Validation the Oral Health Impact Profile (OHIP-14sp) for adults in Spain

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Abstract
Objectives: The oral health-related quality of life indicators are increasingly used to measure the impact of oral conditions on quality of life to complement clinical data in cross-sectional and longitudinal studies. One of the most internationally spread indicators is the Oral Health Impact Profile (OHIP-14), but it has still never been applied in Spain. The aim of this study was to validate the OHIP-14 for use among adults in Spain.

Study design:
A cross-sectional study was performed in Granada (Spain). A consecutive sample (n=270) of the Regional Government staff visiting the Employment Risk Prevention Centre for a routine medical check-up participated in this study. All participants self-completed the piloted OHIP-14sp and were examined according to World Health Organization methodology for caries, periodontal disease and prosthesis. Reliability analyses and validity tests were carried out to evaluate the psychometric properties of the OHIP-14sp by using two different methods of total scoring (i.e. the Additive and the Simple Count).

Results:
The reliability coefficient (Cronbach’s alpha) of the OHIP-14sp was above the recommended 0.7 threshold and considered excellent (alpha: 0.89). Some subjective factors (perceived dental treatment need, complaints about mouth and self-rated oral satisfaction) were strongly associated with both total scoring methods of the OHIP-14sp, supporting the criterion, construct and convergent validity. Moreover the impact levels were mainly influenced by caries data, e.g., number of teeth requiring extraction (r = 0.21; p<0.01) and number of decayed visible teeth (between premolars) (r = 0.17; p<0.01). The prevalence of impacts was 80.7% using the occasional or more frequently threshold. The most prevalently affected OHIP domains were “psychological discomfort” (53.7%), “functional limitation” (51.1%) and “physical pain” (42.2%).

Conclusions:
The OHIP-14sp is a precise, valid and reliable instrument for assessing oral health-related quality of life among adult population in Spain.

Key words: Oral health-related quality of life, sociodental indicators, self-assessment, cross-cultural validation.
Introduction
Measurement of the impact of oral conditions on quality of life should be part of the evaluation of oral health needs because clinical indicators alone cannot describe the satisfaction or symptoms of dental patients or their ability to perform daily activities. The Oral health-related quality of life (OHRQoL) indicators have already been used in cross-sectional and longitudinal studies (1-11).

The Oral Health Impact Profile (OHIP-14) is a 14-items questionnaire designed to measure self-reported functional limitation, discomfort and disability attributed to oral conditions (12). It is derived from an original extended version of 49-items (1) based on a theoretical model developed by the World Health Organization (WHO) (13) and adapted for oral health by Locker (2). In this model the consequences of oral disease are hierarchically linked from a biological level (impairment) to a behavioural level (functional limitation, discomfort and disability) and lastly to the social level (handicap).

The OHIP-14, in spite of being a short-questionnaire, has been shown to be reliable (12); sensitive to changes (14-15); and to have adequate cross-cultural consistency (16). The OHIP-14 is one of the most internationally spread OHRQoL indicators, available in several languages (Chinese, Finish, French, German, Japanese, Malaysian, Portuguese, Sinhalese, Somalian, Swedish...). A Spanish version have been recently validated (17) using a large sample of Chilean adolescents, but its abbreviated-form has still never been applied among adult Spanish populations where the presence and severity of dental disease is expected to be higher and never have been evaluated in terms of impact on quality of life.

The aim of this study was to validate the short-form of OHIP-14 among Spanish Adults.

Material and Methods
OHIP-14 (Oral Health Impact Profile)
The OHIP-14 is a self-filled questionnaire that focuses on seven dimensions of impact (functional limitation, pain, psychological discomfort, physical disability, psychological disability, social disability and handicap) with participants being asked to respond according to frequency of impact on a 5-point Likert scale coded never (score 0), hardly ever (score 1), occasionally (score 2), fairly often (score 3) and very often (score 4) using a twelve-months recall period.

Validation process
The process of developing and evaluating the short form of the OHIP for the Spanish population (OHIP-14sp) consisted of three main steps: linguistic and cultural adaptation of the original instrument to the Spanish setting; pilot study to assess face and content validity and main study to assess the reliability and construct validity. The study was developed during year 2004.

