имале или имате *потешкотии при џвакање на било која храна*?
2.	Дали сте забележале *дека храната се лепи или останува* на протетичката изработка (протезата)?
3.	Дали сте забележале дека вашите *протези не налегнуваат* добро?
4.	Дали сте имале *болки во устата*?
5.	Дали Ви било или Ви е *неудобно (непријатно) да јадете некој вид на храна*?
6.	Дали сте имале или имате *болки во некој дел во устата*?
7.	*Дали протезите ви се неудобни*?
8.	Дали сте *загрижени* заради проблемите со протетичката изработка (протезата)?
9.	Дали сте *свесни* за Вашата протетичка изработка (протеза)? (Дали ви е постојано во потсвеста?)
10.	Дали сте морале да *избегнувате да јадете одреден вид на храна*?
11.	Дали сте забележале дека *не можете да јадете* некоја храна?
12.	Дали сте *прекинале оброк* заради проблеми со вашата протетичка изработка (протеза)?
13.	Дали сте *вознемирени* заради проблемите со протетичката изработка (протезата)?
14.	Дали сте се *чувствувале непријатно* заради проблемите со протетичката изработка (протезата)?
15.	Дали сте *избегнувале излегување или дружење*?
16.	Дали сте *биле помалку толерантни спрема брачниот другар или некој член од семејството*?
17.	Дали сте биле *раздразливи спрема другите (околината)*?
18.	Дали Ви се случило *помалку да уживате во друштво на други луѓе*?
19.	Мислите ли дека *животот ви нуди помалку задоволства*?

translated questionnaire must be psychometrically tested [8]. In North Macedonia, the long version of the OHIP Instrument has already been validated, but not the OHIP-EDENT [9]. Therefore, the aim of the study was to adapt the OHIP-EDENT in the cultural environment of North Macedonia.

METHODS

Subjects

A total of 109 fully edentulous subjects wearing complete dentures (CD) were included in the study. They were contacted by a telephone call and were asked to come for a control examination of their dentures. Of 182 patients, 109 responded. All dentures were previously made by undergraduate dental students under supervision of their teachers, specialists of prosthodontics at the School of Dentistry, Skopje, North Macedonia. The dentures were between nine month and six years old. The participants gave 19 answers using the OHIP-EDENT-MAC questionnaire and rated frequency of experienced difficulty in the previous week. The responses of the OHIP-EDENT-MAC questionnaire were rated using a five-point Likert's scale with the following answers: 0 – never, 1 – hardly ever, 2 – occasionally, 3 – fairly often, 4 – very often. Higher scores represented higher frequency of problems (more difficulties) and lower scores represented less problems and better OHRQoL. Zero represented absence of problems. All participants had to sign a written informed consent before being included in the study. The study was approved by the Ethics Committee of the Faculty of Dentistry, University of Skopje, and is in accordance with the ethical standards of the Declaration of Helsinki.

Translation

The forward–backward translation process of the OHIP-EDENT questionnaire was performed from the English language into the Macedonian language by two experienced dentists with an excellent knowledge of the both languages [8]. The backward translation was made by one professional of the English language who was Macedonian language native speaker. A native English language speaker compared the original and the back-translated version and agreed on the same meaning of the items. The Macedonian version was further tested to check understanding of the questions in 17 patients undergoing treatment with CD. The OHIP-EDENT-MAC version is presented in Table 1.

Reliability

The internal consistency of the OHIP-EDENT-MAC was tested by calculating Cronbach's α coefficient (value > 0.7 was considered acceptable).

The test–retest reliability was assessed by calculating intraclass correlation coefficients (ICC) based on the one-way repeated-measures analysis of variance (ANOVA) for the 27 CD wearers who filled in the OHIP-EDENT-MAC Questionnaire twice with 14–18 days between the tasks. The participants did not receive any dental treatment between the sessions.

Validity

Concurrent validity

The concurrent validity was assessed by calculating the Spearman's rank correlation coefficient between the

OHIP-EDENT-MAC summary score and a single question, which was given to participants at the same time with the OHIP-EDENT questionnaire. In a single question participants rated their satisfaction with the existing dentures on a scale from 1 (completely unsatisfied) to 5 (completely satisfied).

Construct validity

The construct validity was assessed by exploratory factor analysis (EFA). The eigenvalue of one was used for factor extraction. The item loading higher than 0.4 was considered successful.

