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Validation of Nepalese Oral Health Impact Profile14 and Assessment of Its Impact in Patients with Oral Submucous Fibrosis in Nepal

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ABSTRACT

Background: Oral Health Impact Profile–14 (OHIP-14) is one of the most internationally used oral health related quality of life (OHRQoL) questionnaire available in various languages. The study was aimed to validate Nepalese version of OHIP-14 and to assess impact of quality of life (QoL) in patients with oral submucous fibrosis (OSF).

Methods: An interventional OHRQoL study was conducted among OSF patients visiting Department of Oral Medicine and Radiology, BP Koirala Institute of Health Sciences, Dharan using OHIP-14 after translation and validation process. Following the baseline questionnaire, 74 patients were treated with dexamethasone and hyaluronidase for 6 weeks and followed up for 6 months during which OHIP-14 was again administered.

Results: For concurrent validity, Nepalese OHIP-14 scores were associated with self-perceived oral health status, self-perceived dental treatment need and satisfaction with oral health status. For internal reliability, inter-item correlation coefficient varied from 0.2-0.8. Corrected item-total correlation coefficients were between 0.43-0.80. Cronbach's alpha was 0.90. Commercial tobacco product chewing with arecanut (Gutka®) was seen among 45% with median frequency and duration of 7.5(0-20) times/day and 10(0-60) years, respectively. Median OHIP-14 score at baseline 18(0-45), was significantly ($p<0.001$) different from 6 months' follow-up [5(0-15)]. Impact score at baseline was mainly influenced by age ($r_s=0.32$, $p=0.005$), frequency of habit ($r_s=0.44$, $p<0.001$) and duration of habit ($r_s=0.31$, $p=0.006$).

Conclusions: Nepalese version of OHIP-14 is a valid and, reliable instrument to measure OHRQoL in OSF patients. OHRQoL in OSF patients can be improved after professional treatment regime.

Keywords: Oral submucous fibrosis; oral cancer; oral health; oral potentially malignant disorders; quality of life;

INTRODUCTION

Oral submucous fibrosis (OSF) is a chronic, progressive disease of oral mucosa, characterized by blanching, stiffness, trismus, burning sensation, hypomobility of soft palate, tongue, affecting lamina propria leading to loss of fibroelasticity.[1,2] Its prevalence is high in Southeast Asia[3] and symptoms compromise speaking and eating.[4] OSF is oral potentially malignant disorder with malignant transformation rate of 3-19%.[5] It is caused by a masticatory substance, areca nut, fourth most addictive substance,[6,7] chewed with/without tobacco and is an ancient, socially acceptable habit.[8]

Quality of Life (QoL) research guides health professionals in understanding impact of a disease and treatment[9] and Oral health Related Quality of Life (OHRQoL) questionnaire incorporates functional, social and psychological impacts of

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oral diseases.[10] Oral Health Impact Profile 14 is one of the most popular OHRQoL tool. QoL in OSF is severely affected however, has been poorly researched. Hence, it was the purpose of the study to validate Nepalese OHIP-14 and to assess impact of OHRQoL in OSF patients.

METHODS

An interventional OHRQoL study was designed and OHIP-14 was chosen for this study. All the study participants received written information and gave informed consent. The study was approved by the Institutional Ethical Review Board (IERB) of BP Koirala Institute of Health Sciences. The participants were patients visiting the department of Oral Medicine and Radiology (OMR) of the institute for the diagnosis and treatment of oral submucous fibrosis from February 2011- February 2012.

