

# Validation of a Scale Assessing the Impact of Periodontal Diseases on Patients' Quality of Life in Bulgaria (Pilot Research)

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The aim of the paper is to present the validation of a scale for assessing the impact of periodontal diseases on individuals' quality of life in Bulgaria. A pilot research was made among 30 diagnosed patients with periodontitis visiting the Department of Periodontology, Faculty of Dental Medicine, Medical University of Plovdiv, Bulgaria. The minimum sample size of 30 people was established based on a power analysis for sample size calculation. The mean age of participants was  $48.95 \pm 11.85$  years, being  $56.67 \pm 9.05$  years for males and  $43.33 \pm 9.05$  years for females. Standard interviews were conducted using a specific instrument: self-designed questionnaire and a 5-degree ranked scale, containing initially 11 questions. The interviews were repeated after 3 months with the same patients for retest analysis. The data was statistically processed using SPSS v.13 software. Results received after the initial interviews: Cronbach's coefficient ( $\alpha=0.882$ ), Spearman-Brown coefficient ( $r_{sb}=0.998$ ), average inter-item correlation coefficient ( $R=0.426$ ), difficulty of the questions from 0.173 to 0.757 and discrimination power from 0.405 to 0.809. Results after the second interviews:  $\alpha=0.883$ ,  $r_{sb}=0.998$ ,  $R=0.507$ , difficulty from 0.287 to 0.757 and discrimination power from 0.524 to 0.809. In two of the questions, a low level of inter-item correlation with the rest of the items was found and they were excluded. The final version of the questionnaire contained 9 questions. The validation proved that the developed scale is sufficiently reliable and will be used in the final research, the first one to use such an instrument for measuring oral health-related quality of life in Bulgaria.

Key Words: periodontitis, quality of life, validation, scale.

## INTRODUCTION

Periodontal diseases in their most severe forms are one of the common oral diseases affecting 5-15% of the population in industrialized countries (1,2). Periodontal diseases involve structural and functional changes in the organs and tissues of oral cavity and are associated with gingival recession and formation of periodontal pockets. Pockets may lead to tooth mobility, gingival abscesses and loss of teeth (2). Furthermore, alteration of the speaking and chewing functions can be observed in patients with periodontitis (3-5), which may cause other health-related problems and general diseases.

Periodontal diseases are one of the main reasons for tooth loss among the population. A problem with a

great social significance as it leads to a psychological trauma in patients, equivalent to the loss of any other organ. In a result of the worsen aesthetics conditions, tooth loss influences individuals' emotional status by inducing shame (3). It might also lead to limited social interaction and affect other daily activities.

The relationship between individuals' oral health and quality of life has been extensively discussed (6-9) and a number of studies (10,11) have examined the periodontal diseases' impact on patients' quality of life (QoL). In these researches, different general oral QoL instruments, such as Oral Health Impact Profile (OHIP), Oral Health Quality of Life in UK (OHQoL-UK) and Oral Impacts on Daily Performance (OIDP) were used to evaluate oral-health related QoL. The above-

mentioned instruments measure health from a holistic conception including psychological and sociological aspects that only can be expressed by subjective feelings (12). Furthermore, some authors have validated QoL instruments based only on subjective criteria, without relating them to clinical indicators. Their main argument is that the presence of a disease does not always lead to a change in individuals' self-perception of QoL (13). Although these instruments have been used many times and have already proven their assessing qualities, it is hard to determine which of them the most effective one is. All these measures are developed to evaluate the impact of oral conditions on QoL and can be related to every oral disease. However a specific instrument for assessing the impact of periodontal diseases on QoL has not been validated (disease specific measure). This instrument is more likely to detect subtle changes in specific conditions thus having better responsiveness.

The purpose of this paper is to present the validation of a new original self-designed scale developed for assessing the impact of periodontal diseases on individuals' QoL of adult patients.

## MATERIAL AND METHODS

### Questionnaire

A new original instrument was designed and developed. The design phase of the scale included defining its content (writing of items) and construction of its format (type of the scale). The initial version contained 11 items (Table 1).

The authors grouped the 11 items into the following three subscales:

*Choice of food/nutrition, chewing, swallowing, talking:* Do you consider that the conditions of your gingiva/teeth: influence your choice of food, chewing of harder food, cause problems in swallowing and/or cause speaking difficulties?

*Social relations, friends and family, professional life:* Do you consider that the conditions of your gingiva/teeth have an influence on your self-esteem, outlook, family life, and professional and/or social contacts? Have you ever received negative comments from your friends and relatives in regards to your gingiva/teeth?

*Overall health:* Do you consider that the conditions of your gingiva/teeth have an influence on your general health?

### Coding of the Answers

Answers to every question were coded in a five-degree ranked scale depending on the degree of their influence (including 0 point when the patient considered that the asked issue did not have any influence): 1 point: insignificant influence; 2 points: weak influence; 3 points: moderate influence; 4 points: strong influence; 5 points: extremely strong influence. Overall rating (the sum of the points from the answers of all questions) varied from 0 to 45 total score.

