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Development and validation of a quality-of-life questionnaire for patients with oral potentially malignant disorders

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Objective. The aim of this study was to develop and evaluate the validity and reliability of a quality-of-life (QoL) questionnaire for patients with oral potentially malignant disorders (OPMDs).

Study Design. For item generation, 15 personal interviews and three focus group discussions were conducted with OPMD patients existing QoL questionnaires were reviewed, and inputs from specialist clinicians ($n = 10$) were considered. Data collected from patients were analyzed by using NVivo. This led to the identification of themes, item writing, scaling, item reduction, formatting, and pretesting of the newly developed questionnaire. The validity and reliability of the questionnaire were assessed in a separate sample of 300 patients (150 each of patients with OPMD and healthy individuals).

Results. Sixty items were generated from the qualitative data and by reviewing existing questionnaires. After item reduction, the final questionnaire comprised 20 questions, which could be categorized under four domains. Exploratory factor analysis revealed a four-factor structure conforming to the four domains. The OPMD QoL questionnaire exhibited good discriminant and convergent validity, with OPMD patients reporting poorer QoL compared with healthy individuals and correlating significantly with existing questionnaires designed for similar purposes respectively.

Conclusions. Our OPMD QoL questionnaire was found to be valid and reliable. We recommend that it be applied in epidemiologic and treatment studies of these disorders. (Oral Surg Oral Med Oral Pathol Oral Radiol 2017;123:338-349)

Oral potentially malignant disorders (OPMDs) carry a risk of cancer,[1] which can significantly impair quality of life (QoL).[2] The main goal of health care professionals is to uphold the patient's QoL. It is now widely considered an important indicator of health outcome[3,4] and a valuable adjunct to clinical evaluation, particularly in chronic conditions.[4] Such patient-reported perceptions of QoL are usually quantified using questionnaires[5] that can be categorized as generic or condition- or disease-specific.[6] There is debate over the relative merit of generic versus disease-specific QoL questionnaires.[7] The latter offer the advantage of being able to evaluate the impact of a particular condition on every aspect of the daily life activities of affected individuals.[6,8]

Despite OPMDs being chronic and potentially debilitating,[9] there is a paucity of literature related to QoL in such patients,[10] which might, in part, result from the unavailability of a condition-specific questionnaire, as revealed in our recent literature review.[9] In particular, the common symptoms of OPMDs, which include pain, burning sensation, trismus, and altered taste sensation,[11,12] together with diagnostic delays,[13] clearly produce some deterioration in patients' QoL. However, the existing generic questionnaires do not address these issues. A disease-specific QoL questionnaire would also be helpful in detecting changes over time, including response to treatment. Past studies with patients suffering from OPMD have used generic questionnaires, such as the Oral Health Impact Profile questionnaire,[14] Oral Health Quality of Life questionnaire,[15] and the Chronic Oral Mucosal Disease Questionnaire (COMDQ).[16]

Statement of Clinical Relevance

A condition-specific quality-of-life instrument for patients with oral potentially malignant disorders was developed to evaluate the subjective perceptions of the impact of these disorders on everyday aspects of life. The new instrument was found to be valid and reliable.

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The conceptual framework that formed the basis for the development of the questionnaire reported here was modified from the Oral Impacts on Daily Performances theoretical framework.[17] The present study aimed to develop and evaluate the validity and reliability of a self-administered QoL questionnaire for patients with OPMDs.

MATERIALS AND METHODS

Ethics approval for the study was obtained from the Human Research Ethics Committee of Griffith University in Australia (Ref No: DOH/14/14/HREC) and the Panineeya Institute of Dental Sciences & Research in India (Ref No: 00125). Written informed consent was obtained from all participants. Data for developing the OPMD QoL questionnaire were collected at the Panineeya Institute of Dental Sciences & Research in Hyderabad, India, from May to September 2014. Patients who were generally healthy except for their OPMDs were included, whereas those with other severe oral mucosal conditions (e.g., benign or malignant neoplasms, any type of exophytic growth, or acute ulceration) or systemic conditions (e.g., diabetes mellitus, cardiovascular disorders) that might adversely affect QoL were excluded.

The following steps were followed,[18] as demonstrated in Figure 1: (1) item generation, (2) item reduction, (3) formatting, and (4) pretesting of the developed items.