Translation and adaptation process of OHIP-14 into Nepali was carried out. The validity of the Nepalese OHIP-14 was checked using the back-translation technique. The validation process was done in 3 steps namely linguistic and cultural adaptation, pilot testing and the main study. The English version of the questionnaire was translated into Nepali by two individuals who were experts in both the languages. Back translation was done along with linguistic and cultural adaptation by two other individuals who were not a part of the study but were erudite in both the languages. The resultant Nepalese version was produced after the face and content validity results of the pilot study were verified by experts in the use of questionnaires in both languages. Concurrent validity was checked by the association between Nepalese OHIP-14 scores and self-perceived oral health status, self-perceived dental treatment need and satisfaction with oral health status. The questionnaire was pilot tested on 50 individuals. During the pilot study, it took an average of ten minutes to finish the interview and 15 – 20 minutes to complete the proforma. Scheduling for the main study was planned likewise. Participants were also asked about difficulties in understanding items or frequencies. Reliability of the translated version of the OHIP-14 scale was assessed in terms of internal consistency using Cronbach's alpha which measured the overall correlation between items within the scale. In relation to internal consistency, inter-item and corrected item-total correlation coefficients for the different OHIP scale items were also calculated. For each of the 14 items, patients were asked how often they had experienced the problem in the previous 1 year. Responses were coded as 'very often' (scoring 4), 'fairly often' (3), 'occasionally' (2), 'hardly ever' (1) or 'never' (0).[11] The total OHIP-14 score and the subscale scores constituted measures of the 'severity' of adverse impacts caused by OSF. A detailed history was recorded regarding patient's deleterious oral habits in the proforma developed by the department through trained interviewers. Visual Analogue Scale (VAS) for burning sensation in a rating of 0-10 was also recorded. Visual analogue scale is an unidimensional measure of pain intensity which has been widely used in diverse population. It consists of a horizontal line measuring 100 mms denoted by 2 descriptors ie no pain to worst imaginable pain. It is a validated tool available to public freely. Higher score denotes greater pain intensity and vice versa. Inter-incisal mouth opening, cheek flexibility were measured using vernier caliper by a single examiner. Along with these, blanching and fibrotic bands were also recorded on each visit. Staging of OSF was done as described by Kerr et al.[1] Following the self administered baseline questionnaire, 74 patients were enrolled in the study. All patients were given a potent vasodilator, pentoxifylline 400 mg thrice daily for one month along with intralesional dexamethasone 4mg/ml biweekly for the first 2 weeks then in combination with hyaluronidase 1500 IU for the next 4 weeks biweekly for a total period of 6 weeks and followed up for 6 months (2 weeks, 1 month, 3 months and 6 months) during which OHIP-14 was again administered at 6 months to assess the impact.

The data were analyzed using SPSS version 11.5. Continuous data were presented as mean with their Standard deviation. Categorical data were presented as frequencies with percentages. Non-parametric statistics were used for comparison which included Wilcoxon Signed Ranks Test (Pair-wise comparison) and Kruskal Wallis Test (Group-wise comparison). Correlation carried out using Spearman's rho correlation coefficient. Level of

statistical significance was set at p<0.05.

RESULTS

The study population consisting of 52 males and 22 females had a mean age of 36.14±13.52 [median (range) = 35.5(17-74)] years. The psychometric properties of the OHIP-14 in terms of concurrent validity as well as internal reliability were good. For internal reliability, all inter-item correlations (Table 1) were positive and the inter-item correlation coefficient varied from 0.2 to 0.8. The corrected item-total correlation coefficients (Table 2) ranged from 0.43 to 0.80. The Cronbach's alpha of this 14-item scale was 0.90. For concurrent validity the Nepalese OHIP-14 scores were significantly associated with self-perceived oral health status (p<0.001), self-perceived dental treatment need (p<0.001) and satisfaction with oral health status (p<0.001) (Table 3). Commercial tobacco and areca nut product chewing habit (Gutka®) was seen among 44.6% of patients. Other chewing habits were arecanut (4.1%), arecanut with betel leaf (4.1%), betel quid (5.4%), betel quid with tobacco (16.2%) and betel quid with smoking tobacco (20.3%). Median (range) frequency and duration were 7.5(0-20) times per day and 10(0-60) years, respectively. Median(range) OHIP-14 score at baseline of 18(0-45), was significantly (p<0.001) different from the follow- up at 6 months of 5(0-15) (Table 4). Similarly, median (range) visual analogue scale for burning sensation revealed that baseline score of 4(0-10) was significantly (p<0,001) different from 6-month follow-up score of 0(0-4). VAS and OHIP-14 scores were also significantly different between males and females both before and after treatment of OSF (Table IV). Table 5 displays responses to OHIP-14 items before and after treatment. There was weak positive correlation between OHIP-14 score and age [$r_s(72)=0.32$, p=0.005], frequency [$r_s(68)=0.44$, p<0.001] and duration of habit [$r_s(68)=0.31$, p=0.006]. VAS scores also had weak correlation with age [$r_s(72)= 0.27$, p<0.001], frequency of habit [$r_s(72)=0.13$, p>0.05] and duration of habit [$r_s(72)=0.18$, p>0.05.]

