

## Original Research

### Evaluating the Quality of Life in Patients with Oral Submucous Fibrosis and Recurrent Aphthous Stomatitis: A Questionnaire Based Pilot Study

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#### ABSTRACT:

**Background:** Oral sub mucous fibrosis (OSMF) is a precancerous condition characterized by juxta-epithelial inflammatory reaction and progressive fibrosis of the submucosal tissue affecting the oral cavity, oropharynx and sometimes the upper third of the oesophagus. Blisters, ulcerations, and recurrent stomatitis are seen as early symptoms of OSMF. The classic clinical presentation of OSMF and RAS includes, limited mouth opening and tongue protrusion along with difficulties in swallowing, eating and speaking. **Objective:** To evaluate the quality of life using OHIP-14 in OSMF and RAS patients.

**Methodology:** The demographic data were collected for all consecutive patients with a diagnosis of Oral submucous fibrosis (OSMF) and RAS during study duration of six months. The quality of life in the study patients were measured using OHIP-14. OHIP-14 is an oral health related quality of life (OHRQoL) questionnaire that is assessed on a 5-point Likert scale.

**Results:** In OSMF group 30 (75%) patients were above 26 years, 10 (25%) patients were below 25 years of age. In RAS group 23 (57.5%) patients were below 25 years of age and 17 (42.5%) patients were above 26 years. There was a significant positive correlation between handicap and all the other subscales of OHIP-14 profile (Handicap vs Functional disability, R= 0.6260; Physical pain, R= 0.6348; Psychological discomfort, R= 0.6837. Physical disability, R= 0.5620; Psychological disability, R= 0.7866; social disability, R=0.695, all P value < 0.05). In RAS, significant positive correlation seen between handicap and functional limitation, psychological disability and physical pain (handicap vs functional limitation, R=0.3162, psychological disability, R=0.3820, psychological pain, R=0.3372). **Conclusion:** To conclude the results of our study demonstrated reduced OHRQoL in patients with OSMF and RAS predominantly because of physical pain and psychological discomfort. Further studies with larger sample size evaluating the association of QOL with disease stages and different therapies are warranted.

**Keywords:** OSMF, RAS, Quality of Life

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#### INTRODUCTION

Oral submucous fibrosis (OSMF) is a precancerous condition characterized by juxta-epithelial inflammatory reaction and progressive fibrosis of the submucosal tissue affecting the oral cavity, oropharynx and sometimes the upper third of the

oesophagus. OSMF is a chronic condition that was initially confined to South Asian countries like India, Pakistan and Bangladesh.<sup>1,2</sup> However due to higher rates of immigration in the current scenario, this condition has been reported even in Western countries.<sup>2-4</sup> Among all the global registries, India

ranks first in the incidence of OSMF with a reported estimate of 5 million cases and mostly affecting females (1.2-4.57% in female and 0.2-2.3% in males).<sup>5,6</sup>

Areca nut chewing is a well-established etiological factor of OSMF.<sup>7,8</sup> Areca nuts contain substances called alkaloids that stimulate fibroblasts thereby increasing the production of collagen and flavonoids. The increased production of collagen and flavonoids inhibit collagenase enzyme leading to reduction in collagen degradation which ultimately result in the variation of fibro-elasticity of oral tissues.<sup>9</sup>

Blisters, ulcerations, and recurrent stomatitis are seen as early symptoms of OSMF. The classic clinical presentation of OSMF include stiffness in oral mucosa, limited mouth opening and tongue protrusion along with difficulties in swallowing, eating and speaking.<sup>6</sup> The initial stages of OSMF are characterized by burning sensation either on eating spicy, hot food or on intake of hot beverages, hyper salivation or xerostomia and blanching of mucosa with pathognomonic marble like appearance.<sup>5,10</sup> The clinical features in the advanced stages include palpable fibrous bands, decreased mouth opening, dysphagia, dysarthria, hearing defects and reduced gustatory sensation.<sup>11,12</sup> Evidences from literature has described epithelial dysplasia in about 7- 43% of the OSMF,<sup>13,14</sup> with malignant transformation reported in 3 to 19% of the cases.<sup>14,15</sup>

Recurrent aphthous stomatitis (RAS) or canker sore is a most frequently seen painful and ulcerative disorder of the oral mucosa.<sup>16,17</sup> It is well recognized that the symptoms caused by recurrent or chronic oral mucosal lesions such as pain during speaking, eating, and swallowing, impairment in food and liquid intake, and problems in interpersonal relationships and self-esteem can deeply affect the oral health-related quality of life (OHRQoL) of patients.<sup>18,19</sup> RAS, the most frequent oral mucosal disease, was shown to cause all of these symptoms with a significant negative impact in patients' OHRQoL indicating significantly high scores.<sup>19</sup>

The aetiology of RAS is still unclear and thought to be multifactorial with precipitating factors such as hematologic deficiency<sup>17,20</sup> food hypersensitivity,<sup>8</sup> familial tendency,<sup>1</sup> medications,<sup>9</sup> hormone imbalance,<sup>1,2</sup> immunologic abnormalities,<sup>1,3</sup> and imbalance of oral microbiome.<sup>10-12</sup> Additionally, several studies suggest that stress may serve as a trigger or a modifying factor for RAS.<sup>13</sup> In modern society, a number of diseases have been on the rise with changing lifestyles or environmental influences including, diet and psychoemotional stress.<sup>14</sup> Such impact may contribute to the development and prevalence of RAS.