Item generation

This involved inputs from patients and also expert clinicians in the field of oral medicine. Patients diagnosed with oral leukoplakia (OL), oral submucous fibrosis (OSF), and oral lichen planus (OLP) undergoing treatment at the Department of Oral Medicine and Radiology were invited to participate. Diagnoses for OL, OSF, and OLP were made by specialists at the Department of Oral Medicine and Radiology on the basis of clinical examination and confirmed by histopathologic examination. All who were invited agreed to participate, which resulted in the inclusion of patients with a wide range of severity of these conditions. Of the 32 patients (eight patients with OL, 11 with OSF, and 13 with OLP) who agreed to participate, 15 individuals took part in personal interviews, and 17 patients made contributions in three focus groups. In qualitative research, patient diversity and interview quality are more important than the actual sample size, which is determined by data saturation.[5] “Saturation” is described as a point beyond which no new information can be obtained from additional qualitative data.[5]

The semistructured interviews and focus groups were designed to elucidate the impact of patients’ oral condition on performing specific aspects of daily life activities. These were conducted by a single interviewer (J.T.) in the native language of the patients (Telugu) with one of the authors (S.K.) as an observer. Recordings were transcribed in English by using the parallel transcription method, and content analysis was performed. The contents of the existing head and neck cancer QoL questionnaires,[19-22] COMDQ,[23] and oral health−related QoL questionnaires[24,25] were also reviewed, and a long list of potential items was generated by taking the above approaches. Duplicate and redundant items were identified and deleted. Items were checked for clarity and length and for the presence of any negative wording.

The next step involved the Delphi technique,[26] in which 10 clinicians with specialization in Oral Medicine and expertise in the area of OPMD took part. The initial list was introduced to these clinical experts, and their feedback obtained on the suitability of each item, which led to reduction in the number of items in a second round and a third round. The final list of items that achieved consensus, including their ratings, was circulated to all experts for approval.

Item reduction

A questionnaire including all the items was framed for item reduction by using a judgment or clinical impact method, as described by Juniper et al.[27] For this process, the items were translated into Telugu by using a standard translation procedure.[28] This involved translation of the English questionnaire into Telugu by two independent translators. A single version of the Telugu questionnaire was derived from the two translations with the consensus of both the translators. The questionnaire was translated back into English independently by two different translators to check if the Telugu version represented the same item content as the original English version. Following the forward and backward translation procedures, all versions were consolidated to develop a final questionnaire by a committee that included all of the translators and two oral health care professionals. The questionnaire thus obtained was pilot tested by administering it to five patients, who were asked if they found the items understandable. This was followed by the administration of the items to 15 patients (five each of patients with OL, OSF, or OLP) who had not participated in item generation. For each item, the patients were asked to report if they had experienced that item and to rate its importance on a five-point Likert scale, from 1 = not important at all to 5 = very important. The impact score of each item was calculated

