INTRODUCTION The Oral Health Impact Profile (OHIP-14) has been used extensively to measure the impact of oral disease on oral health-related quality of life (HRQoL) but has not been validated in the Urdu language or tested in gastroenterology.

AIMS To validate the OHIP-14 for use in Pakistan and its ability to assess oral health in patients with upper gastrointestinal (GI) and hepatic disorders.

DESIGN Multicentre, cross-sectional.

SETTING Four major tertiary care hospitals.

METHODS The OHIP-14 was tested for reliability and validity in 700 patients referred for oesophago-gastro-duodenoscopic (OGD) investigation of the symptoms of upper GI or hepatic disease. Socio-demographic details and oral examination findings (for oral lesions and DMFT) were recorded.

RESULTS The mean (±standard deviation) total OHIP-14 score (range 0–56) was estimated to be 23.38 ± 10.47, indicating a significant impact of upper gastrointestinal and hepatic disorders on oral health. The reliability coefficient of the OHIP-14 was above 0.7 threshold, and the tool had good internal consistency (α = 0.83). When associated with worsening DMFT (decayed, missed, and filled teeth) index value, the highest correlations (p < 0.01) were detected with functional limitation (rs = 0.234), physical disability (rs = 0.230), and psychological discomfort (rs = 0.221).

CONCLUSION The OHIP-14 is a precise and valid instrument for assessing oral-HRQoL in a gastroenterological setting amongst Pakistani population.
The OHIP-14 has been translated, validated, and implemented in many countries and languages, including Greek,26 Arabic,21 Hindi,22 Brazilian,23 Spanish,5,20 Sinhalese,25 and Burmese.26 However, it has not been validated in the Urdu language in Pakistan or in patients with upper gastrointestinal (GI) or hepatic disease.17,19-22 The aims of this study were to assess the reliability and validity of the OHIP-14 in the Pakistani population and to demonstrate its psychometric properties with regard to OHRQoL in patients undergoing endoscopy (oesophago-gastro-duodenoscopic (OGD)) for upper GI or hepatic disease.

MATERIALS AND METHODS

Design

A cross-sectional study was carried out in patients referred for OGD investigation of symptoms of upper GI or hepatic disease in Karachi and the twin cities of Rawalpindi–Islamabad, where more than 10% of the Pakistani population resides,22 between December 2014 and April 2015. The sampling units comprised four major tertiary care hospitals (Civil Hospital Karachi, Jinnah Postgraduate Medical Centre, Pakistan Institute of Medical Sciences Islamabad, and Holy Family Hospital Rawalpindi). A free dental consultation was provided for all study participants and intraoral examination was performed by a calibrated single examiner (IW).33 All participants also attended an interview during which a self-administered questionnaire was completed. Patients who had extremely limited mouth opening that precluded an oral examination, those undergoing emergency procedures, those who had extremely limited mouth opening that precluded an oral examination, those undergoing emergency procedures, those who were unconscious or non-cooperative, and those who were attending only for follow-up were excluded.

The study protocol was approved by the ethical committees at each participating hospital before any patients were enrolled. Written informed consent was taken from all study participants after explaining the study protocol.

HRQoL assessment using the OHIP-14

The OHIP-14 was piloted after translation into Urdu using the translation technique described by Guillemin et al.34 and then assessed for its reliability and validity in the Pakistani setting. A pilot study was undertaken in 30 subjects to ensure that the proforma was comprehensive. The study participants then underwent an oral clinical examination for any abnormal hard or soft-tissue findings, which might contribute adversely to oral health and health in general.

Sample size

The sample size was calculated using OpenEpi software taking the highest-recorded mean percentage for the OHIP-14,5 i.e., 80% with a 5% margin of error and a 95% confidence interval. A minimum study sample size of 246 was calculated to be necessary; however, we were able to recruit a sample of 760 patients from the four tertiary hospitals, which cater patients from all states in Pakistan.

