


# Impact of oral potentially malignant disorders on quality of life

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**Background:** Oral potentially malignant disorders (OPMDs) could have a significant psychological impact on patients, principally because of the unknown risk of malignant transformation, while the physical and functional impairments could differ. This study aimed to assess the impact of three different OPMDs and their disease stages on the quality of life (QoL) of affected patients.

**Methods:** Oral leukoplakia (OL), oral lichen planus (OLP) and oral submucous fibrosis (OSF) patients who were undergoing treatment at an oral medicine clinic of a dental teaching hospital in India were the study population. All subjects completed the recently developed OPMDQoL questionnaire and a short form 12 item (version 2) health survey questionnaire (SF-12v2). OPMDQoL questionnaire consists of 20 items over four dimensions. A higher score denotes poor OHRQoL. SF-12v2 has two components, a Physical Component Summary (PCS) and Mental Component Summary (MCS).

**Results:** A total of 150 subjects (50 each of OL, OLP and OSF) participated. OL patients ( $37.7 \pm 7.9$ ) reported significantly better OPMDQoL scores than OLP ( $47.3 \pm 5.8$ ) and OSF ( $45.4 \pm 9.2$ ) patients. OLP patients reported significant problems in obtaining a clear diagnosis for their condition, more so than the other OPMDs. OL patients reported fewer problems for the dimension, "physical impairment and functional limitations" than the OLP and OSF patients. A significant trend was observed with the overall OPMDQoL and MCS, deteriorating as the disease stage increased.

**Conclusions:** OLP and OSF have a significant impact on the QoL of affected individuals: OL less so. Increasing stage of the disease is associated with worsening QoL.

## KEYWORDS

oral leukoplakia, oral lichen planus, oral submucous fibrosis, quality of life

## 1 | INTRODUCTION

Patients' input in evaluating their oral health needs and treatment plans has been extensively promoted,<sup>1</sup> and the subjective perception of the impact of oral health status on quality of life (QoL) has become an important method of evaluating treatment outcomes.<sup>2</sup> Studies indicate that oral diseases like periodontal diseases and tooth loss significantly impact QoL.<sup>3</sup> In particular, oral malignancies

are significantly associated with physical, psychological and functional problems that influence overall QoL. Hence, QoL is used as an important treatment outcome in head and neck cancer patients.<sup>4</sup> Although oral potentially malignant disorders (OPMD) are not life threatening until they transform into malignancies they might cause pain, affect the functioning of the oral cavity, or cause psychosocial impairment due to anxiety associated with their potentially malignant nature.<sup>5</sup>

Although national health bodies in the developed world are now encouraging evaluation of the impact of disease by use of patient reported outcome measures,<sup>6</sup> the use of QoL assessments is limited in oral medicine practice.<sup>7</sup> The literature on the QoL in OPMD patients is scanty, but from the limited literature available, a few generic QoL instruments have been used in the past.<sup>8</sup> Recently, we developed a condition-specific OPMDQoL questionnaire, which was found to be valid and reliable in assessing the QoL in oral leukoplakia (OL), oral lichen planus (OLP) and oral submucous fibrosis (OSF) patients in a Telugu-speaking Indian population.<sup>9</sup> Despite all three of these conditions having a similar psychological impact, principally because of the unknown risk of malignant transformation, the physical and functional impairments could differ. Here, we aimed to assess the ability of the instrument to differentiate the impact of three different OPMDs on various aspects of QoL. This assessment helps in further evaluating the discriminant validity of the OPMD-QoL questionnaire. Also, we aimed to determine the differences in QoL based on the extent of the disease. This will help to determine if the instrument has utility for studies of disease progression and response to therapy. In addition, we compared the impact of the three different OPMDs and their disease stages on general health-related QoL.

## 2 | MATERIAL AND METHODS

All OL, OLP and OSF patients, with no other mucosal conditions or systemic diseases, undergoing treatment at the oral medicine clinic of Panineeya Institute of Dental Sciences and Research Centre, Hyderabad, India, were invited to participate. The study was conducted during the period, October 2014 to May 2015. Written informed consent was obtained from all participants. The Ethics Committees of Griffith University and Panineeya Institute of Dental Sciences and Research Centre granted approval for the study.