### Patients

A pilot research was conducted for the validation

Table 1. Questions of the initial version of the pilot research.

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1. Do you consider that the conditions of your gums/teeth have an influence on your outlook?
  2. Do you consider that the conditions of your gums/teeth have an influence on your self-esteem?
  3. Do you consider that the conditions of your gums/teeth have an influence on your general health?
  4. Do you consider that the conditions of your gums/teeth have an influence on your choice of food?
  5. Do you consider that the conditions of your gums/teeth might cause problems in chewing of harder food?
  6. Do you consider that the conditions of your gums/teeth might cause problems in swallowing?
  7. Do you consider that the conditions of your gums/teeth might cause speaking difficulties?
  8. Do you consider that the conditions of your gums/teeth have an influence on your family life?
  9. Do you consider that the conditions of your gums/teeth have an influence on professional life?
  10. Do you consider that the conditions of your gums/teeth have an influence on your social contacts?
  11. Have you ever received a negative comments from your friends and relatives in regards to your gums/teeth?
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of face and content validity. The internal and external consistency of the scale was tested. Thirty patients were interviewed ( $n=30$ ) using a pilot version of the instrument. The minimum sample size of 30 people has been established based on a power analysis for sample size calculation. Age < 20 years was an exclusion criterion. The mean age of participants was  $48.95 \pm 11.85$  years, being  $56.67 \pm 9.05$  years for males and  $43.33 \pm 9.05$  years for females. As much as  $60.00 \pm 8.94\%$  had a high level of education.

All participants were clinically diagnosed with periodontitis and were visiting the Department of Periodontology, Faculty of Dental Medicine, Medical University of Plovdiv, Bulgaria in relation to their treatment. All patients were informed about the purpose of the research and gave their agreement to participate. After 3 months the same patients were interviewed again with the same questionnaire for the purpose of testing the stability of the scale and its reliability during the whole period of research.

### Statistical Processing

The results were processed statistically with the help of SPSS Statistical Package for Social Science, version 13 (SPSS Inc., Chicago, IL, USA). First, the internal consistency was assessed with the coefficient of Cronbach (Cronbach's alpha). Second, the changing factors were researched using the coefficients of Pearson ( $r$ ) and Spearman-Brown ( $r_{sb}$ ). Afterwards

in the research authors checked the reliability of the result by a performed test-retest analysis. The next step was to conduct an item analysis and to calculate the difficulty and discrimination power of all questions. Authors measured the difficulty as a proportion in which the average value refers to the maximum value, as the lowest level of response was coded with "0". The discrimination power was measured by the coefficient of linear correlation between the item rating and the overall unprocessed rating, from which the respective item was excluded.

## RESULTS

After the conduction of the above-explained pilot research with 30 patients diagnosed with periodontitis, the face and content validity of the instrument were confirmed. The Cronbach's alpha coefficient value in the initial version of the pilot research was equal to ( $\alpha=0.882$ ), the Spearman-Brown coefficient ( $r_{sb}=0.998$ ). Its high value confirmed the reliability of the scale. Important information about the reliability was derived from the average value of inter-item correlations ( $R=0.425$ ). In general, the lower the values of this coefficient, the greater the validity of the results (11) (Table 2).

The Pearson's coefficient in the conducted further research was  $r=0.997$ . The internal consistency was first evaluated by analyzing the matrix of inter-item correlations. Coefficients ranged from  $(-0.112)$  to

Table 2. Correlation coefficients between the items (initial version - 11 questions).

Q	1	2	3	4	5	6	7	8	9	10	11
1	1										
2	0.869	1									
3	0.851	0.775	1								
4	0.445	0.487	0.513	1							
5	0.440	0.435	0.415	0.786	1						
6	0.273	0.288	0.273	0.495	0.564	1					
7	0.394	0.373	0.296	0.633	0.747	0.784	1				
8	0.459	0.542	0.359	0.459	0.271	0.153	0.323	1			
9	0.467	0.576	0.382	0.288	0.113	-0.112	0.121	0.780	1		
10	0.705	0.779	0.500	0.289	0.124	0.199	0.280	0.662	0.672	1	
11	0.252	0.306	0.098	0.327	0.373	0.031	0.428	0.396	0.368	0.249	1

Average value of the inter-item correlations.  $R=0.425$ .

(0.869). In this initial version the coefficients of the discrimination power were relatively even and with high values from (0.405) to (0.809). The difficulty of the questions varied from (0.173) to (0.757).

After the statistical processing of the pilot version, two of the questions had to be excluded from the initial questionnaire (questions 6 and 11). After the second processing of the remaining 9 questions, the results were as follows: Cronbach's coefficient was  $\alpha=0.883$ , Spearman-Brown's coefficient was  $r_{sb}=0.998$ , the average inter-item correlation coefficient was  $R=0.507$ ; the values for difficulty of questions were: min = 0.287, max = 0.757. Also, authors defined the discrimination power values as being the lowest 0.524 and the highest 0.809 (Table 3).