Data collection

The proforma consisted of three domains. The first domain was history-taking to obtain data on socio-demographics and associated risk factors. The second domain consisted of an assessment of the oral, upper GI, and hepatic disorders based on the HRQoL and was measured using a universal validated index, i.e., the OHIP-14.6 The third domain comprised an oral examination that recorded clinical changes in the hard and soft tissues, dental caries assessment, and the presence of oral submucosal fibrosis (OSF) using the oral screening methods recommended by the World Health Organization (WHO).35

Assessment of socio-demographics and risk factors

A self-administered questionnaire was used to elicit data on age, sex, monthly income and socio-economic status, race/ethnicity, residence, dietary pattern, smoking, alcohol, tea, and oral tobacco consumption, medical history, drug history (including use of non-steroidal anti-inflammatory drugs (NSAIDs), opioid painkillers, and other over-the-counter medications), and comorbidities. Findings of OGD, laboratory investigations, or detailed upper GI examination suggestive of a current upper GI or hepatic disorder were recorded.

Oral examination

Oral examinations were performed according to an established ethical protocol.33 In line with WHO community indices,35 all patients were screened for abnormal mucosal or/and hard or soft-tissue lesions, including gingivitis, angular cheilitis, xerostomia, dental erosions, ulceration, abscess, leukoplakia, erythroplakia, lichen planus, and candidiasis. Inter-incisal mouth opening was measured and intra-oral palpation was performed to assess fibrotic banding and stiffness of the oral mucosa for diagnosis and staging of OSF.36 Dental hard-tissue status was assessed using DMFT (decayed, missed, and filled teeth) index values.25

Statistical analysis

The data were analyzed using SPSS version 21.0 software (SPSS Inc., Chicago, IL, USA). Descriptive statistics are presented as the mean (and standard deviation) and and frequency percentage. Associations between the study variables were assessed using non-parametric tests.

The psychometric properties of the OHIP-14 tool were analyzed using reliability and validity tests.37 The validation process consisted of language adaptation of the original instrument, a pilot study to eliminate confusing and conflicting parts and make it culturally adaptable for all ethnicities, and the main study to assess reliability and validity.37,38 The reliability of the OHIP-14 is based on internal consistency and homogeneity. Internal consistency was calculated using the standardized Cronbach’s alpha and alpha item if deleted.20 The degree of homogeneity was evaluated within seven subscales on the basis of corrected item-total correlation coefficients.25

Convergent validity was used as a tool to establish the validity of the OHIP-14.37 Based on the method of evaluation followed by the previous study,20 our study assumed that a higher value of DMFT (i.e., poorer dentition/oral hard tissues) would be associated with higher OHIP-14 scores and hence, with lower levels of OHRQoL.6,20 In addition, the statistical significance of differences in mean OHIP-14 scores and DMFT index value, OSF, and oral lesions was assessed using the Mann–Whitney U and Kruskal-Wallis tests.

Total OHIP-14 scores were calculated using the additive scoring method devised by Robinson et al.39 The scores possible on the OHIP-14 range from 0 to 56, with higher scores indicating poor oral health (lower OHRQoL) and vice versa. Roumani et al.20 illustrate OHIP-14 cut-off values for ‘good oral health (OH)’ with OHIP-14 score <9.33 (SD ± 6.5) and ‘poor OH ≥11.0 (SD ± 6.9).

RESULTS

Sixty of the 760 patients initially considered eligible for the study were excluded because of the failure to answer all questions on the questionnaires, leaving data on 700 patients available for analysis (response rate 100%, while generating a completion rate of 92%).