Diagnosis of the OPMD was made by specialists at the oral medicine clinic based on a clinical examination which was confirmed by histopathological assessment. Detailed disease history was recorded, and a thorough clinical examination of the head, neck and mouth was conducted by a single examiner (JT). Information obtained included age, gender, past medical and dental history, history of the present complaint and details of relevant habits.

Habit history included information on the use of cigarettes, bidi (tobacco rolled in a dried Temburni leaf), smokeless tobacco or areca nut. Those subjects who smoked or used smokeless tobacco or areca nut for at least 6 months prior to diagnosis were considered as current users.<sup>10</sup> Those few patients who claimed to have indulged in any of these habits in the past but not now were considered as non-users. As only two subjects stated that they consumed only beedis, these were included with cigarette users. Most of the subjects used areca nut along with tobacco (gutka and pan with areca nut). Users of areca nut with or without tobacco were considered as one variable. Those using only smokeless tobacco were very few, and thus, the association of smokeless tobacco use with the outcome could

not be evaluated. In addition, data on duration of substance use in years (categorised as 1-5 years, 6-10 years and >10 years) and units of cigarettes smoked or areca nut/tobacco chewed per day were also recorded (categorised as 1-5 units/day, 6-10 units/day and >10 years units/day).

Disease severity was assessed based on the extent of clinical signs and symptoms. The speed of progression could not be considered due to the cross-sectional nature of the study. Disease severity was divided into stages as described by the specified authors, as follows: the staging of OSF was based on the extent of mouth opening assessed by measuring interincisal distance.<sup>11</sup> Patients were classified into, stage 1 - mouth opening >35 mm, stage 2 - mouth opening of 30-35 mm, stage 3 - mouth opening of 20-29 mm and stage 4 - mouth opening of <20 mm. The scoring proposed by Escudier et al<sup>12</sup> was used for grading OLP. Each patient was given a site, severity and pain score, the final score being the addition of the product of site and severity score and the pain score. Most OLP patients had a severity score ranging from 3 to 6 and were categorised into; stage 1 - score of 3 or less, stage 2 - score of 4, stage 3 - score of 5 and stage 4 - score  $\geq 6$ . Staging of OL was based on the system proposed by van der Waal et al (2000) which considers size and the presence of homogenous and/or non-homogenous lesions: Stage 1 - single or multiple homogenous lesions which are <2 cm in size; stage 2 - single or multiple homogenous lesions which are 2-4 cm in size; stage 3 - single/multiple homogenous lesions which are >4 cm in size or single/multiple non-homogenous lesions measuring up to 4 cm in size; stage 4: - single or multiple non-homogenous lesions which are >4 cm in size.<sup>13</sup>

The newly developed OPMDQoL questionnaire was used to evaluate the condition-specific QoL.<sup>9</sup> OPMDQoL has been found to be valid and reliable in this study population.<sup>9</sup> This instrument consists of 20 items categorised under four subscales; Difficulties with diagnosis, Physical impairment and functional limitations, Psychological and social well-being and Effect of treatment on daily life. The response for each item is scored on a five-point Likert scale, the total score ranging from 0 to 80 with a greater score representing poorer QoL.<sup>9</sup> Also, we used the short form 12 item (version 2) health survey questionnaire (SF-12 v2) to measure the self-perception of general health and well-being of the study subjects.<sup>14</sup> SF-12v2 was also used as several researchers recommend using both generic and specific instruments because generic questionnaires reflect the impact of the condition on general well-being while the disease-specific questionnaires evaluate the activities and physical functioning directly affected by the disease.<sup>15</sup> The Telugu translation of SF-12v2, software to score the completed questionnaires "Health Outcomes scoring Software" and the manual were sourced from the developers, QualityMetrics (Licence #: QMO22969). All the derivatives of health survey forms including the Telugu translation used in this study are translated using standardised "International Quality of Life Assessment" Project translation methodology.<sup>16</sup> The scoring software uses a scoring algorithm derived from the United States (US) general population. The developers of SF-12v2 have proposed using US norm-based scoring as it helps in international

comparability.<sup>17</sup> The twelve items of SF-12v2 are categorised under eight subscales: four of these (physical functioning, mental health, role physical and role emotional) consist of two items each, while the other four (bodily pain, general health, vitality and social functioning) comprise one item each. Subscale scores are used to calculate summary scores on two components; Physical Component Summary (PCS) and Mental Component Summary (MCS). The scores on the PCS and MCS could range from 0 to 100 with a greater score indicating better health status.<sup>14,18</sup>