Table 1. Inter-item correlation of 14 items of OHIP-14.

Impact item	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Trouble pronouncing any words	1.00													
Sense of taste has worsened	0.28	1.00												
Painful aching in mouth	0.63	0.31	1.00											
Uncomfortable to eat any foods	0.56	0.34	0.44	1.00										
Felt self conscious	0.63	0.49	0.72	0.39	1.00									
Felt tense	0.22	0.24	0.44	0.26	0.52	1.00								
Diet been unsatisfactory	0.38	0.58	0.37	0.56	0.51	0.28	1.00							
Had to interrupt meals	0.51	0.37	0.63	0.58	0.76	0.30	0.64	1.00						
Difficult to relax	0.61	0.25	0.58	0.33	0.56	0.28	0.50	0.50	1.00					
Been a bit embarrassed	0.56	0.23	0.48	0.34	0.62	0.36	0.49	0.58	0.80	1.00				
Been a bit irritable with others	0.37	0.26	0.37	0.28	0.36	0.33	0.22	0.25	0.32	0.36	1.00			
Had difficulty doing usual jobs	0.52	0.29	0.32	0.33	0.37	0.06	0.61	0.34	0.44	0.48	0.25	1.00		
Life in general was less satisfying	0.42	0.33	0.47	0.20	0.41	0.50	0.26	0.20	0.46	0.46	0.60	0.23	1.00	
Been totally unable to function	0.41	0.33	0.30	0.32	0.45	0.20	0.54	0.47	0.55	0.50	0.25	0.57	0.28	1.00

Table 2. Corrected item-total correlation.

OHIP item	Corrected inter-item total correlation	Cronbach's Alpha if item deleted
Trouble pronouncing any words	0.71	0.89
Sense of taste has worsened	0.46	0.90
Painful aching in mouth	0.71	0.89
Uncomfortable to eat any foods	0.53	0.90
Felt self conscious	0.80	0.89
Felt tense	0.43	0.91
Diet been unsatisfactory	0.66	0.89
Had to interrupt meals	0.72	0.89
Difficult to relax	0.70	0.89
Been a bit embarrassed	0.73	0.89
Been a bit irritable with others	0.44	0.90
Had difficulty doing usual jobs	0.54	0.90
Life in general was less satisfying	0.53	0.90
Been totally unable to function	0.58	0.90

Table 3. Construct validation of OHIP-14.

	n(%)	OHIP-14		P value
		Mean rank	Median (range)	
Perceived oral health status				
Good	10	6.5	12.5 (0-29)	
Fair	18	28	18 (0-33)	<0.001
Poor	22	59	24 (0-45)	
Perceived need for oral care				
No	12	6.5	18 (0-34)	<0.001
Yes	38	33.5	22 (2-45)	
Perceived oral satisfaction				
No	21	49	24.5(1-45)	<0.001
Yes	29	12	15.5(0-29)	

Table 4. Mean distribution and comparison of OHIP Scale and VAS scores.

OHIP Scale	Median (Range)	
	Before	After
OHIP score	18(0-45)	5(0-15)*
Male	18(0-45)	4.5(0-15)*
Female	17(1-45)	6(0-10)*
Visual analogue scale		
VAS score	4(0-10)	0(0-4)*
Male	4(0-10)	0(0-4)*
Female	6(0-8)	0(0-3)*

*p<0.001

Table 5. Responses to OHIP-14 items before and after treatment.