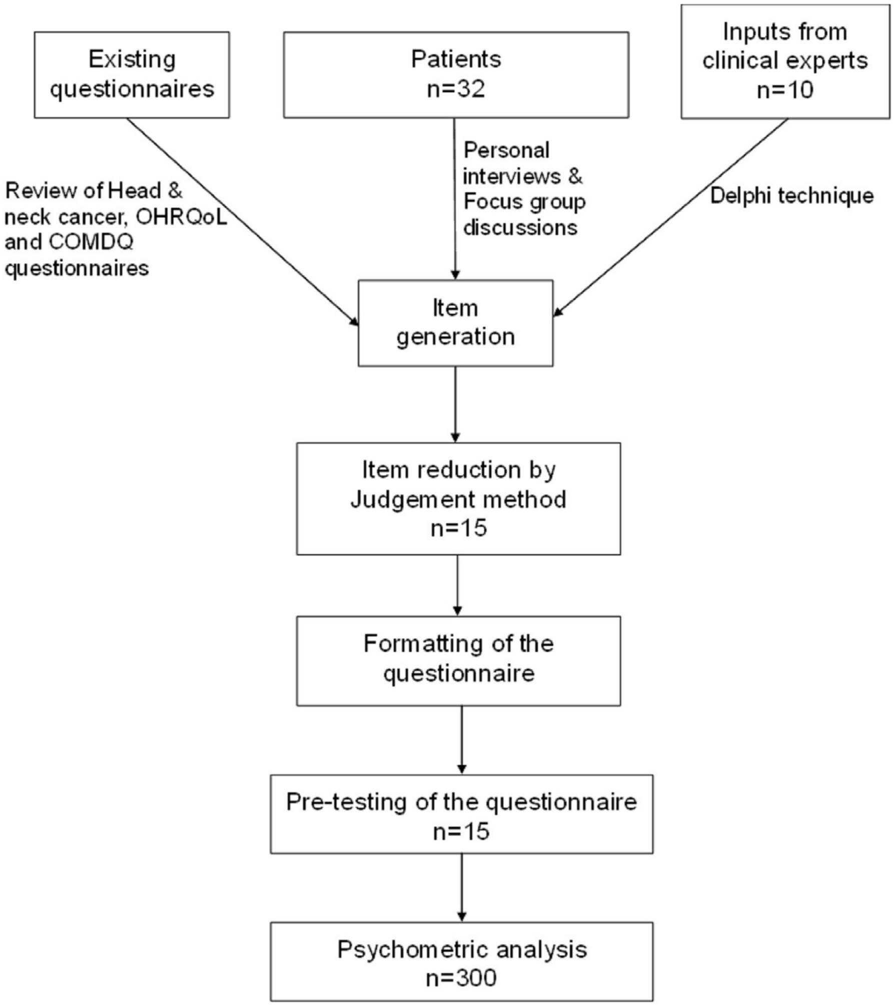

Fig. 1. Flowchart depicting the steps followed in developing and validating Oral Potentially Malignant Disorders Quality of Life (OPMD QoL) questionnaire.

as the product of "frequency" (proportion of patients who reported experiencing the item) and "mean impact score" (mean of the importance score of the item based on the scores from all the patients). Items that had an impact score of more than 1.5 and those endorsed by 50% or more individuals were considered for inclusion in the final questionnaire.[29] Items were then arranged in descending order of impact score, and the highest scoring items were selected for the final questionnaire.

Formatting of the questionnaire

To improve understanding of the questionnaire, items were ordered chronologically, with questions related to diagnosis placed first, followed by items related to the physical, psychological, and social implications of the disease, and items related to treatment placed at the end. Attention was paid to the font size and layout of both the question area and the response area of the document, with brief, clear, written instructions.[30]

Pretesting of the questionnaire

The questionnaire so developed was administered to 15 patients (five each of patients with OL, OSF, or OLP) who had not participated in item generation or item reduction. Interviews were then conducted with each patient to determine the acceptability and comprehensibility of each of the questions, to explore any problems experienced, and to invite suggestions for improvement. A final version of the OPMD QoL questionnaire was then developed.

Validity and reliability

To evaluate the psychometric properties of the questionnaire, 150 OPMD patients (50 each of patients with OL, OSF, or OLP) who were undergoing treatment were recruited during the period October 2014 to May 2015. To evaluate the discriminant validity of the OPMD QoL questionnaire, an equal number of healthy patients matched for age and gender were recruited

Table I. Impact scores and the proportion of patients reporting of experiencing the item

	Item	*Domain*	*Frequency*	*Mean impact score*	*Impact rating*
1	How much burning sensation do you experience while having spicy food?	PIF	0.89	3.50	3.12
2	How much pain and agony does your mouth condition cause to you?	PIF	1	3.11	3.11
3	How scared are you about the possibility of your oral condition turning into cancer?	PSB	0.94	3.17	2.98
4	How scared are you about the outcome of this condition affecting your life?	PSB	0.94	3.17	2.98
5	How difficult was it for you to get your mouth condition diagnosed?	DD	0.94	2.83	2.66
6	How frustrated are you because of your oral condition?	PSB	0.84	3.00	2.52
7	How depressed or low do you feel because of your mouth condition?	PSB	0.83	3.00	2.49
8	How much pain do you experience with treatment of your oral condition?	TRE	0.83	3.00	2.49
9	How much is your mouth condition affecting your satisfaction with life?	PSB	0.83	2.89	2.40
10	How stressful was it for you to take a variety of treatments before being diagnosed with your mouth condition?	DD	0.83	2.83	2.35
11	How much is the difficulty you have in opening your mouth preventing you from having certain foods (e.g., apple)?	PIF	0.83	2.78	2.31
12	In general, how much is your mouth condition affecting your relationship with family and friends?	PSB	0.83	2.67	2.21
13	How much is your oral condition causing you to limit your desired foods?	PIF	0.83	2.61	2.17
14	How difficult is it for you to open your mouth widely?	PIF	0.83	2.56	2.12
15	How much did the need to visit many doctors for getting your mouth condition diagnosed affect daily life activities?	DD	0.72	2.89	2.08
16	How much is your mouth condition limiting you from enjoying your meals?	PIF	0.83	2.44	2.03
17	How much does your mouth condition affect your taste sensation?	PIF	0.72	2.78	2.00
18	How satisfied are you with the effectiveness of treatment for your mouth condition?	TRE	0.67	2.89	1.94