## 2.1 | Statistical analysis

SPPS (Version 23.0. Armonk, NY: IBM Corp) was used for statistical analysis. As the overall OPMDQoL score and subscale scores were normally distributed, parametric tests were used. One-way analysis of variance (ANOVA) was used to compare the overall QoL and subscale scores between the three OPMDs and their disease stages. Post hoc analysis using Tukey HSD was executed for multiple comparisons between the three OPMDs and stages of the disease. Also, a multivariate linear regression analysis with the generalised linear model (GLM) was performed to assess the adjusted effect of independent variables (OPMD condition, staging of disease, age, gender, occupation, education, treatment duration, tobacco and areca nut habits) on OPMDQoL. For regression analysis, age and treatment duration were used as covariates (continuous variables). G-power was used to calculate the sample size, a sample size of 131 is adequate for 13 predictors in a linear regression analysis with a power of 80% and an alpha error of 5% to detect an effect size of 0.15. A *P* value of <.05 was considered statistically significant.

## 3 | RESULTS

A total of 150 (50 each of OL, OLP and OSF) patients participated in this study. The response rate was 100% as none of the cases approached declined to participate. More than half (63.3%) the subjects were male, and the mean age was 39.8 years. The most commonly reported complaints among the study population were burning sensation, difficulty in opening mouth, roughness on the cheek mucosa and pain in the mouth. Only a fifth of the patients have reported of being to the dentist in the past for issues other than the OPMD (not presented in tables).

There were significant differences for overall QoL, and subscale scores of "Difficulties with diagnosis" and "Physical impairment and functional limitations" between the three OPMDs (Table 1). On the post hoc analysis, OL patients (Mean  $\pm$  Standard deviation:  $37.7 \pm 7.9$ ) reported significantly better QoL than OLP (Mean  $\pm$  Standard deviation:  $47.3 \pm 5.8$ ) and OSF (Mean  $\pm$  Standard deviation:  $45.4 \pm 9.2$ ) patients. OLP patients reported significant problems in obtaining a clear diagnosis for their condition compared to the other OPMDs. OL patients also reported significantly fewer problems for the dimension, "physical impairment and functional limitations" than the OLP and OSF patients. There were

no differences between the OPMDs for the dimensions, "effect of treatment on daily life" and "psychological and social well-being."

Table 2 demonstrates that there was a significant trend with the overall QoL scores increasing as the stage of the disease increased. Moreover, the scores of most of the individual dimensions of OPMD-QoL also increased with the increase in the stage of the disease. In particular, subjects with stage 4 disease had significantly greater scores for the dimension "physical impairment and functional limitations" than those with stages 1, 2 and 3. Table 3 shows that OLP patients had better PCS scores than OSF patients, while there were no differences between the three OPMDs for MCS scores. Subjects with stage 4 disease had significantly lower MCS scores, indicating poor QoL than those belonging to other disease stages (Table 4).

Table S1 presents the results from the multiple linear regression analysis. Females had poorer QoL than males. Age, education status, occupation and the "treatment duration" did not have any influence on overall OPMDQoL. As observed in univariate analysis, OPMD condition and disease stages were significantly associated with OPMDQoL. OL patients had an estimated 4.87 units less OPMDQoL score than OSF patients. Also, subjects with mild disease had significantly lower OPMDQoL scores than those who had more severe disease, with subjects in stage 1 presenting 7.87 units less OPMDQoL score (better QoL) than those in stage 4. Subjects who smoked 6-10 cigarettes per day had better QoL ( $\beta = -4.15$ ) than those who were smoking more than ten cigarettes per day. Also, those patients who were using areca nut with or without tobacco for 1-5 years and 1-5 times per day reported better QoL than those who used for more than ten years and greater than ten units per day, respectively.

## 4 | DISCUSSION

In this study, we assessed the effect of three different OPMDs and the disease stages on QoL. To our knowledge, this is the first study to use a condition-specific instrument to compare the QoL between the three most common OPMDs (OL, OLP and OSF) in South Asia. It was observed that there were significant differences between the three OPMDs and their disease stages for overall OPMDQoL scores and few subscale scores.