Responsiveness

Responsiveness is the ability of a questionnaire to detect clinical changes elicited by a therapy. For that purpose, 33 participants complaining of loose dentures participated. A specialist of prosthodontics checked flanges and trimmed off excess material if it was present. After that, the dentures were relined chairside using the self-curing resin (GC Hard Reline, GC Corporation, Tokyo, Japan). During the procedure, the patients had to move lips, cheeks, and tongue, and tap the teeth of the maxillary and the mandibular CD together. That was repeated until the material set. After that, the excess material was removed and the CDs were polished in the dental laboratory. The patients were appointed for check-ups for the adjustment of the relined dentures. Seven to 15 days after completing all adjustments, the participants filled out the OHIP-EDENT-MAC questionnaire again. Paired t-test was made to analyze the significance of the differences. The standardized effect size was calculated with the following formula: mean (baseline OHIP-EDENT score – follow up OHIP-EDENT) / standard deviation of the baseline OHIP-EDENT score. According to Cohen, values < 0.2 were considered a trivial effect, 0.2–0.5 a small effect, 0.5–0.8 a moderate effect, and > 0.8 a large effect [10].

RESULTS

Participants in this study were CD wearers whose mean age was 67.27 ± 10.88 years, and 53.1% were females. The description of the participants is shown in Table 2.

Reliability

The Cronbach's α coefficient of the OHIP-EDENT-MAC summary scores showed good reliability (α = 0.892), which exceeded the minimum reliability standard of 0.7. The corrected item-total correlations ranged from 0.309 (item 19) to 0.716 (item 10). All items reached the recommended minimum correlation of 0.2. Test–retest reliability was confirmed by ICC calculation for the OHIP-EDENT-MAC summary score, which was 0.986 (95% confidence intervals ranged 0.968–0.993).

Table 2. Description of the participants

Variable	Frequency
Sex	
Male	45%
Female	55%
Smoking habits	
Yes	46%
No	54%
Ability to live alone	
Yes	96%
No	4%
Employment	
Employed	11%
Retired or unemployed	89%
Education	
Primary school	18%
Vocational school	42%
Secondary school	29%
University degree	11%

Validity

Concurrent validity

The concurrent validity was confirmed by the Spearman's rank correlation coefficient (r = -0.654) between a single question about participants' satisfaction with the existing dentures (dentures were rated 1–5, higher scores represented higher level of satisfaction) and the OHIP-EDENT-MAC summary score.

Construct validity

The Kaiser–Meyer–Olkin measure of sampling adequacy, which was 0.85, and the significance of the Bartlett's test of sphericity (approx. χ^2 = 1120.76; p < 0.0001) demonstrated sufficient values to perform the EFA. Factor loadings of the Macedonian version of the OHIP-EDENT questionnaire are shown in Table 3, together with mean values, standard deviations, corrected item-total correlations and Cronbach's α if item deleted. All items had factor loadings above 0.4. The smallest factor loading was 0.47 for item 2 (food catching), while the highest factor loading was 0.75 for item 7 (uncomfortable dentures). The EFA revealed four factors (domains), which accounted for 66.25% of the variance, in both unrotated and rotated matrices. Table 4 shows item distribution after the varimax rotation. Loadings with less than 0.1 are omitted from Table 4.

Responsiveness

In 33 participants who complained on loose dentures, the dentures were relined chairside. Their OHIP Summary score before treatment was 33.09 ± 11.61, and dropped down significantly after the treatment to 24.39 ± 8 (t = 7.68; df = 32; p < 0.001). The standardized effect size was 0.75.

Table 3. Item mean values and standard deviations, corrected item-total correlation, Cronbach's α if item is deleted, and factor loadings of the North Macedonian Oral Health Impact Profile for Edentulous Subjects (OHIP-EDENT) questionnaire