(*continued on next page*)

Table I. Continued

	Item	*Domain*	*Frequency*	*Mean impact score*	*Impact rating*
19	How much are your treatment appointments affecting your daily schedule?	TRE	0.72	2.67	1.92
20	How much dryness do you feel in your mouth?	PIF	0.77	2.39	1.84
21	How embarrassing is it for you to eat foods at parties, functions, or other social gatherings?	PSB	0.67	2.50	1.68
22	How well informed are you about the oral condition you have?	DD	0.67	2.22	1.49
23	How worried are you about the chances of your condition coming back in spite of availing treatment?	TRE	0.61	2.39	1.46
24	How satisfied are you with the way your medicines are provided to you (e.g., swallowing a tablet, chewing a tablet, having an injection in the mouth)?	TRE	0.67	2.17	1.45
25	How much is your oral condition affecting your concentration at work?	PSB	0.61	2.33	1.42
26	How much does your mouth condition affect your spirituality and faith in God?	PSB	0.61	2.33	1.42
27	How much bad breath do you experience because of your mouth condition?	PIF	0.67	2.11	1.41
28	How much are your efforts to stop habits such as *paan* or *gutkha* chewing or smoking affecting your daily life activities?	TRE	0.61	2.28	1.39
29	How much pain do you experience while having rough textured food (e.g., chips)?	PIF	0.55	2.50	1.38
30	How awkward do you feel because of the stains on your teeth?	PSB	0.61	2.22	1.36
31	How much is your oral condition affecting your chewing ability?	PIF	0.55	2.44	1.34
32	How much informed are you about the various kinds of treatments available for your oral condition?	DD	0.61	2.17	1.32
33	How much are the stains on your teeth influencing your social activities?	PSB	0.61	2.17	1.32
34	How much is your mouth condition affecting your smile?	PIF	0.61	2.17	1.32
35	How much is the cost of medicines affecting you financially?	TRE	0.55	2.39	1.31

(*continued on next page*)

Table I. Continued

	Item	*Domain*	*Frequency*	*Mean impact score*	*Impact rating*
36	How much is your bad breath influencing your social interactions?	PSB	0.61	2.11	1.29
37	How much did your need to see many doctors affect you financially?	DD	0.61	2.06	1.25
38	How difficult is it for you to gargle or use a toothbrush for maintaining regular oral hygiene?	PIF	0.55	2.28	1.25
39	How frustrated or depressed do you feel because of the efforts you have to make to stop habits such as *paan* or *gutkha* chewing or smoking?	PSB	0.55	2.28	1.25
40	How much difficulty do you face in speaking because of your mouth condition?	PIF	0.55	2.17	1.19
41	How much is your mouth condition preventing you from swallowing solid foods?	PIF	0.55	2.00	1.10
42	How difficult is it for you to eat in front of your family?	PSB	0.5	2.11	1.06
43	How much pain does your mouth condition cause you in the throat?	PIF	0.44	2.17	0.95
44	How much are your treatment “side effects” affecting your daily life activities?	TRE	0.44	2.17	0.95
45	How much is your mouth condition preventing you from swallowing liquid foods?	PIF	0.44	2.00	0.88
46	How much does your oral condition make you uncomfortable while having hot or cold foods/ drinks?	PIF	0.44	1.94	0.86
47	How much is your mouth condition affecting eating habits (e.g., had to use a spoon to eat instead of hand)?	PIF	0.33	1.78	0.59
48	How much difficulty do you face in using a straw for drinks?	PIF	0.28	1.44	0.40

DD, difficulties with diagnosis; *PIF*, physical impairment and functional limitations; *PSB,* psychological and social wellbeing; *TRE,* effect of treatment on daily life.