The response rate in this study was excellent with all patients agreeing to participate. As hypothesised, there were differences in OPMDQoL dimension scores between the three OPMDs. When the subscale scores were compared, OLP patients reported significant problems in being given a clear diagnosis of their condition compared to those with either of the other disorders. This difference might be because, OSF is clearly associated with areca nut chewing while the aetiopathogenesis of OLP is both unclear and multifactorial, involving anxiety, stress, genetics and associations with several systemic diseases.<sup>19</sup> The multifactorial nature of OLP makes the diagnosis difficult for general dental practitioners. Reports from several parts of India indicate that general dentists have poor knowledge of OPMDs and oral cancers. For example, a survey among dentists of one district in Karnataka state found that approximately

**TABLE 1** Effect of different OPMD conditions on overall and subscale scores of OPMDQoL

	Oral Leukoplakia (A) N = 50	Oral Lichen Planus (B) N = 50	Oral Submucous Fibrosis (C) N = 50	F value, significance	Post hoc
Difficulties with diagnosis	4.1 ± 1.2	7.0 ± 1.6	3.9 ± 1.0	90.049, P < .001	A < B B > C
Physical impairment and functional limitations	10.5 ± 4.0	16.8 ± 2.1	17.4 ± 4.2	57.805, P < .001	A < B A < C
Psychological and social well-being	17.8 ± 4.3	18.3 ± 3.0	18.6 ± 4.9	0.392, P = .677	
Effect of treatment on daily life	5.3 ± 1.8	5.7 ± 1.7	5.6 ± 2.0	0.438 P = .646	
Overall OPMDQoL	37.8 ± 8.0	47.8 ± 5.2	45.4 ± 9.2	23.445, P < .001	A < B A < C

OPMDQoL, Oral potentially malignant disorders quality of life.

**TABLE 2** OPMDQoL and subscale scores in relation to the disease severity

	Stage 1 (A) N = 39	Stage 2 (B) N = 35	Stage 3 (C) N = 40	Stage 4 (D) N = 36	F value, significance	Post hoc
Difficulties with diagnosis	4.0 ± 1.4	4.8 ± 1.8	4.8 ± 1.6	6.4 ± 2.1	12.15, P < .001	A < D B < D C < D
Physical impairment and functional limitations	11.5 ± 4.7	14.6 ± 3.9	15.1 ± 4.3	18.7 ± 2.7	20.68, P < .001	A < B A < C A < D B < D C < D
Psychological and social well-being	16.0 ± 3.5	17.8 ± 3.0	18.7 ± 4.2	20.6 ± 4.3	9.499, P < .001	A < C A < D B < D
Effect of treatment on daily life	4.8 ± 2.1	6.5 ± 1.6	5.7 ± 1.8	5.3 ± 1.5	5.731, P < .001	A < B B > D
Overall OPMDQoL	36.2 ± 8.1	43.7 ± 5.5	44.3 ± 7.3	51.0 ± 6.8	27.401, P < .001	A < B A < C A < D B < D C < D

OPMDQoL, Oral potentially malignant disorders quality of life.

**TABLE 3** PCS and MCS scores in patients with different Oral Potentially Malignant Disorders

	Oral Leukoplakia (A) N = 50	Oral Lichen Planus (B) N = 50	Oral Submucous Fibrosis (C) N = 50	F value, significance	Post hoc
Physical Component Summary	54.2 ± 5.6	55.1 ± 5.4	51.5 ± 7.0	4.785, P = .01	C < B
Mental Component Summary	45.6 ± 8.6	43.6 ± 5.1	46.9 ± 7.0	2.794, P = .064	

**TABLE 4** SF-12 v2 component scores in relation to the disease severity

	Stage 1(A) N = 50	Stage 2(B) N = 50	Stage 3(C) N = 50	Stage 4(D) N = 50	F value, significance	Post hoc
Physical Component Summary	53.6 ± 6.2	51.0 ± 7.3	53.4 ± 6.1	56.4 ± 3.4	4.947, P < .05	D > B
Mental Component Summary	50.7 ± 8.5	45.0 ± 5.6	44.2 ± 6.3	41.2 ± 3.5	15.162, P < .001	A < B, A < C, A < D

half of the dentists were not aware that some innocuous looking oral mucosal lesions could transform into oral cancer.<sup>20</sup> Another study reported that only just above a third of the dentists of Bangalore city in the state of Karnataka routinely examined the oral mucosa.<sup>21</sup>

OSF patients reported greater levels of physical impairment and functional limitations than OL and also OLP. This can be attributed to the multiple signs and symptoms associated with OSF, which includes limited mouth opening due to the fibrosis—a matter not of major concern in OLP patients.<sup>22</sup> On the other hand, OL patients reported low scores in this dimension which might be because some of them were diagnosed incidentally during regular dental screening.

