

Validation of the Italian version of the Oral Health Impact Profile-14 (IOHIP-14)

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Summary

Objective. The original english version of Oral Health Impact Profile (IOHIP) was translated in Italian language, and then validated among a consecutive sample of patients attending in the dental ward at the Dental Institute of the “Sapienza” University of Rome, Italy.

Research design. The original english version of IOHIP-14 was translated into the Italian language by a professional translator and subsequently back-translated into English by an independent person and then validated. Participants: 852 person, 342 males (40.1%) and 510 females (59.9%) participated to this survey.

Results. The Cronbach’s alpha of the scale was 0.90. No correlation was negative and the correlation coefficients extended from 0.27 (the correlation between “pain” “irritable”) to 0.69 (the correlation between “totally unable to function” and “difficult to do jobs”). The coefficients ranged from 0.42 to 0.74 with no value above the drop-out value of 0.20 recommended for included an item in a 15 points scale. A highly significant relationship between the IOHIP scores and the perceived oral health status was observed. The subjects who perceived their oral health status to be poor had a higher IOHIP score than those thought their oral health status was good or fair. Similarly there was a significant relationship between the IOHIP scores and the perceived need for dental care.

Conclusions. The translated Italian version of

IOHIP-14 demonstrates an acceptable method to assess the impact of oral health on the quality of life, with evidence of reliability and validity, making it a promising instrument for assessing IOHIP in an adult population.

Key words: oral health, quality of life, IOHIP-14.

Introduction

Very few valid tools existed to assess functional and psychological outcomes of oral disorders until recently. The impact of health on an individual’s quality of life has been defined as ‘health-related quality of life’ (1). Oral health-related quality of life (OHRQoL) come out of the development of socio-dental indicators, in order to find out non-clinical aspects of oral health, broadening the focus of oral epidemiological research (2). Self-reported health measures have been demonstrated to reflect a pervasive mood disposition of negative affectivity (3). OHRQoL measures should also correspond to decision-making criteria (like treatment needs, timing etc).

The original 49-item IOHIP (Oral Health Impact Profile) was developed by Locker and Slade (2-4) and based on Locker’s conceptual model of oral health (5). It includes seven domains namely: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap. The validity and reliability of a short version of the questionnaire, the IOHIP-14, has been documented in several different clinical conditions like oral surgery, elderly, etc (6-7).

Three different scoring methods of the IOHIP-14 have been reported: 1- a simple summary of the recorded score (which is expressed as the sum of the seven raw sub-scale scores on a scale from 0 to 4 where a high score signifies worse OHRQoL); 2- a weighted and standardized summary score (where weights are attributed to every question within the domain); 3- the total number of problems reported (i.e. occasionally, often, or very often with a possible range of 0–14 problems) (8-10). The IOHIP scale originally developed in English has been recently translated into different languages (10-12) and the various versions of this scale have shown to be valid and reliable instruments to assess oral health-related quality of life in the different populations.

The aims of the study were to assess the validity and reliability of the Italian version of the Oral Health Impact Profile-14 (IOHIP-14).

Materials and methods

The study protocol received an ethical approval from the Ethics Committee of the "Sapienza" University of Rome n° 507/ 2007.

Study design

In 2005 a small pilot study (13) was carried out, in which the original 49-IOHIP was translated and then pre-validated. The results of this pilot study showed good reliability of the index, however an excessively time-consuming was noted. Since the IOHIP-49 is a long questionnaire and time-consuming to administer, the same research group decided to translate and validate the shorter and self-administrate IOHIP-14 scale in a larger sample population.

Translation procedure

In order to ensure a correct procedure for cross-cultural adaptation and linguistic validation, the Authors followed a translation/back-translation procedure. The IOHIP-14 scale was forward translated into Italian by two translators who are native Italian, are fluent in English and have experience of the issue; then a consensus version was identified and subsequently back-translated into English by an independent person who was not involved in the study to guarantee accuracy and comparability of the translation.

Selection of the sample

A consecutive sample of patients attending the Dental Department of the "Sapienza" University of Rome, Italy was invited to take part in this cross-sectional study during the first three weeks of the month of June 2007. All the subjects were recruited by the clinical staff, trained in the study protocol and procedures by the investigator team. The clinical staff explained the aim of the research and the procedures involved and asking the participation and to sign a consent form. Participants completed the questionnaire in the waiting room.

Cognitive disparity and communication problems among the participants may hamper the use of an instrument and seriously affect the results of scoring systems, so subjects with more than 5 missing answers were excluded from further analysis.

During the study period 1045 person attended to the Dental Department of the "Sapienza" University of Rome. All of them were asked to participated, 878 (acceptance rate 84.0%) accepted but the questionnaire was completed by 852 person, 342 males (40.1%) and 510 females (59.9%) that were enrolled for this survey. The IOHIP-14 scale consists of 14 questions or items about impacts that could arise as a result of problems in teeth, mouth or dentures and are grouped into seven dimensions or domains. The responses are made on a

5-point Likert type scale: 0=never, 1=hardly ever, 2=occasionally, 3=fairly often and 4=very often.