from the same institution. Such individuals had never been diagnosed with any chronic systemic disease and had a functional natural dentition,[31] with at least 20 teeth, no deep periodontal pockets, and no oral mucosal abnormalities. All patients completed a questionnaire consisting of the OPMD QoL questionnaire, global self-ratings of oral health, the impact of the disease on overall well-being, and the COMDQ.[16] The COMDQ was translated into Telugu for this purpose by using a standard forward—backward translation technique, as described earlier.[28] The self-ratings of oral health and overall well-being were scored by using a five-point Likert scale, ranging from *excellent* to *very poor* and from *not at all* to *very much*, respectively. The dimensionality of the 20-item OPMD QoL questionnaire was assessed by

Table II. Final questionnaire: This questionnaire asks about the effect of your mouth condition on daily life activities. Please tick one box for each item to indicate the extent to which you have been affected by the below provided problems during the past 4 weeks

		Not at all	*A little*	*Somewhat*	*Quite a bit*	*Very much*
1	How difficult was it for you to get your mouth condition diagnosed?					
2	How much did the need to visit many doctors for getting your mouth condition diagnosed affect daily life activities?					
3	How stressful was it for you to take a variety of treatments before being diagnosed with your mouth condition?					
4	How much pain and agony does your mouth condition cause you?					
5	How much burning sensation do you experience while having spicy food?					
6	How difficult is it for you to open your mouth widely?					
7	How much is your oral condition causing you to limit your desired foods?					
8	How much is your mouth condition limiting you from enjoying your meals?					
9	How much does your mouth condition affect your taste sensation?					
10	How much dryness do you feel in your mouth?					
11	How frustrated are you because of your oral condition?					
12	How depressed or low do you feel because of your mouth condition?					
13	In general, how much is your mouth condition affecting your relationship with family and friends?					
14	How much is your mouth condition affecting your satisfaction with life?					
15	How scared are you about the possibility of your oral condition turning into cancer?					
16	How scared are you about the outcome of this condition affecting your life?					
17	How embarrassing is it for you to eat foods at parties, functions, or other social gatherings?					
18	How much pain do you experience with treatment of your oral condition?					
19	How satisfied are you with the effectiveness of treatment for your mouth condition?					
20	How much are your treatment appointments affecting your daily schedule?					

using an exploratory factor analysis (EFA). After 2 weeks, the OPMD QoL questionnaire was again administered to 40 of the above 150 patients with OPMDs (11 with OL, 15 with OSF, and 14 with OLP), who attended the clinics for follow-up treatment, to assess its reliability on repeated administrations.

Statistical analyses

Content analysis of the qualitative data obtained from patients was performed with NVivo, using established qualitative methodology.[32,33] Coding in NVivo was done by two individuals independently. The agreement between the coders was measured by using kappa agreement. Kappa measures of 0.60 to 0.80 and greater than 0.80 are considered "substantial" and "perfect," respectively.[34] Statistical analysis for assessing the validity and reliability of OPMD QoL questionnaire was conducted by using SPSS Statistics for Windows, Version 22.0 (SPSS Inc., Chicago, IL). Spearman and Pearson correlation coefficients were used to evaluate the correlation of OPMD QoL questionnaire and its

Table III. Discriminant validity and reliability statistics of the OPMD QoL

	Cronbach's alpha	*ICC (95% CI)*	*OPMD patients*	*Comparison group*	*t value, significance*
Difficulties with diagnosis	0.75	0.89 (0.79-0.94)	4.99 (1.93)	3.64 (1.44)	6.85, **0.0001**
Physical and functional limitations	0.91	0.88 (0.77-0.94)	14.90 (9.69)	4.72 (3.57)	10.77, **0.0001**
Psychological and Social wellbeing	0.86	0.86 (0.73-0.93)	18.24 (4.13)	9.57 (3.30)	20.11, **0.0001**
Effect of treatment on daily life	0.70	0.89 (0.79-0.94)	5.53 (1.86)	4.06 (1.77)	7.02, **0.0001**
OPMD QoL questionnaire overall score	0.93	0.95 (0.90-0.97)	43.66 (8.73)	26.97 (8.84)	16.45, **0.0001**

CI, confidence intervals; *ICC,* intra-class correlation coefficient; *OPMD,* oral potentially malignant disorder; *QoL,* quality of life.