Item	OHIP-EDENT-MAC				
	Mean	SD	Corrected Item-Total Correlation	Cronbach's α if item deleted	Factor loadings
1. Difficulty chewing	2.12	1.24	0.61	0.88	0.65
2. Food catching	1.61	1.11	0.41	0.89	0.47
3. Dentures not fitting	1.83	1.46	0.46	0.89	0.68
4. Painful aching	0.88	1.03	0.51	0.89	0.68
5. Uncomfortable to eat	1.99	1.24	0.64	0.88	0.61
6. Sore spots	1.28	1.16	0.54	0.88	0.74
7. Uncomfortable dentures	1.68	1.39	0.65	0.88	0.75
8. Worried	1.88	1.29	0.64	0.88	0.57
9. Self-conscious	2.13	1.38	0.32	0.89	0.81
10. Avoid eating	1.83	1.24	0.72	0.88	0.65
11. Unable to eat	1.5	1.16	0.54	0.88	0.5
12. Interrupt meals	0.93	1.25	0.61	0.88	0.7
13. Upset	1.83	1.27	0.67	0.88	0.71
14. Embarrassed	1.51	1.21	0.58	0.88	0.69
15. Avoid going out	1.02	1.16	0.45	0.89	0.74
16. Less tolerant	0.31	0.68	0.55	0.89	0.68
17. Irritable with others	0.68	0.9	0.35	0.89	0.64
18. Unable to enjoy company	0.83	1.07	0.33	0.89	0.67
19. Life less satisfying	1.25	1.12	0.31	0.89	0.64

Table 4. Item loadings in the Oral Health Impact Profile for Edentulous Subjects questionnaire after varimax rotation

Rotated Component Matrix				
Item	Component			
	1	2	3	4
1. Difficulty chewing	0.751		0.278	
2. Food catching	0.642	-0.102		0.208
3. Dentures not fitting	0.794		0.146	-0.148
4. Painful aching	0.204		0.775	0.174
5. Uncomfortable to eat	0.696		0.287	0.190
6. Sore spots	0.262		0.809	0.127
7. Uncomfortable dentures	0.805		0.308	
8. Worried	0.519	0.283	0.191	0.430
9. Self-conscious			0.193	0.874
10. Avoid eating	0.686	0.268	0.287	0.156
11. Unable to eat all kinds of food	0.495		0.487	0.121
12. Interrupt meals	0.379	0.144	0.730	
13. Upset	0.432	0.514	0.107	0.502
14. Embarrassed	0.335	0.677		0.347
15. Avoid going out		0.847		0.151
16. Less tolerant	0.259	0.601	0.428	-0.266
17. Irritable with others		0.785	0.112	-0.103
18. Unable to enjoy company		0.818		
19. Life less satisfying	-0.127	0.767		0.162

DISCUSSION

The need to culturally adapt a questionnaire when translated into another language has become very important, especially in international multicenter studies focusing on patient-reported outcome measures assessing self-perceived OHRQoL. Although the adaptation of the OHIP49 (questionnaire with 49 items) has already been provided in the North Macedonia (the OHIP49-MAC Questionnaire), the OHIP questionnaire aimed specifically for edentulous subjects has not been translated and validated yet [9]. A high prevalence of edentulousness among adults over 65 years old was found in North Macedonia, and, therefore, there was a need for cultural adaptation of the OHIP-EDENT questionnaire [11]. It was translated first into the Macedonian language (forward translation) and then back translated, according to the accepted standards. After one native English language speaker confirmed there were no significant differences in the meaning of the back-translated questions, the clarity of the items was discussed with edentulous patients who were prescribed new CDs. They stated that it was easy to understand the questions and to give answers. Therefore, it was possible to continue with further procedures of psychometric validation of the OHIP-EDENT-MAC questionnaire. In fact, the OHIP-DENT-MAC questionnaire showed good internal consistency, indicating that the Macedonian version can measure the desired theoretical construct. Even when one of the items was deleted, Cronbach's α coefficient remained satisfactory far above the value of 0.7. Moreover, the corrected item-total correlations were well above the recommended level of 0.2. Reliability was also confirmed by high ICC of the OHIP-EDENT-MAC summary scores, pointing out a high degree of agreement when filling in the same questionnaire on two separate occasions, without any treatment provided between them. A period of 14 days was considered long enough for the participants to forget the questions from the first completion of the questionnaire, similar to the strategy of other studies [9, 12–15].