Data analysis

The unweighted Italian IOHIP-14 score was calculated by summing the scores of the responses to the 14 items while the unweighted IOHIP subscale scores were calculated by summing the scores of the responses to items corresponding to the subscales. Accordingly the IOHIP score could therefore range from 0 to 14 for an individual. Instrument reliability was measured by assessing internal consistency and test-retest reliability. Internal consistency was assessed using Cronbach's α (which measures the correlation between items, i.e. questions), for each of the seven health domains, and for all 14 items. To assess test-retest reliability, the intraclass correlation coefficient (ICC) was calculated based on the repeated subadministration of the questionnaire to 25% of the sample after 60 days. Cronbach's α values and test-retest ICCs above 0.5-0.7 (14-16) are generally considered to indicate sufficient reliability for an instrument or scale to be used to make group comparisons; instruments or scales with coefficients above 0.85 are considered reliable enough for individual patient comparisons. With regard to internal consistency, inter-item and corrected item-total correlation coefficients for the different IOHIP scale items were also calculated (Pearson's coefficient). The homogeneity of the scale was evaluated on the basis of the corrected item-total correlation coefficients computing the correlation between each individual item in the scale and the rest of the scale with the item of interest eliminated. Construct validity of the scale was assessed examining the association between perceived oral health status, perceived need for treatment, type of visit (first examination or recall visit) and the IOHIP scores using Kruskal Wallis test. The acceptability of the instrument was evaluated by calculating the number of missing items (non-responses). All data entry and analyses were conducted with the STATA SE 9.0 statistical analysis software from STATA Inc. (USA). Unless stated otherwise, the criterion for statistical significance was set at $\alpha=0.05$.

Results

Of the 852 individuals included in the survey, more than a quarter of the sample (30.99%) was aged more than 50 years and more than half of them (69.01%) were between 20-49 years (Tab. 1). Table 2 displays the correlation matrix for the 14 items of the IOHIP-14 scale. No correlation was negative and the correlation coefficients extended from 0.27 (the correlation between "pain" "irritable") to 0.69 (the correlation between "totally unable to function" and "difficult to do jobs"). The reliability was evaluated on the basis of the corrected item-total correlation coefficients (Tab. 3). The coefficients ranged from 0.42 (difficult

to relax) to 0.74 (interrupted meals) with no value above the drop-out value of 0.20 recommended to include an item in a 15 points scale. The Cronbach's alpha of the scale was 0.90. The results of the assessment of construct validity are shown in Table 4. A highly significant relationship between the IOHIP scores and the perceived oral health status was observed. The subjects who perceived their oral health status to be poor had a higher IOHIP score than those who thought their oral health status to be good or fair. Similarly there was a significant relationship between the IOHIP scores and the perceived need for dental care. These results support the construct validity of the translated IOHIP-14 scale.

Intraclass correlation coefficients for patients between baseline and second administration of the questionnaire (n= 219 subjects 25.70% of the total sample examined) were 0.74, and 0.72 using the total IOHIP-14, weighted and number of problems scoring methods, respectively (*data not in table*).

All subjects answered to all 14 items of the IOHIP questionnaire and there were no missing values. 7 items (8, 9, 18, 26, 30, 39, 44) lead to impact on less than 5% of the participants. At a closer examination, these items showed a connection to severe oral health related impacts such as eating/digestion impairment and the use of prostheses, which can be expected to be rather infrequent among young people.

Table 1. Gender and age distribution of the sample.

Age in years	Males	Females	Total
18-29	52	76	128
30-39	70	134	204
40-49	94	162	256
50-59	48	62	110
60-69	38	42	80
>69	40	34	74
Total	342	510	852

Discussion

The measurement of the oral health-related quality of life is, ideally, a culturally sensitive instrument, but this procedure is a costly and time-consuming work; an alternative method would be to translate an existing instrument and adapt it in an other language *i.e.* Italian. The present study therefore attempted at validating an Italian translation of the IOHIP-14 and to adapt the original English IOHIP version to the Italian cultural environment and to investigate its psychometric properties. The topic of the cross-cultural adaption of health-related self-reported measure have been debated in several reports (4, 17). The adopted instruments must be culturally and socially appropriate and reliable for the local population demonstrating also good psychometric properties. Therefore a rigorous translation and validation process is fundamental before an instrument build up for one culture could be used in another population group with a different culture.

The results of this study were considered sufficient for the instrument's use to discriminate subjects with different levels of perceived oral health and to evaluate changes in the OHRQoL in a typical target population of the questionnaire survey. The reliability of the instrument, assessed using Cronbach's alpha, was higher the standard criteria deemed (18); furthermore the value achieved in our paper was higher than those reported in the original English version (19). Since its development, the IOHIP-14 has been preferred to the IOHIP-49 by a number of researchers due to its practicality (10, 19). A considerable scientific evidence now exists on the validity and reliability of the IOHIP-14 (20).

The main reason for using the short form was to make available an efficient way of data collection based on the premise that a long questionnaire cannot be used in some research settings and clinical practices even though it provides more comprehensive data. A measure that takes a long time to be filled in may be not useful in a clinical setting (like a Dental Clinic) due to the burden placed on patients and clinicians (4, 20).