Table IV. Correlation of OPMD QoL scores with global self-ratings and chronic oral mucosal disease questionnaire for concurrent validity

	Pain and functional limitation	*Medications and side effects*	*Social and emotional*	*Patient support*	*Overall COMDQ score*	*Self-rating oral health*	*Self-rating impact on overall well-being*
Difficulties with diagnosis	0.36†	0.36†	0.46†	0.07*	0.46†	0.36†	0.42†
Physical and functional limitations	0.59†	0.64†	0.70†	0.14*	0.75†	0.49†	0.53†
Psychological and Social wellbeing	0.33†	0.61†	0.89†	0.25†	0.76†	0.60†	0.65†
Effect of treatment on daily life	0.51†	0.71†	0.58†	0.16†	0.69†	0.47†	0.45†
Overall OPMD QoL questionnaire score	0.53†	0.72†	0.86†	0.21†	0.85†	0.60†	0.64†

COMDQ, Chronic Oral Mucosal Disease Questionnaire; *OPMD,* oral potentially malignant disorder; *QoL,* quality of life.

*$P = .05$.

†$P = .01$.

domains with global self-ratings and the COMDQ, respectively. Correlation coefficients greater than 0.30 were considered high.[35] Unpaired *t* test was used to compare the overall and domain scores of OPMD QoL questionnaire between patients with OPMDs and healthy individuals.

Data collected from patients with OPMDs were used for factor analysis. A minimum sample size of 140 was calculated for the factor analysis, based on the range of observed communalities for the items and an item/factor ratio of 5.[36] Principal axis factor analysis rotation was conducted by using Varimax. As the final items obtained by item reduction could be grouped into four domains, we restricted the number of factors to be extracted to four. Kaiser's criterion (eigenvalue >1) was used to determine the number of factors to be retained. The reliability of the questionnaire was evaluated by internal consistency and test–retest reliability by using Cronbach's alpha and intraclass correlation coefficient (ICC) with 95% confidence interval, respectively. Cronbach's alpha values of 0.7 or greater were considered "acceptable,"[37] and ICCs greater than 0.8 were considered "excellent," whereas ICCs in the range of 0.6 to 0.8 were considered "good."[38]

RESULTS

More than half of the participants (59%) who contributed to item generation were males, and the mean age was 34.5 ± 11.5 years. Among those patients who participated in the evaluation of validity of reliability of the OPMD QoL questionnaire, 62% were males, and the mean age was 37.8 ± 10.2 years.

Item generation

Fifteen personal interviews and three focus groups were considered adequate samples for qualitative analysis, as data saturation was reached by the 11th interview. There was a strong level of agreement between the coders for qualitative analysis (unweighted kappa agreement 0.66 and weighted kappa agreement 0.65). A total of 60 items (48 from the qualitative analysis of interviews and focus group discussions, and 12 items by reviewing the existing questionnaires) were generated. Following the Delphi technique with the clinical experts, 48 items remained after deletion of a few items for redundancy and repetition. These 48 items (Table I) could be categorized under four domains on the basis of clinical experience, being similar to the themes identified through thematic analysis, as follows: *difficulties with*

Table V. Factor matrix of the final 20 items of OPMD QoL instrument demonstrating factor loadings from exploratory factor analysis

	Factor loading			
Items	*1**	*2*†	*3*‡	*4*§
How difficult is it for you to open your mouth wide?	0.781			
How much is your oral condition causing you to limit your desired foods?	0.779			
How much is your mouth condition limiting you from enjoying your meals?	0.777			
How much burning sensation do you experience while having spicy food?	0.771			
How much does your mouth condition affect your taste sensation?	0.679			
How much dryness do you feel in your mouth?	0.406			
How much pain and agony does your mouth condition cause to you?	0.334			
How scared are you about the possibility of your oral condition turning into cancer?		0.844		
How scared are you about the outcome of this condition affecting your life?		0.824		
How depressed or low do you feel because of your mouth condition?		0.710		
How much is your mouth condition affecting your satisfaction with life?		0.651		
How frustrated are you because of your oral condition?		0.601		
In general, how much is your mouth condition affecting your relationship with family and friends?		0.563		
How embarrassing is it for you to eat foods at parties, functions, or other social gatherings?		0.446		
How much did the need to visit many doctors for getting your mouth condition diagnosed affect daily life activities?			0.899	
How difficult was it for you to get your mouth condition diagnosed?			0.859	
How stressful was it for you to take a variety of treatments before being diagnosed with your mouth condition?			0.650	
How satisfied are you with the effectiveness of treatment for your mouth condition?				−0.805
How much are your treatment appointments affecting your daily schedule?				0.631
How much pain do you experience with treatment of your oral condition?				0.581