It is known that OL which is homogenous (white in colour with a flat, thin and smooth surface) is usually asymptomatic.<sup>23</sup> One of the striking findings in this study was that all three OPMDs had similar scores for impaired psychological and social well-being, scores which demonstrate that the potentially malignant nature of the disease had its impact on this aspect of their life, irrespective of differences in the functioning of the oral cavity. Prolonged treatment regimes with no definitive cure are in itself distressing for OPMD patients.<sup>24,25</sup> However, no differences were observed between the three OPMDs for the dimension “Effect of treatment on daily life.”

In relation to disease stages, there was a significant trend of patients in advanced stages of disease reporting poorer overall

OPMDQoL and worse subscale scores than those in the initial stages. This finding might serve as a proxy measure of instrument's responsiveness to treatment. Further research is recommended to evaluate the utility of the questionnaire in recording response to treatment over time through changes in the effects sizes.<sup>26</sup>

In this study, SF-12v2 was used as it is simple, and less time-consuming than the longer forms. It has also been found to be valid and reliable in a diverse range of populations in several countries.<sup>17</sup> It was observed that OLP patients had better physical health (PCS) than OSF patients. This could be attributed to the differences in social status among the three OPMDs. OSF is associated with areca nut chewing, and those subjects with OSF usually belong to manual occupations that need physical labour and therefore might have reported difficulties with regular physical activities. As was observed with the "psychological and social well-being" domain of the OPMDQoL questionnaire, MCS scores did not differ significantly between the three disorders. Patients with severe disease had significantly greater MCS scores than those with milder forms, perhaps because of greater anxiety regarding the risk of malignant transformation: apart from the inevitable pain and disfigurement of oral cancer, there is a considerable stigma attached to cancer in Indian communities.<sup>27</sup>

Findings from the multivariate analysis confirmed that clinical diagnosis and disease stages are associated with OPMDQoL scores. Also, females were found to report poorer QoL than males. Gender-based differences in QoL are evident from the literature.<sup>28</sup> Smoking was associated with poor QoL, and similar findings were observed in previous research on head and neck cancer patients.<sup>29</sup> QoL is used as a clinical measure in smokers, and a systematic review has concluded that a negative association exists between the number of cigarettes smoked and QoL which is in accordance with our findings.<sup>30</sup> Areca nut usage with or without tobacco was also found to be negatively associated with QoL. Although we could not trace any literature evaluating this association, this is likely to reflect the severity of Areca nut-induced diseases.

Our study helps in understanding patient perceptions and experiences in different OPMDs, and we believe this helps in clinical decision making. For instance, OLP and OSF patients reported greater physical impairment and functional limitations while all three conditions reported similar levels of psychological and social impact. Although we have not found any published studies which have formally compared QoL in different OPMDs, a few have observed differences in perceived QoL among patients with different oral mucosal diseases.<sup>31</sup>

The present work is thus original but is not free of limitations. This is a cross-sectional study and the findings, specifically those indicating an association between disease stages and QoL, cannot be assumed as causal. The study sample constituted subjects attending only one teaching hospital in India, and the results might not be generalisable to all OPMD patients of India, nor to other populations or ethnic groups. The sample size was, nevertheless, adequate to draw

valid conclusions and inferences representative of the target population under study.

In conclusion, OLP patients reported higher scores for the subscale "Difficulties with diagnosis" than OL and OSF patients. OLP and OSF have a significant impact on the QoL of affected individuals: OL less so. OL patients also had better scores for "Physical impairment and functional limitations" than those with OLP and OSF. There were no differences between the three OPMDs for the dimensions, "effect of treatment on daily life" and "psychological and social well-being." Increasing stage of the disease is associated with worsening QoL. Therefore, OPMDQoL instrument might have utility in monitoring response to treatment. In particular, this instrument helps clinicians to understand the psychological and social impact of OPMD on the life of their patients. Clinicians might also be able to use this information to motivate patients for habit cessation and treatment adherence

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## CONFLICT OF INTEREST

All authors declare that they do not have any conflict of interests.

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## SUPPORTING INFORMATION

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