Demographics

Table 1 shows the socio-demographics of the 700 patients (male, 55%; mean age 45 years) who underwent OGD. Sixty-two percent were urban-dwellers and 38% were rural-dwellers. The majority were from the Punjab (44.3%) and Sindh (39.3%) regions and most (69%) of them were of very-low socio-economic status. Habitual drinking of tea was common (77.6%), along with consumption of
Table 1. Socio-demographics and risk factors

| Demographic characteristics | Frequency (n) | (%) |
|-----------------------------|--------------|-----|
| Gender                      | Male         | 385 | 55 |
|                             | Female       | 315 | 45 |
| Age groups (in years)       |              |     |    |
|                             | 12–19        | 51  | 7.3|
|                             | 20–30        | 96  | 13.7|
|                             | 31–40        | 122 | 17.4|
|                             | 41–50        | 181 | 25.9|
|                             | 51–60        | 130 | 18.6|
|                             | 61–70        | 93  | 13.3|
|                             | 70 and above | 25  | 3.6|
| Residence/background         | Urban        | 434 | 62 |
|                             | Rural        | 266 | 38 |
| Province                     | Sindh        | 275 | 39.3|
|                             | Punjab       | 310 | 44.3|
|                             | Balochistan  | 19  | 2.7|
|                             | Khyber       | 66  | 9.4|
|                             | Pakhtunkhwa  | 30  | 4.3|
|                             | Kashmir      | 483 | 69 |
| Monthly income (in PKR)     |              |     |    |
|                             | <15000       | 196 | 28 |
|                             | 15000–3000    | 21  | 3.0|
|                             | 30000–5000    | 302 | 43.1|
| Dietary pattern              | Healthy diet | 86  | 12.3|
|                             | Satisfactory diet | 312 | 44.6|
|                             | Unhealthy diet| 302 | 43.1|
| Addiction profile           | Smoking      | 151 | 21.6|
|                             | Alcohol      | 13  | 1.9|
|                             | Oral tobacco | 190 | 27.1|
|                             | Tea          | 543 | 77.6|
| Comorbid conditions          | Diabettes mellitus (DM) | 150 | 21.4|
|                             | Hypertension | 228 | 32.6|
| Pain history and NSAIDS consumption | General body pain (NSAIDS) | 285 | 40.7|
|                             | Pain killer intake | 342 | 48.9|
| Weight loss (kilograms)     | 0            | 201 | 28.7|
|                             | 01–05        | 297 | 42.4|
|                             | 05–10        | 65  | 9.3|
|                             | 10–15        | 74  | 10.6|
|                             | 15–20        | 44  | 6.3|
|                             | >20          | 19  | 2.7|
| Gastric maladies            | Oesophagal varices | 256 | 36.6|
|                             | GORD         | 187 | 26.7|
|                             | Gastritis    | 169 | 24.1|
|                             | Peptic ulcer disease (PUD) | 58  | 8.3|
|                             | Oesosophagitis | 39  | 5.6|
|                             | Other minor GI disorders | 129 | 18.4|
| Liver disorders             | Hepatitis B  | 25  | 3.6|
|                             | Hepatitis C  | 230 | 32.9|

Table 1 continued

| Demographic characteristics | Frequency (n) | (%) |
|-----------------------------|--------------|-----|
| Pain history and NSAIDS consumption | General body pain (NSAIDS) | 285 | 40.7|
|                             | Pain killer intake | 342 | 48.9|
| Weight loss (kilograms)     | 0            | 201 | 28.7|
|                             | 01–05        | 297 | 42.4|
|                             | 05–10        | 65  | 9.3|
|                             | 10–15        | 74  | 10.6|
|                             | 15–20        | 44  | 6.3|
|                             | >20          | 19  | 2.7|
| Gastric maladies            | Oesophagal varices | 256 | 36.6|
|                             | GORD         | 187 | 26.7|
|                             | Gastritis    | 169 | 24.1|
|                             | Peptic ulcer disease (PUD) | 58  | 8.3|
|                             | Oesosophagitis | 39  | 5.6|
|                             | Other minor GI disorders | 129 | 18.4|
| Liver disorders             | Hepatitis B  | 25  | 3.6|
|                             | Hepatitis C  | 230 | 32.9|

Age groups (in years) 12–19: 51 (7.3%); 20–30: 96 (13.7%); 31–40: 122 (17.4%); 41–50: 181 (25.9%); 51–60: 130 (18.6%); 61–70: 93 (13.3%); 70 and above: 25 (3.6%)