Linguistic and cultural adaptation
Because, to our knowledge, the OHIP-14 had not previously been used in Spain, it was piloted to assess the face and content validity within the target population. The OHIP-14 was linguistically and culturally adapted to our setting by using the back translation technique (18) in order to maintain cross-cultural equivalence. In this procedure, translations were independently made by two bilingual dentists, who then discussed and produced a consensus Spanish version, which was translated back into English by a professional English native translator who had never seen the original version. The conceptual equivalence between the original instruments and the back-translated versions was supported by an expert committee (formed by 5 University researchers on quality of life studies). The definitive Spanish version was produced after the face and content validity results in the pilot study had been approved by this committee.

Pilot study
All changes required to improve the intelligibility of OHIP-14sp were carried out before the main study started. Ethical approval and specific written consent were obtained from the relevant authorities (Bioethical Committee of the University of Granada) before the pilot and main studies were started. The pilot study was conducted in a convenience sample (n=54) obtained from patients and their companions who came to the School of Dentistry (Granada University) for an oral check-up. Participants were clinically examined according to the WHO methodology (19) and completed the pilot OHIP-14sp. The comprehensiveness of the instrument was tested by asking about difficulties in understanding items or frequencies, in order to optimise the face and content validity before the main study.

Main Study
A cross-sectional epidemiological study was performed in Granada capital and province (Andalusia, Spain). A consecutive sample of healthy Andalusiа’s Government staff visiting the Employment Risk Prevention Centre for a routine medical check-up was invited to take part in this study. All participants were briefed about the purpose and process of the study and the approved written consent was obtained. Ethical authorities (Bioethical Committee of the University of Granada) before the pilot and main studies were started. The pilot study was conducted in a convenience sample (n=54) obtained from patients and their companions who came to the School of Dentistry (Granada University) for an oral check-up. Participants were clinically examined according to the WHO methodology (19) and completed the pilot OHIP-14sp. The comprehensiveness of the instrument was tested by asking about difficulties in understanding items or frequencies, in order to optimise the face and content validity before the main study.

OHRQoL data were gathered by using the piloted OHIP-14sp which was self-administered and completed in the waiting room and after the oral examination was conducted in a private quiet room by a trained and calibrated examiner. Oral examinations were performed by an examiner calibrated for the criteria established in the 1987 WHO dossier (19). Moreover, participants were asked to rate their global oral satisfaction on a 0 to 10 visual analogue scale. Measuring self-assessment of oral satisfaction is an attractive method to contrast the convergent validity of OHRQoL instruments (20, 21).

As there is no universally accepted gold-standard for assessing criterion and construct validity of quality of life measures, data on perceived dental treatment needs and complaints related to the mouth were also collected because
these subjective criteria could be used as a proxy, since a key property of these instruments is their contribution to needs assessment and perceived impairments evaluation.

Data analysis

The psychometric properties of an instrument for measuring perceptions must be tested by evaluating its reliability and its validity. In multi-items instruments, the reliability must be evaluated by testing the internal consistency or homogeneity of the scale, which means that each domain of the instrument assesses distinct aspects of the same attribute or construct (22). The internal consistency was calculated using standardised Cronbach’s alpha, alpha if item deleted, inter-item and item-total correlation coefficients.

The OHIP-14sp utility was tested according to different types of validity. Face and content validity were checked in Pilot Study. Criterion and construct validity were tested by using the Student’s T test, ANOVA and correlations coefficients.

Two different methods of scoring were used. First, the “simple count method” (OHIP-SC) in which total score was calculated by summing the number of impacts reported as occasionally or more frequently. Second, the “additive method” in which total score was calculated summing the item codes for the 14 items at whatever frequency (OHIP-A). In the original derivation of the instrument, items were weighted according to data collected among older people in Australia (12), but subsequent investigation has confirmed that items weights did not improve the performance over an unweighted scoring method (23, 24).

The Statistical Package for Social Sciences (SPSS) v.15 (SPSS Inc., Chicago, IL) was used for the statistical analyses taking the cut-off level for statistical significance at 0.05.

Results

Sample description

For a three-week period of data collection, 295 healthy workers visited the Center, 270 of whom participated in the study (91.5%) and 25 were drop out, but all were similar in terms of socio-demographic characteristics. The mean age of participants was 45.2 ± 9.5 years (mean ± standard deviation), 45.6% were male, 83.3% were non manual workers and 57% live in Granada capital. In behavioural terms 93% of subjects brushed their teeth at least once a day and 33% visited routinely the dentist at least once a year.