Table 2. Internal consistency: IOHIP inter-item correlation, correlation coefficients.

IOHIP	1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
1. Difficult pronounce words	—													
2. Worsened taste	0.53	—												
3. Pain	0.38	0.41	—											
4. Uncomfortable to eat	0.42	0.45	0.58	—										
5. Self-conscious	0.48	0.49	0.58	0.65	—									
6. Feel tensed	0.45	0.45	0.53	0.54	0.62	—								
7. Diet unsatisfactory	0.43	0.44	0.35	0.52	0.48	0.49	—							
8. Interrupted meals	0.47	0.50	0.48	0.54	0.56	0.52	0.58	—						
9. Difficult to relax	0.40	0.47	0.52	0.49	0.55	0.64	0.44	0.61	—					
10. Embarrassed		0.39	0.43	0.42	0.49	0.63	0.58	0.47	0.55	0.56	—			
11. Irritable	0.39	0.38	0.27	0.33	0.39	0.39	0.42	0.43	0.38	0.47	0.38	—		
12. Difficult to do jobs	0.41	0.39	0.36	0.35	0.39	0.40	0.49	0.52	0.53	0.43	0.49	0.49	—	
13. Life less satisfying	0.45	0.46	0.38	0.45	0.50	0.51	0.50	0.54	0.55	0.50	0.50	0.61	0.61	—
14. Totally unable to function	0.43	0.44	0.37	0.43	0.42	0.44	0.48	0.58	0.51	0.42	0.45	0.69	0.68	0.68

Pearson coefficient

Table 3. Reliability analysis: corrected item-total correlation and Cronbach's alpha.

IOHIP	Item-total correlation	Average total-item covariance	alpha
1. Difficult pronounce words	0.58	0.65	0.90
2. Worsened taste	0.60	0.65	0.90
3. Pain	0.59	0.64	0.90
4. Uncomfortable to eat	0.66	0.62	0.90
5. Self-conscious	0.72	0.61	0.89
6. Feel tensed	0.69	0.62	0.89
7. Diet unsatisfactory	0.64	0.64	0.90
8. Interrupted meals	0.74	0.62	0.89
9. Difficult to relax	0.42	0.61	0.92
10. Embarrassed	0.67	0.63	0.90
11. Irritable	0.55	0.66	0.90
12. Difficult to do jobs	0.64	0.64	0.90
13. Life less satisfying	0.70	0.63	0.89
14. Totally unable to function	0.67	0.64	0.90

Table 4. Association between type of visit, perceived oral health status, perceived need for dental care and IOHIP-14 scores.

Variable IOHIP-14 scores	Self perceived oral health	Self perceived oral health	
	status on first examination n (%)	status on recall examination n (%)	
Poor	190 (50.2)	251 (53.2)	P=0.02
Fair	132 (35.2)	172 (36.4)	
Good	55 (14.6)	52 (10.4)	
Variable IOHIP-14 scores	Self perceived need for dental care on first examination n (%)	Self perceived need for dental care on recall examination n (%)	
Yes	211 (55.8)	189 (39.9)	P=0.001
No	133 (35.2)	243 (51.3)	
Don't know	34 (9.0)	42 (8.9)	

Kruskal-Wallis test was used to test the differences between groups.

The high alpha value (0.90) indicates that the 14 items of translated IOHIP scale measures the same construct. The fit of a specific item to the scale was considered deleting the item and examining the change in the alpha value of the scale. It was evident from the results that the omission of any of the 14 items did not raise the Cronbach's alpha score of the scale. If an item is well fitted to its scale, the value of alpha would decrease when the particular item is deleted from the scale. This provides further evidence for the very satisfactory internal consistency of the translated scale.

The significant associations between the IOHIP-14 and subscales scores and the self-rated oral health status and subject's perceived treatment need supported the construct validity of the Italian version of IOHIP. All these results were able to suggest that the Italian version of IOHIP demonstrated good validity and reliability. The inclusion in this sample of irregular attenders – *i.e.* patients who only register when attending for an immediate problem may be considered a limitation of the

study, but the response rate was high and the results permitted to draw conclusions about the validity of the Italian version of IOHIP-14 in a wider general practice population of patients.

No general consensus exists about which method should be used to assess reliability, validity and responsiveness (10, 21). However, the α coefficients and test-retest coefficients observed seemed indicate the Italian IOHIP-14 as a reliable method.

However, a limitation in this study is that only subjective outcomes were used. Clinical data could reduce personal beliefs' influences on answers in a quality of life-related questionnaire.

Therefore, further studies of the properties of the Italian IOHIP-14 should be carried out including clinical assessment and testing of the questionnaire in populations with a higher disease burden/disease variation *i.e.* diabetic patients or older groups. Other aspects of the questionnaire should be checked as the responsiveness of Italian IOHIP-14 to changes in oral health conditions.

Conclusions

In conclusion, the translated Italian version of IOHIP was valid and reliable as the original English version of IOHIP and then it could be considered a valuable instrument for measuring oral health-related quality of life for the Italian population.

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