Residence/background Urban: 434 (62%); Rural: 266 (38%)

Province Sindh: 275 (39.3%); Punjab: 310 (44.3%); Balochistan: 19 (2.7%); Khyber: 66 (9.4%); Pakhtunkhwa: 30 (4.3%); Kashmir: 483 (69%)

Monthly income (in PKR) <15000: 483 (69%); 15000–30000: 196 (28%); 30000–50000: 21 (3.0%)

Dietary pattern Healthy diet: 86 (12.3%); Satisfactory diet: 312 (44.6%); Unhealthy diet: 302 (43.1%)

Addiction profile Smoking: 151 (21.6%); Alcohol: 13 (1.9%); Oral tobacco: 190 (27.1%); Tea: 543 (77.6%)

Comorbid conditions Diabettes mellitus (DM): 150 (21.4%); Hypertension (HTN): 228 (32.6%)

Pain history and NSAIDS consumption General body pain (NSAIDS) Pain killer intake: 342 (48.9%)

Weight loss (kilograms) 0: 201 (28.7%); 01–05: 297 (42.4%); 05–10: 65 (9.3%); 10–15: 74 (10.6%); 15–20: 44 (6.3%); >20: 19 (2.7%)
the basis of corrected item–total correlation coefficients. The degree of homogeneity within the seven subscales of the OHIP instrument ranges from 0.1 (psychological discomfort) to 0.7 (physical and psychological disability). The corrected item–total correlation coefficient values ranged from 0.335 to 0.587, i.e., >0.2,
which is the standard for inclusion of an item in OHIP subscale.22,37

Validity
The results for the convergent validity of the OHIP-14 are shown in Table 5. According to the WHO guidelines, a DMFT index value <3 is categorized as very low caries, a score of 4–10 as average, and a score of 11–32 as poor.35,40 An increasing trend for OHIP-mean with worsening DMFT is evident, with most affected subscales being social disability (7.31 ± 2.63), physical disability (5.55 ± 2.73), and psychological discomfort (4.64 ± 1.89); while the least affected being physical pain (0.84 ± 1.10). All Spearman’s rank correlation coefficients were positive and statistically significant (p < 0.001), with the highest correlation being for the functional limitation subscale (rs = 0.234) and the lowest for the physical pain subscale (rs = 0.160).

Table 5. Convergent validity of OHIP-14 using decayed, missed, and filled teeth (DMFT) index

| OHIP-14 Subscales Characteristics | DMFT category | Acceptable DMFT <3 | Average DMFT 4–10 | Poor DMFT >10 |
|-----------------------------------|---------------|--------------------|-------------------|--------------|
| N = 341                           |               | 2.1056 (1.95252)   | 2.8545 (1.93660)  | 3.1871 (2.05563) | 0.234 |
| % = 48.7                          |               | 0.5073 (0.96289)   | 0.7545 (0.99484)  | 0.8489 (1.10934) | 0.160 |
| Mean subscale (S.D)               |               | 3.3842 (2.39034)   | 4.1136 (1.95633)  | 4.6403 (1.89968) | 0.221 |
|                                  |               | 3.8358 (2.87525)   | 4.7273 (2.70771)  | 5.5540 (2.73775) | 0.230 |
|                                  |               | 3.1554 (2.73042)   | 3.6591 (1.85973)  | 4.1727 (1.84520) | 0.220 |
|                                  |               | 5.6452 (3.33611)   | 6.3545 (2.82224)  | 7.3165 (2.63487) | 0.194 |
|                                  |               | 1.2669 (1.41496)   | 1.4727 (1.32216)  | 1.7914 (1.24222) | 0.172 |

*All rs values have p-value < 0.01; statistically significant. Bold represents the highest correlations between OHIP-14 subscales and affected DMFT