	Never n (%)	Hardly ever n (%)	Occasionally n (%)	Fairly often n (%)	Very often n (%)
Functional limitation					
Trouble pronouncing any words	34 (45.9)	12 (16.2)	5 (6.8)	18 (24.3)	5 (6.8)
	57 (77)[a]	7 (9.5)[a]	8 (10.8)[a]	2 (2.7)[a]	0 (0)[a]
Sense of taste has worsened	42 (56.8)	10 (13.5)	11 (14.9)	8 (10.8)	3 (4.1)
	56 (75.7)[a]	16 (21.6)[a]	2 (2.7)[a]	0 (0)[a]	0 (0)[a]
Physical pain					
Painful aching in mouth	10 (13.5)	22 (29.7)	14 (18.9)	16 (21.6)	12 (16.2)
	22 (29.7)[a]	45 (60.8)[a]	7 (9.5)[a]	0 (0)[a]	0 (0)[a]
Uncomfortable to eat any foods	21 (28.4)	8 (10.8)	17 (23)	13 (17.6)	15 (20.3)
	31 (41.9)[a]	33 (44.6)[a]	10 (13.5)[a]	0 (0)[a]	0 (0)[a]
Psychological discomfort					
Felt self conscious	25 (33.8)	8 (10.8)	13 (17.6)	20 (27)	8 (10.8)
	40 (54.1)[a]	31 (41.9)[a]	3 (4.1)[a]	0 (0)[a]	0 (0)[a]
Felt tense	11 (14.9)	12 (16.2)	21 (28.4)	18 (24.3)	12 (16.2)
	39 (52.7)[a]	34 (45.9)[a]	1 (1.4)[a]	0 (0)[a]	0 (0)[a]
Physical disability					
Diet been unsatisfactory	31 (41.9)	7 (9.5)	12 (16.2)	18 (24.3)	6 (8.1)
	55 (74.3)[a]	18 (24.3)[a]	1 (1.4)[a]	0 (0)[a]	0 (0)[a]
Had to interrupt meals	26 (35.1)	17 (23)	11 (14.9)	15 (20.3)	5 (6.8)
	57 (77)[a]	17 (23)[a]	0 (0)[a]	0 (0)[a]	0 (0)[a]
Psychological disability					
Difficult to relax	32 (43.2)	12 (16.2)	12 (16.2)	9 (12.2)	9 (12.2)
	63 (85.1)[a]	10 (13.5)[a]	0 (0)[a]	1 (1.4)[a]	0 (0)[a]

Been a bit embarrassed	32 (43.2)	19 (25.7)	13 (17.6)	5 (6.8)	5 (6.8)
	61 (82.4)[a]	12 (16.2)[a]	1 (1.4)[a]	0 (0)[a]	0 (0)[a]
Social disability					
Been a bit irritable with other people	39 (52.7)	15 (20.3)	13 (17.6)	7 (9.5)	0 (0)
	64 (86.5)[a]	10 (13.5)[a]	0 (0)[a]	0 (0)[a]	0 (0)[a]
Had difficulty doing usual jobs	40 (54.1)	18 (24.3)	8 (10.8)	5 (6.8)	3 (4.1)
	59 (79.7)[a]	15 (20.3)[a]	0 (0)[a]	0 (0)[a]	0 (0)[a]
Handicap					
Life in general was less satisfying	23 (31.1)	20 (27)	23 (31.1)	6 (8.1)	2 (2.7)
	58 (78.4)[a]	14 (18.9)[a]	1 (1.4)[a]	1 (1.4)[a]	0 (0)[a]
Been totally unable to function	34 (45.9)	10 (13.5)	18 (24.3)	10 (13.5)	2 (2.7)
	47 (63.5)[a]	15 (20.3)[a]	6 (8.1)[a]	5 (6.8)[a]	1 (1.4)[a]

DISCUSSION

OHIP-14 is one of the most popular OHRQoL instrument. The cultural and linguistic adaptation is an important aspect of the validation process. The translation in Nepalese was straightforward and there was no difficulty in finding the equivalent words used in the English version of OHIP-14, hence, there was no conceptual or content difference. OHIP-14 has been translated in various other languages like Chinese,[13] Greek,[14] Persian,[15] Spanish,[16] Sinhalese,[17] Hebrew,[18] Hindi[19] and Sudanese-Arabic.[20]