(*continued on next column*)

OPMD, oral potentially malignant disorder; *QoL,* quality of life.
*Factor 1: Physical impairment and functional limitations.
†Factor 2: Psychological and social well-being.
‡Factor 3: Difficulties with diagnosis.
§Factor 4: Effect of treatment on daily life.

diagnosis, *physical impairment and functional limitations*, *psychological and social well-being*, and *effect of treatment on daily life*. A five-point bipolar Likert response scale was used to quantify the 48 items. The five options used were *not at all*, *a little bit*, *somewhat*, *quite a bit*, and *very much*.

Item reduction

The mean impact score for all the items ranged from 0.40 to 3.12. The item “burning sensation” had the highest impact score, whereas the question on “using straw” had the lowest. There were 21 items that had an impact score of more than 1.5 and were endorsed by 50% or more individuals: three each in the domains of *difficulties with diagnosis* and *effect of treatment on daily life*, eight in *physical impairment and functional limitations*, whereas *psychological and social well-being* consisted of seven items.

Pretesting of the questionnaire

During pretesting, most patients felt that two items (“How much is the difficulty you have in opening your mouth preventing you from having certain foods?” and “How difficult is it for you to open your mouth widely?”) belonging to the domain *physical impairment and functional limitations* to be similar. The redundant item was deleted, and the final questionnaire consisted of 20 items (Table II). Items 1 to 3 belong to the domain *difficulties with diagnosis*, and the domain *physical impairment and functional limitations* consists of items 4 to 10. Items 11 to 17 and 18 to 20 belong to the domains *psychological and social well-being* and the *effect of treatment on daily life*, respectively.

Validity and reliability

Table III demonstrates that patients with OPMDs had significantly higher scores in all of the domains, and their overall summary scores were also higher than those of the healthy group. In particular, the score for the *physical and functional limitations* domain in patients with OPMDs was approximately three times of that found in the healthy group (14.90 vs 4.72). All of the dimensions of the OPMD QoL questionnaire correlated significantly positively with the domains of the COMDQ and also with global self-ratings (Table IV). The highest correlation ($r = 0.89$) was observed between the *psychological and social well-being* domain of the OPMD QoL questionnaire and the *social and emotional* domain of the COMDQ. In addition, the OPMD QoL questionnaire and the COMDQ exhibited a strong overall correlation ($r = 0.85$). All the domains of the OPMD QoL questionnaire and the overall questionnaire exhibited acceptable internal consistency. The *physical and functional limitations* domain had the highest Cronbach's alpha value (0.91) among all the domains, and the overall scale had a Cronbach's alpha value of 0.93. All of the domains and the overall scale also had excellent reliability on repeated administrations (see Table III) with the overall OPMD QoL scale having an ICC of 0.95 (95% confidence interval 0.90-0.97). Factor loading for all the items ranged from 0.334 to 0.890, and there were no cross-loadings (Table V). All of the factors had eigenvalues greater than 1, and the total variance explained by the four factors was 54.5%. Results from the EFA revealed a four-factor structure that exactly conformed to the four domains of the questionnaire.

DISCUSSION

We have reported here the development and psychometric properties of a condition-specific QoL questionnaire for patients with OPMDs. This was motivated by our systematic review that revealed the literature on QoL in patients with OPMD to be very limited.[9] Our questionnaire consists of 20 items, with five responses for each item. A score is given to each response, and the sum of the scores on all the items constitutes the overall score. The response for each item is scored from 0 to 4 with "not at all = 0" and "very much = 4." The item "How satisfied are you with the effectiveness of your treatment for this mouth condition?" is scored reversely with "not at all = 4" and "very much = 1." The summary score of the questionnaire ranges from 0 to 80, with a higher score indicating poorer QoL.

In this study, we took inputs from both patients and clinicians. Steiner and Norman[8] stated that clinicians could be considered experts at the observation of the outward clinical manifestations of a disease or disorder; however, only those who have the condition can report on subjective perceptions.[16] Riordain et al. also stressed the importance of including patients in developing a QoL questionnaire.[39] Our use of more than one source for item generation—patients, previous questionnaires, and clinical experts—provides high content validity to the newly developed OMPD QoL questionnaire.