**DISCUSSION**
To our knowledge, this is the first study to validate the OHIP-14 in the Pakistani population and the first to focus on OHRQoL in patients with upper GI disorders.17,27-31 Cross-cultural adaptation is a critical component in the validation of a health assessment tool.5,37 The convergent validity method was used to establish the validity of the OHIP-14 in our population, as described by Roumani and Montero-Martín.5,20 Unlike many studies,5,20-25,31,42,43 in which validity was assessed using weak tools such as oral hygiene, self-perceived status of oral health, and subjective symptoms, with comparison of both additive and simple counting; we established the validity of the OHIP-14 using a clinical parameter, i.e., effect on oral hard tissues (assessed using DMFT index), adding strength to this study. Our mean OHIP-14 scores are higher than those previously reported,64 and can be attributed to the underlying upper GI disease.

Our socio-demographic findings for age, sex, and socioeconomic status are in agreement with those of another local study reported by Ghani et al.29 The literature identifies the major risk factors for upper GI disorders to be the addiction profile and dietary habits, and the confounding risk factors to be rural residence and very-low to low socioeconomic status.11 Pakistan faces big challenges in regard to maintenance of oral health,45 in that the bulk of its population does not prioritize health, being addiction-prone, having neglected health issues, seeking self-medication, and often living in rural areas,32 with limited access to health care, all of which render individuals prone to ill health.1,2,19

The present study demonstrates that the presence and severity of oral lesions is associated with oral morbidity (Table 3), which compromises oral and systemic health. To date, there have been no reports of the OHIP-14 being used to address the impact of oral lesions, abnormal mucosal conditions, or OSF, so another novel element of our study is that it confirms significant associations in this regard.19,20,23,42 Oral candidiasis manifests as xerostomia, burning-mouth syndrome, altered taste sensation, redness, and soreness,46 and was the oral lesion with the worst impact on oral health in our study. These symptoms were severe enough to cause eating or swallowing difficulties, a diminished sense of taste, inadequate food intake, interrupted meals, and loss of appetite, culminating in weight loss in 71.3% of our study population. Weight loss is a marker of the severity and progression of disease, and oral disability might contribute to compromised health and/or decreased appetite.47 We observed a trend of increasing mean OHIP-14 scores with increasing severity of oral lesions. The associations between OHIP-14 scores and ulceration, angular cheilitis, glossitis, leukoplakia, and candidiasis were statistically significant. Of these, candidiasis and glossitis had the worst impact on OHRQoL.

Our data (Table 4) also indicate that the Pakistani-Urdu version of the OHIP-14 has very good internal reliability (α = 0.83), as found for the most recent Indian-Hindi validation study of the OHIP-14 (α = 0.80) by Batra et al.22 This can be attributed to the similarities in these regional populations, indicating that the results of these regional versions are generalizable. Similarly, α = 0.89 (considered excellent), as reported for the Spanish version by Montero-Martín et al.5 highlights that our regional reliability α-values are in accordance with European studies.5,20,22 Internal reliability is a critical psychometric property for a health measurement tool,37 and our finding in this regard indicates that the OHIP-14 is suitable for the assessment of OHRQoL in the Pakistani population. In addition, our study findings revealed that OHIP-14 mean responses (ranging from 0.65 to 2.26) were relatively higher in patients suffering from oro-dental problems in the presence of systemic illness; in comparison with an Australian study,48 where responses of OHIP-14 were ranging from 0.14 to 1.36 and no underlying systemic illness was present that could have negatively influenced the oral health quality of the participants. Hence, this study serves as a control for comparing OHIP-14 means in healthy population versus population suffering from gastroenterological illness.