## DISCUSSION

The purpose of this study was to evaluate the validity of an original scale to assess the impact of periodontal diseases in the QoL of patients, not prove the suitability of the use this instrument for a given age group. It is the first research to use such an instrument in measuring oral health-related QoL in Bulgaria. The scale was proven to be a precise, valid and reliable disease-specific instrument. The high value of the coefficient Cronbach's alpha in the present case equal to ( $\alpha=0.882$ ) proved the reliability of the instrument.

Two questions occurred to be problematic during the research of the internal consistency - the question of related to "swallowing problems" and to "negative comments by the closest friends and relatives". When calculating their correlation with the rest of the items (inter-item correlations), the results were extremely minimal values and even a negative value in one of the cases (-0.112). As in general, it is possible for a certain scale to have a high inter-item correlation as a whole, but between some of its items to exist low correlation or other adverse features, an item analysis was performed by the authors to avoid this problem.

In the present research the coefficients of the

discrimination power were relatively equal and with high values (varied in the range of 0.405- 0.809) with the exception of the above described two questions (0.405 and 0.417) where the lowest values were observed. The authors explained this with the fact that both questions are logically connected with already asked before questions. In the first case the chewing of harder food and the process of swallowing were in a close relation. In the other question the negative comments of the closest friends and relatives were directly related to family life and social contacts which patients had already commented. This was the logical ground based on which these questions were eliminated from the second statistical processing of data.

In the present study, the difficulty of the questions varied from 0.173 to 0.757. In general the acceptable limits for the difficulty are between 0.1 and 0.9 (14). Items for which the difficulty is below these limits give little information, therefore they can be excluded. Again the results for the two questions mentioned above were with the lowest values (0.173 and 0.207), another reason for excluding them from data processing. For greater certitude of the results the Cronbach's coefficient was calculated after the exclusion of every item of the scale. When excluding a well reconciled item this coefficient diminishes. In the current research, with the elimination of the two questions, which showed low inter-item correlation with the rest, the coefficient increased insignificantly to ( $\alpha=0.883$ ). All of the above arguments supported authors' decision that in the final research a 9-item scale should be used.

The analysis of the correlation coefficients among the questions of the scale in the pilot research and the results received after three months (test-retest) has proven the stability of the questions over a period of time. These coefficients showed insignificant differences, e.g.: at the beginning: 0.817; after 3 months: 0.800; or at the beginning: 0.639; after 3 months: 0.648.

Finally, the influence of periodontitis was assessed by calculating the total sum of the number of points that the answers to every question had given.

Table 3. Difficulty and discrimination power of the 9 questions remaining after revising the initial version of the scale to obtain a final version.

Question N	1	2	3	4	5	7	8	9	10
Difficulty $T_i$	0.717	0.690	0.757	0.500	0.470	0.287	0.390	0.413	0.553
Discrimination power	0.765	0.809	0.662	0.667	0.552	0.524	0.665	0.564	0.656

With the above described validation, the authors proved that the originally designed scale described in this paper is sufficiently reliable for assessing the impact of periodontal diseases on the QoL of patients. The instrument was efficient, easy to complete and easy to be administrated. These factors convinced the authors that the scale could be used in the final version of the research.

## RESUMO

O objetivo deste artigo é apresentar a validação de uma escala que mede o impacto das doenças periodontais sobre a qualidade de vida das pessoas na Bulgária. Foi feito um estudo piloto com 30 indivíduos diagnosticados com doença periodontal, entre os pacientes do Departamento de Periodontologia da Faculdade de Medicina Odontológica da Universidade de Medicina de Plovdiv, Bulgária. A amostra mínima de 30 pessoas foi estabelecida baseada em análise de potência para cálculo do tamanho de amostra. A idade média dos participantes foi de  $48,95 \pm 11,85$  anos, sendo de  $56,67 \pm 9,05$  para homens e de  $43,33 \pm 9,05$  para mulheres. Foram feitas entrevistas padronizadas usando um instrumento específico: um questionário com uma escala de 5 graus, contendo 11 perguntas iniciais. As entrevistas foram repetidas 3 meses depois, com os mesmos pacientes, para reanalisar o teste. Os dados foram processados estatisticamente pelo programa SPSS v.13. Os resultados das entrevistas iniciais foram: coeficiente de Cronbach ( $\alpha=0,882$ ), coeficiente de Spearman-Brown ( $rsb=0,998$ ), coeficiente de correlação média inter-item ( $R=0,426$ ), dificuldade das questões de 0,173 a 0,757 e potência de discriminação de 0,405 a 0,809. Os resultados da segunda série de entrevistas foram:  $\alpha=0,883$ ,  $rsb=0,998$ ,  $R=0,507$ , dificuldade de 0,287 a 0,757 e potência de discriminação de 0,524 a 0,809. Duas das questões apresentaram baixo nível de correlação inter-item e foram excluídas. A versão final do questionário continha 9 perguntas. A validação comprovou que a escala desenvolvida é suficientemente confiável e será usada na pesquisa final, a primeira a utilizar tal instrumento para mensurar a qualidade de vida relacionada à saúde oral na Bulgária.

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