This questionnaire has covered several specific symptoms related to OPMDs, as well as issues related to psychological and social well-being in this group of patients. It has also included questions related to the effect of delayed diagnosis, which is a common feature in OPMD cases, and the effect of prolonged treatment procedures on the everyday aspects of life. These questions have not been covered comprehensively in any of the previous oral health−related QoL questionnaires or head and neck cancer−specific questionnaires that we reviewed. For instance, the Oral Health Impact Profile questionnaire[14] is too generic and only records the overall effect of the oral cavity on various aspects of life. Furthermore, its development involved patients from a private dental practice and not from an Oral Medicine speciality.[16,24] In contrast, cancer-specific QoL questionnaires, such as the head and neck module of the European Organisation for Research and Treatment of Cancer QoL Questionnaire consists of items very specific to head and neck cancer, not all of which might have relevance to patients with OPMDs.[19] Also, the development of the COMDQ did not include patients with OSF and OL, which are habit-related disorders,[11] which are common in our study region.[40]

For our questionnaire, we chose to use a recall period of 4 weeks, taking into consideration that OPMDs are chronic conditions that progress gradually if left untreated and symptoms can increase or decrease over time. A 4-week recall period was considered suitable as the U.S. Food and Drug Administration's Patient-Reported Outcome guidelines demonstrate that those questionnaires that rely on patients' memory by using a long recall period have less content validity.[41] A recall period similar to our questionnaire has been used for QoL questionnaires for patients with many other chronic diseases.[41]

For item reduction, we used the clinical impact method, rather than a psychometric technique (viz., factor analysis). Juniper et al.[27] compared both these approaches to an asthma QoL questionnaire and found that the two approaches resulted in quite different questionnaires. They demonstrated that the three most important and clinically relevant items failed to make their place in the questionnaire that was developed by factor analysis.[27] Therefore, a clinical impact method seems more sensible, as it allows inclusion of items of particular importance to patients.

As recommended by the U.S. Food and Drug Administration for the development of patient-reported outcome questionnaires, the response options used in this questionnaire were kept simple and clear.[42] All the patients who participated in pretesting were able to differentiate between the responses, and none of them reported any difficulty in choosing the appropriate response. Further, the choice of response scale chosen for this questionnaire conforms to the responses usually expressed by the patients in interviews and focus discussions when probed on the strength of the impact of the disease on their daily life activities.

On evaluating the psychometric properties of the newly developed questionnaire, it was observed that the four-factor structure obtained by EFA conformed to the hypothesized multidimensionality of the questionnaire. The OPMD QoL questionnaire also exhibited good convergent validity and discriminant validity. In addition, the OPMD QoL questionnaire had excellent reliability. For reliability on repeated administrations, we have used an interval of 2 weeks, as this avoids any clinical change and recollection bias.[43]

This study has several strengths and weaknesses. Important established guidelines[27,30,42,44] were followed in the development of this questionnaire. Inputs from both patients and clinical experts were obtained. The applicability is, however, focused on disorders common in South Asia—less so in the Western world. There was a marginal over-representation of patients with OLP in qualitative data collection. The questionnaire was developed in a particular language but is available in English and is ready for use in different contexts after translation and cross-cultural adaptation.

The risk of malignant transformation in OPMDs varies according to disease entities, individual patients, and anatomic sites. Such a risk causes concern to patients, impacting their QoL. However, the study was not designed to quantify this risk. There is much controversy over the accuracy of clinical, histologic, and molecular markers of risk,[45] and attempts to record these (e.g., epithelial dysplasia, human papillomavirus infection status, or genetic changes) were beyond the scope of this study.

CONCLUSIONS

The OPMD QoL questionnaire is the first condition-specific questionnaire to evaluate QoL in patients with OPMDs. The questionnaire comprises 20 items measuring four domains and was found to be simple and comprehensible by the target population. The factor structure of the questionnaire conformed to the four hypothesized domains. The overall scale demonstrated good concurrent validity, with strong correlations with the COMDQ and global self-ratings. It also had good discriminant validity, with patients with OPMDs reporting poorer QoL compared with healthy individuals. The internal consistency of the overall scale and the domains was acceptable, and the reliability on repeated administrations was excellent. We recommend the use of this questionnaire in epidemiologic and treatment studies on this group of disorders.

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