Concurrent validity of the Macedonian version of the OHIP-EDENT questionnaire was confirmed by significant negative Spearman's rank correlation coefficient between the OHIP-EDENT summary scores and a degree of satisfaction with dentures (the higher the degree of satisfaction with the dentures, the lower the OHIP-EDENT-MAC summary score was registered). Construct validity was confirmed by high item loadings. The EFA analysis was used to assess the latent structure of the data. It identified only four domains, explaining 66.25% of the variability. None of the studies performing EFA could not find the originally proposed seven domains of the OHIP-EDENT, and concluded that the proposed seven domains had actually been based on the expert's opinion [16]. However, Japanese version did not provide EFA [17]. The items of the Macedonian OHIP-EDENT questionnaire actually clustered around the domains describing masticatory function (factor 1, Table 4), pain

(factor 3, Table 4), social impact (factor 2, Table 4), and psychological impact (factor 4, Table 4). However, more research will be necessary, even introduction of some additional items focused on orofacial esthetics into the OHIP-EDENT questionnaire to construct a new tool for edentulous population which would fit into the recently developed four-dimensional model of the oral health quality of life, together with the CFA [18, 19, 20].

Responsiveness of a questionnaire actually measures its sensitivity in a changed environment (e.g., changes elicited by a therapy). For that purpose, the dentures were relined in patients complaining of loose CDs after thorough examination of the respective dentures by a specialist of prosthodontics, who proposed and performed the therapy. Seven days after the denture adjustments due to sore spots had been completed, participants again filled out the questionnaire. The summary scores, as expected, dropped significantly, pointing out good responsiveness of the Macedonian OHIP-EDENT version. The effect size was 0.75, which represented a moderate effect. However, even when the dentures fit better, the patients still have difficulties inherent to complete denture wearing [21, 22, 23]. It is well known that dental implant placement improves

denture support and elicits much larger effect size than a therapy which includes only a relining procedure [24–30]. The limitation of the present study may be in the fact that only summary scores of the OHIP-EDENT-MAC questionnaire were analyzed. Each of the proposed seven domains was not analyzed separately. However, the EFA of the OHIP-EDENT-MAC found only four domains of the questionnaire, and therefore it was decided to use only summary scores. Another limitation may be a diversity in patients' age and educational level, which also might have influenced the self-reported outcome measures.

CONCLUSION

The evaluation of the psychometric properties of the Macedonian language version of the OHIP-EDENT showed satisfactory cultural adaptation which provides evidence that the OHIP-EDENT-MAC can be used for the assessment of OHRQoL in edentulous population in North Macedonia.

Conflict of interest: None declared.

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Психометријске карактеристике северномакедонске верзије упитника *Oral Health Impact Profile* за безубе пацијенте

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САЖЕТАК

Увод/Циљ Мерења исхода лечења у области квалитета живота повезана са оралним здрављем су веома важна, нарочито у специфичним популацијама као што су безуби пацијенти.

Циљ студије био је да се прилагоди инструмент Профил утицаја оралног здравља (*Oral Health Impact Profile – OHIP-EDENT*) у културном окружењу Северне Македоније.

Методе У студији је адаптирана оригинална верзија упитника *OHIP-EDENT* за безубе пацијенте од 19 питања. У складу са међународним стандардима, након превода *напред-назад*, упитник је психометријски тестиран код 109 носилаца тоталних протеза.

Резултати Коефицијент Кронбахове алфе од 0,892 показао је добру унутрашњу конзистенцију. Тест–ретест поузданост је потврђена високом унутрашњом корелацијом укупног скора (0,986; уз 95% интервал поузданости 0,968–0,993). Конкурентна валидност је потврђена Спирмановим корелационим коефицијентом (r = -0,654) између укупног скора

тестираног упитника и једног питања којим је оцењено задовољство постојећим протезама на скали 1–5 (1 = незадовољавајуће, 5 = потпуно задовољавајуће). Конструкциона валидност је потврђена помоћу експлораторне анализе фактора. Оптерећење свих питања је било изнад 0,4. Питања су се груписала у четири фактора (димензије), што је објаснило 66,25% варијансе како у неротираним тако и у ротираним матрицама. Добра респонзивност је потврђена код 33 пацијента након подлагања тоталне протезе. Њихов укупни скор упитника *OHIP*-19 (33,09 ± 11,61) био је значајно смањен (t = 7,68; df = 32; p < 0,001) после третмана (24,39 ± 8,0). Стандардизован ефекат величине је био 0,75, што представља умерени до велики ефекат.

Закључак Упитник *OHIP-EDENT-MAC* показао је задовољавајуће психометријске карактеристике и показао могућност за његову употребу код безубе популације Северне Македоније.

Кључне речи: упитник *OHIP-EDENT*; психометрија; поузданост; респонзивност валидности; Северна Македонија