In our study, convergent validity (Table 5) pertained to two construct measures, i.e., the DMFT index and the OHIP-14, which are both theoretically and clinically related.37 Our present findings are consistent with those of previous validation studies, in which all researchers have agreed with the approach that functional limitation (rs = 0.234), physical disability (rs = 0.230), and psychological discomfort (rs = 0.221) have the highest correlation with compromised oral health (which in this study is measured with
More than half of our study population had a DMFT index value >3, which is beyond the acceptable threshold, and amongst that group, a significant portion (around 20%) had a value >10. These data indicate that our sample population included a substantially larger group of individuals who were at risk of caries than in previous studies, in which samples were classified as at negligible- low risk (a DMFT index value of 0), low–medium risk (3.2), medium risk (5.4), or high risk (8.8). Moreover, social disability, physical disability, and psychological discomfort were the items in the OHI-P-14 worst affected in respect to worsening DMFT index value (i.e., poor DMFT >10, p < 0.01). These findings support the concept that the DMFT index has a significant role in determining oral health, and according to our data, oral health is compromised in the presence of an upper GI or hepatic disorder. In contrast, a WHO report based on Peterson’s world map of dental caries in 2003 suggests that the Pakistani population is at low risk (a mean DMFT index value of <1.2 for those up to 12 years of age, and <5 for those aged 35–44 years). In light of our present findings, we would suggest that the WHO update its recent findings with regard to DMFT index values in Pakistan.

Other important findings in this study were a lack of health awareness and a high rate of self-medication in Pakistanis. Low socio-economic status and poor literacy, are major drivers of health neglect in Pakistan. This neglect was reflected in the high proportions of subjects reporting general body pain (40%) and self-medicating with NSAIDs (48%), which are known to have adverse effects on the liver and upper GI tract. Our study has several limitations. First is its cross-sectional design, which meant that only a small window of time was available for interviews with subjects and limited the levels of association that could be found; however, this design was needed for validation of the OHI-P-14. Longitudinal or case-control studies are needed in the future to detect dynamic changes in oral well-being after therapeutic interventions and to document the sensitivity and specificity of the OHI-P-14 and its suitability for use in Pakistan in more detail.

Second, we could not rule out the potential contributions of comorbidities and self-medication (particularly with NSAIDs) to upper GI and hepatic disease. Third, the oral lesions detected in our study population were not histologically confirmed, so our findings in this regard only have applicability for screening. It is recommended that future researchers include biopsies of oral lesions in their study protocols. Fourth, the use of DMFT index despite being widely criticized as a weak tool for distinguishing between the aetiology of decay or missing tooth, yet it is still widely used in epidemiological studies for the screening of dental decay. This study was the first in its kind to assess OHRQoL in systemic disease-specific population, therefore, DMFT was used as a central measure for the analysis of oral hard tissues. Fifth, as it was not our study objective and also by not associating between decayed, missed, and filled teeth separately, we might have missed out identifying a potential relationship with decay or missing of tooth. We strongly recommend future researchers to explore the effects on OHRQoL in systemic diseases having oral manifestations, while clinical trials and prospective longitudinal studies are needed to determine the temporal relationship between the diseases commonly encountered by gastroenterologists and dentists.

CONCLUSION

Upper GI and hepatic disorders produce an array of oral manifestations that not only compromise oral health but also significantly affect OHRQoL. Dentists, general physicians, and gastroenterologists need to play a very proactive role in educating their patients regarding the implications of poor oral health and its effect on the quality of life. Referring to a dentist could become part of the treatment protocol in gastroenterology. The Urdu version of the OHI-P-14 instrument showed similar and reliable characteristics as in the original English version and is not only validated for use in Pakistan as an oral health assessment tool in patients with upper GI or hepatic disease but can also be employed for assessment of OHRQoL among general Pakistani population with different age ranges.

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AUTHOR CONTRIBUTIONS

I.W., study conception, data collection/analysis, manuscript writing, and editing; A.Y., study design, manuscript writing, and editing; A.R., statistical analysis and proofreading; J.A., data collection and data entry/analysis; H.M., manuscript editing; R.H., data collection and data entry; and A.Q., dentistry research supervision and proofreading.

ADDITIONAL INFORMATION

Competing interests: The authors report no support from any organization for the submitted work; no financial relationships with any organizations that might have an interest in the submitted work in the previous 3 years; and no other relationships or activities that could appear to have influenced the submitted work.

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