On clinical examination, participants mostly showed a good state of oral health. More than 90% were dentate with a mean of 6.4 ± 2.2 posterior occlusal units and 5.7 ± 1.0 anterior occlusal units. The sample had a mean of 26.4 ± 5.6 healthy non-restored teeth. The Decayed, missing and filling teeth (DMFT) index was 10.7 ± 5.0, with 3.2 ± 2.5 being decayed, 3.3 ± 3.7 missing and 4.3 ± 3.5 filling teeth. The periodontal status showed a Community Periodontal Index (CPI) score of zero in 3.1 ± 2.2 sextants.

Cross-cultural adaptation

The comparison between the original OHIP-14sp and the back translated English version did not reveal conceptual content differences. The high intelligibility was verified in the pilot study with no missing items of the self-answered questionnaire. In main study, 9 of the 270 subjects (3.3%) were required to fill one or two missing items, but no more items were missing per person, and no misunderstanding items were reported.

Reliability

The OHIP-14sp internal consistency was first evaluated by analysing the matrix of inter-item correlations which found a positive correlation between all items. Coefficients ranged from 0.10 (between item-2 and item-14) to 0.63 (between item -3 and item -4) but no variations in magnitude were large enough for an item to be considered redundant. Also the item-total correlation analysis (correlation between an item and the rest of the scale) showed that all items coefficients were above the minimum recommended (0.20) for inclusion in a scale (22), ranging from 0.39 (item-1) to 0.72 (item-6). The standardised Cronbach’s alpha value derived from the correlation matrix was 0.89, considered excellent (22). Moreover it was also demonstrated that this alpha value was not increased by the removal of any item. In fact, the removal of some items lowered this value, supporting the inclusion of all original items.

Validity

Face and content validity were confirmed in the pilot study with no missing or misunderstanding items. The simple format of the self-administered questionnaire with a frequency Likert-type scale of self-reported oral impacts was considered sufficient by the expert committee to verify its face validity. The content validity was also considered satisfactory since OHIP-14sp enquires into a broad spectrum of physical, psychological and social dimensions potentially affected by oral conditions and because these dimensions emerge from a sound theoretical base that has been tested among a wide range of cultural profiles.

Criterion validity was assessed by using a single-item assessment of perceived treatment need (Table 1). Individuals reporting dental treatment need obtained a significantly higher OHIP score with both additive (10.4 – 13.2) and simple count scoring methods (3.1 – 4.1) compared with those perceiving no treatment need. With respect to the construct validity, the mean total OHIP scores were significantly lower in those with no complaints about the mouth. Regarding convergent validity, the OHIP scores were significantly lower in the than in the neutral or dissatisfied groups.

Construct validity was also supported by the fact that oral diseases normatively assessed are coherently correlated with total OHIP scores (Table 2). The impact levels were mainly influenced by caries data, e.g., number of teeth requiring extraction (r = 0.21) or endodontic treatment (r = 0.19), and number of decayed visible teeth (r = 0.17). Also some prosthodontic variables were found statistically correlated with OHIP (Type of edentulism, number of occlusal units, number of missing and replaceable teeth...), but no periodontal variables were significantly associated with oral impacts. Furthermore the normative need estimations for dental restoration were significantly correlated with both scoring methods.
### Table 1. Validity Test for OHIP-14 with both additive (OHIP-A) and simple count (OHIP-SC) scoring method (n=270). Student Test and ANOVA.

<table>
<thead>
<tr>
<th></th>
<th>n (%)</th>
<th>OHIP-A (95% Confidence Interval)</th>
<th>OHIP-SC (95% Confidence Interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CRITERION VALIDITY</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PERCEIVED DENTAL NEED</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NO</td>
<td>150 (55.5%)</td>
<td>6.7 – 8.9</td>
<td>1.7 – 2.5</td>
</tr>
<tr>
<td>YES</td>
<td>120 (44.4%)</td>
<td>10.4 – 13.2</td>
<td>3.1 – 4.1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>p&lt;0.001</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td><strong>CONSTRUCT VALIDITY</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PERCEIVED ORAL WELLBEING</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No complaint</td>
<td>178 (65.9%)</td>
<td>4.8 – 6.8</td>
<td>1.1 – 1.7</td>
</tr>
<tr>
<td>With complaint</td>
<td>92 (34.1%)</td>
<td>10.4 – 4.8</td>
<td>3.1 – 4.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>p&lt;0.001</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td><strong>CONVERGENT VALIDITY</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ORAL SATISFACTION</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;= 5 (DISSATISFIED)</td>
<td>40 (14.8 %)</td>
<td>15.7 – 21.1</td>
<td>4.9 – 7.0</td>
</tr>
<tr>
<td>5 (NEUTRAL)</td>
<td>25 (9.3 %)</td>
<td>8.2 – 12.2</td>
<td>2.6 – 4.2</td>
</tr>
<tr>
<td>&gt;5 (SATISFIED)</td>
<td>205 (75.9 %)</td>
<td>7.0 – 8.7</td>
<td>1.8 – 2.4</td>
</tr>
<tr>
<td></td>
<td></td>
<td>p=0.001</td>
<td>p&lt;0.001</td>
</tr>
</tbody>
</table>