The present study is an institutional based research and we as clinicians at times fail to understand the psychological impact any disease can have on an individual. This study is an attempt to understand this domain of quality of life of patients along with function, symptoms, social-psychological disability and handicap. OSF is marked clinically by blanching and stiffening of the oral mucosa leading to limitation in oral opening. The presence of fibrous bands in lips, cheeks and soft palate is a hallmark of the disease. The disease extends over time to include the oropharynx and the upper third of the esophagus[1] severely compromising the quality of life. The study assessed the impact of OSF on QoL pertaining to oral health. The results show that all multi-item oral health specific quality of life measures scored a high internal consistency and validity. In this study it was evident that 94.6% had areca nut habit which strongly supports that areca nut with or without tobacco causes OSF.[21] The OSF targeting younger generation is worth taking note of and about 45% of them used commercial preparations as these are easily available sachets at a minimal cost. It has been a well known fact that any form of areca nut quid and tobacco practice can cause OSF.[6] In the baseline questionnaire, it was found that the most impact was in the psychological domain where patients felt tensed (40.5%) about their oral condition and they were self conscious about the condition (37.8%). This was followed by physical pain where patients felt uncomfortable while eating (37.9%) and painful ache (37.8%). This clearly shows that there is a compromise in their daily activity due to the disease.

There was a normal age distribution ranging from 17-74 years with a mean age (SD) of 36.14 (13.52). However, it is quite important to note that 75.7% of the patients are below 40 years and nearly 40% of study population was under 30 years of age. This age bracket is considered the most productive years of an individual and their productivity is lost due to the compromise in their health. In regards to functional limitation 31.1% had difficulty in pronouncing the words. This could be attributed to the involvement of tongue. There is inability to protrude the tongue due to involvement of floor of the mouth and ventral surface of the tongue. 14.9% individuals had worsened taste sensation and studies have shown that there is altered taste sensation in OSF.[22, 23] Almost 38% of patients often had pain in their mouth and discomfort in eating daily food which shows that their eating is compromised. This can lead to sequelae of events like deranged metabolism, malnutrition, decreased bone density and starvation, and their consequences in the body as a whole. Almost 40% of them felt that they had psychological discomfort. The food generally relished by rest of the family is no longer enjoyable to them. The quantity of food taken is also less to avoid pain and discomfort and once the diagnosis is known to the patient as oral potentially malignant disorder, this develops tremendous fear of cancer. Patients also reported

their psychological disability with 24.4% not being able to relax and 13.6% being embarrassed. Though social disability accounted for less than 10%, it should not be ignored. This was quite evident in our study showing higher value of Cronbach's alpha. Oral health impact and the visual analog significantly reduced with medical and physical therapy as shown in Table 4. Though the chance of complete cure of OSF cannot be guaranteed, there is significant improvement in quality of life of these patients. When burning sensation reduced, the food generally avoided by patients in the past, was being relished following the treatment. As shown in Table 5, comparison between baseline and 6 months post treatment were made and most of the items had improvements in functional limitation, physical pain-disability, psychological discomfort-disability along with social disability and handicap. The quality of life of these patients seems to have significantly improved following the treatment. This is very encouraging for clinicians in evaluating the treatment outcome of the therapy provided.

There was significant weak positive relationship between OHIP-14 scores and age of patients, frequency of deleterious habit and duration of habit. Moreover, there was weak and almost no association between these factors and VAS scores. Such is expected as oral health related quality of life of OSF patients would be directly influenced by the condition itself and indirectly by other factors. Perhaps a stronger correlation would be observed between OHIP-14 scores and severity of OSF. However, such was not recorded in the present study and may be recommended for future studies. Similar may be suggested for VAS scores and OSF.

The OHRQoL is affected in OSF patients and can be improved after cessation of deleterious areca habit and professional treatment regime. If OSF is treated at an early stage then the degree of malignant transformation can be reduced thereby reducing the cancer burden and improving the overall quality of life.

CONCLUSIONS

Our study revealed that the translated Nepalese version of OHIP met the standard criteria for reliability, validity, and responsiveness hence, can be considered a scientifically valid, reliable oral health related quality of life instrument. However, it needs to be used in larger longitudinal studies to evaluate the sensitivity of Nepalese version of OHIP-14 on other oral diseases in different age groups. OHRQoL has been assessed for the first time for OSF and shows strong evidence that the OHRQoL is severely affected in OSF patients. If oral submucous fibrosis is treated at an early stage then it can reduce the cancer burden and improves the quality of life. It is also recommended to research the relationship between Nepalese version of OHIP and health related quality of life in different oral diseases.

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