### Table 2. Construct Validity. Correlations with clinical criteria and normative needs for the total score of OHIP-14sp using both additive and simple count methods. (n = 270).

<table>
<thead>
<tr>
<th>CLINICAL VARIABLES</th>
<th>OHIP-A</th>
<th>OHIP-SC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nº healthy unfilled teeth</td>
<td>r = -0.12*</td>
<td>r = -0.14*</td>
</tr>
<tr>
<td>Nº teeth requiring extraction</td>
<td>r = 0.19**</td>
<td>r = 0.21**</td>
</tr>
<tr>
<td>Nº teeth requiring endodontic treatment</td>
<td>r = 0.17**</td>
<td>r = 0.19**</td>
</tr>
<tr>
<td>Nº decayed visible teeth</td>
<td>r = 0.17**</td>
<td>r = 0.16**</td>
</tr>
<tr>
<td>DMFT Index (Decayed Missing and Filled Teeth)</td>
<td>r = 0.13*</td>
<td>r = 0.13*</td>
</tr>
<tr>
<td>Type of edentulism (Eichner Index)</td>
<td>r = 0.15*</td>
<td>r = 0.15*</td>
</tr>
<tr>
<td>Nº occlusal units</td>
<td>r = -0.13*</td>
<td>r = -0.15*</td>
</tr>
<tr>
<td>Nº missing teeth</td>
<td>r = 0.13*</td>
<td>r = 0.14*</td>
</tr>
<tr>
<td>Nº replaceable functional teeth</td>
<td>r = 0.10</td>
<td>r = 0.13*</td>
</tr>
<tr>
<td>Nº natural teeth present</td>
<td>r = 0.11</td>
<td>r = 0.13*</td>
</tr>
<tr>
<td>NORMATIVE NEEDS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normative Needs for dental restoration</td>
<td>r = 0.16**</td>
<td>r = 0.18**</td>
</tr>
<tr>
<td>Normative Needs for prosthesis</td>
<td>r = 0.04</td>
<td>r = 0.13*</td>
</tr>
<tr>
<td>Normative Needs for periodontal treatment</td>
<td>r = 0.01</td>
<td>r = 0.04</td>
</tr>
</tbody>
</table>
**Fig. 1.** Prevalence of impacts and mean scores of the OHIP-14 domains and total scores using an “occasional” threshold.

**Fig. 2.** Correlation (Pearson’s Coefficient) of self-rated oral satisfaction with OHIP-14 domains and total scores. (p<0.01)
{

Prevalence of oral impacts
In this study, 80.7% of participants reported at least one impact in an occasional or more frequently manner during the last year (Figure 1). Using this threshold the most prevalent domain was “psychological discomfort” 53.7% followed by “functional limitation”, “physical pain”, “psychological disability”, “physical disability”, “social disability” and “handicap”. The mean total “additive score” of the OHIP-14sp was 8.7 – 10.5. Using the “simple count” method for “occasional” threshold OHIP-14sp scored 2.5–3.1 and mean domain scores ranged between 0.2 – 0.3 for ‘handicap’ and 1.1 – 1.3 for ‘psychological discomfort’ (Figure 1).

A high correlation was found between self-rated oral satisfaction scores and Global OHIP-A (r = -0.51; p<0.01) showing the expected inverse relationship. Moreover this high correlation was also observed within all domains of the OHIP, ranging between r = -0.40 for “social disability” and r = -0.49 for “psychological discomfort” and “physical pain” (Figure 2). Thus, oral satisfaction was mainly influenced by the “physical pain” and “psychological discomfort” domains. Another impact-related issue was that 44.4% of the sample perceived dental treatment needs and 34.1% had any complaint related to mouth, but only the 14.8% were dissatisfied with mouth (Table 1).

Discussion
Cross-cultural adaptation procedures are a critical component of the validation process of an instrument that has been developed among other target population. In the present study, the translation process from English to Spanish was straightforward and the comparison between the original OHIP and the back translated English version did not reveal conceptual nor content differences. The equivalent words needed for translation of the questionnaire were not difficult to find because of the simple structure of the OHIP-14, and the universal nature of its contents.

This study was, to our knowledge, the first using the OHIP-14 on Spanish population and the first in focusing on oral health-related quality of life among adult population in Spain. However it was carried out in a specific region (Andalusia) of a country that presents a variety of cultural, gastronomic and social values, so that it could not represent the wide range of Spanish population values. But in clinical terms the oral health status of this sample is comparable with that reported in the last National Oral Health Survey in Spain for such age and socio-occupational group (25).

The OHIP-14sp is a precise, valid and reliable instrument for use among adult population in Spain, since it could discriminate between groups (Table 1), it is coherently correlated with different clinical conditions (Table 2), and it has an excellent internal reliability (α=0.89). These are the critical psychometric properties for health status measures (22) that make the OHIP-14sp suitable for assessing OHRQoL in adult Spanish population.

Construct validity of the instrument was mainly supported by using subjective criteria (Table 1), as other authors (26-28), because quality of life indicators are designed to measure health from a holistic conception which is increasingly recognized as including psychological and sociological aspects that only can be expressed by subjective feelings. This was confirmed in our setting since the highest correlation between self-rated oral satisfaction and the seven subscales was found in “psychological discomfort” and “physical pain” (r = -0.49; p<0.01), and also the former was the most prevalent domain (53.7%) for the occasional threshold (Figure 1). Furthermore, discriminative validity was confirmed by checking that the instrument was able to discriminate between subgroups (Table 1). From a clinical perspective the presence of decayed teeth needing extraction or endodontic treatment were found to be the main factors affecting OHRQoL, since they are usually pain-related conditions. But also the localization of decayed teeth in the visible area (premolars, canines or incisors) demonstrated significant association (p<0.01) with the impact level, because the social and psychological dimensions of oral diseases should be of paramount importance among this population and it is properly gathered by the OHIP. However no periodontal variables were found to be correlated with the impact level, maybe because they only had an influence when the disease was advanced and accompanied by tooth mobility, and that was a rarely event among this healthy sample. All these clinical modulating factors were previously found in epidemiological studies using the OHIP (29-30).

The prevalence of oral impacts found in this study is higher than previous reports using the extended versions of the OHIP among comparable populations (17) or the original OHIP-14 derivation study (12), but is similar to that reported in the last National Oral Health Survey in Spain in which two single items of “physical pain” and “functional limitation” were assessed using the same response Likert-format (25). The highest oral health impact was observed within the following domains; ‘psychological discomfort’, ‘functional limitation’ and ‘physical pain’; suggesting that these dimensions are the most prevalently affected among this sociodemographic profile of the Spanish population. The high prevalence is of concern since the sample was comprised by individuals with a good oral health state who were not seeking dental treatment.

We have used the “occasional” threshold to estimate the prevalence as it was made in the original derivation of the instrument (12) but it probably contributes to “false positive” because rare impacts could be incorrectly reported at the occasional threshold. Also a twelve-months recall period could influence the overestimation of such occasional episodes.

The two scoring methods of the total OHIP score (Additive and Simple Count) seemed to be of comparable utility and must be used for complementary analyses since they correlated with different criteria.

Future efforts must be directed towards exploring the ultimate modulating factors or traits that make subjects to feel needs for dental treatment, complaints or to perceive frequently
some oral impacts in spite of the good oral health status and the high satisfaction level. Despite of the increasing number of rigorous studies focusing on quality of life we still know relatively little about how oral conditions affect people feelings of wellbeing.

The cross-sectional design adopted in this study, although indicated for validation, reduces the level of evidence of the associations found. Longitudinal case-control studies are warranted to evaluate the sensitivity of the OHIP-14sp to detect changes in oral well-being after therapeutic interventions. In that sense the high sensitivity of the OHIP-14sp to capture oral impacts in this setting of non-dental patients, could favour the “size effect” calculation since almost all total scores could be improved.

References

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The OHIP-14sp is freely available from the corresponding author at jamiont@usal.es.