As OSMF and RAS are associated with several deleterious effects on an individual's oral health, it is important to evaluate the impact of the disease on the overall quality of life (QOL) of the affected patients. The WHO defines QOL as an individual's perception

of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns.<sup>21</sup> Further Carr and colleagues defined QOL as an individual's subjective experience with both direct and indirect relation to health, disease, disability, and impairment.<sup>22</sup> There are several measuring tools to assess the health related QOL (HRQoL) and can be broadly classified into generic, disease-specific and discipline- specific questionnaires.<sup>23</sup> Oral health impact profile (OHIP), developed by Slade and Spencer in 1994 is a generic measure that is used to evaluate the patient's perception based on the social impact of oral disorders on their well-being. Later in 1997, a short form of OHIP was developed by Slade and was termed as OHIP 14 as it included only 14 questions.<sup>24</sup>

Even though there are numerous studies reporting the etiology, epidemiology, classification and different treatment modalities for OSMF, studies evaluating the quality of life in these patients are limited especially in places like coastal belt of Karnataka

**OBJECTIVE:** To evaluate the quality of life using OHIP-14 in OSMF and RAS patients.

#### **MATERIALS AND METHODS:**

The Present cross-sectional study was conducted at Department of Oral Medicine and Radiology, Oxford Dental College, Bengaluru from June 2014 to December 2014

A total 80 subjects were included in the study.

#### **Inclusion Criteria:**

- 1) Aged were aged  $\geq 18$  years
- 2) Had habit of tobacco chewing and presented with clinical signs and symptoms of OSMF (mucosal blanching, limited mouth opening, loss of puffed-out appearance of cheeks, burning sensation and fibrosis in mouth and tongue.
- 3) Patients with all clinical grades of OSMF were included in the study.

#### **Exclusion Criteria:**

Patients with chronic diseases (diabetes mellitus, hypertension, psychiatric disorders, cancer and other oral mucosal disorders), lactating and pregnant women and those who were not able to understand the questionnaire were excluded from the study.

#### **Evaluating the quality of life**

The quality of life in the study patients were measured using OHIP-14. OHIP-14 is an oral health related quality of life (OHRQoL) questionnaire that is assessed on a 5-point Likert scale. It evaluates the adverse impacts of oral conditions on aspects of well-being including pain, psychological status, social interaction and daily activities. The responses of each patient were coded as per the predefined criteria [0 =never, 1=hardly ever, 2 =occasionally, 3=fairly often, 4=very often]. All the responses were summed up to arrive at the final OHRQoL score. The total

OHRQoL score using OHIP-14 ranged between 0 to 56, with high scores indicating a compromised OHRQoL.

**STATISTICAL ANALYSIS**

All statistical analyses were performed using SPSS version 21.0 (IBM Corporation, Armonk, NY, USA). Descriptive statistics were used to present the

demographic characteristics. The association of OHIP-14 and subscales of the questionnaire were assessed using Mann-Whitney tests. We also evaluated the responses of each question of the questionnaire using ANOVA. Further the correlation among sub scales of OHIP-14 scores were performed by Karl Pearson’s correlation coefficient test. A P value of <0.05 was considered statistically significant.

**RESULTS:**

A total of 40 Study subjects were enrolled in the study in each group. Patients were divided into two groups as OSMF and RAS.

**Table 1: Social Profile of Study subjects**

		OSMF group		RAS group		P Value
		N	%	N	%	
<b>Age Group</b>	≤25yrs	10	25.00	23	57.50	Chi-square=8.7171 p=0.0031*
	26+yrs	30	75.00	17	42.50	
<b>Gender</b>	Male	36	90.00	24	60.00	Chi-square=9.6001 p=0.0019*
	Female	4	10.00	16	40.00	

In OSMF group 30 (75%) patients were above 26 years, 10 (25%) patients were below 25 years of age. In RAS group 23 (57.5%) patients were below 25 years of age and 17 (42.5%) patients were above 26 years. The age group was found to be statistically significant. In OSMF group 36 patients (90%) were males and 4 patients (10%) were females. In RAS group 24 patients (60%) were males and 16 (40%) patients were females. P<0.05 which was significant (Table1).

**Table 2 : Comparison of OSMF and RAS groups in each Question by Mann-Whitney U test (numbers are mean response)**

Questions	OSMF group	RAS group	Z-value	p-value
Difficulty in pronouncing words due to teeth or mouth related problems	0.6	1.5	-3.6790	0.00001*
Any abnormality in taste sensation due to teeth and mouth related problems	1.8	2.5	-2.9630	0.0030*
Do you have painful aching in mouth	1.3	1.9	-2.5940	0.0090*
Do you find difficulty while eating food due to tooth and mo0uth related problems	2.1	2.8	-2.9900	0.0030*
Do you feel self-conscious	1.7	2.1	-1.6380	0.1010
Did you feel tense due to tooth related problems	2.0	1.6	-1.7140	0.0870
Did you feel discomfort while having food	2.1	2.2	-0.3990	0.6900
Did you have interruption while having Food	1.2	1.4	-0.5790	0.5630
Do you find difficult to relax	1.1	1.1	-0.1410	0.8880
Did you feel embarrassed	0.6	0.8	-1.2510	0.2110
Do you feel irritable with other people	0.8	0.9	-0.6310	0.5280
Do you feel difficulty in other jobs	0.9	0.9	-0.1380	0.8900
Do you feel less satisfied	1.0	0.9	-0.5780	0.5630
Do you feel difficulty in socializing and functioning	0.4	0.4	-0.3560	0.7220

The overall response of the study patients to the 14 different questions of the OHIP-14 profile is shown in Table 2. The mean of the responses to the OHIP-14 revealed that OSMF and RAS patients were uncomfortable in eating any foods because of the underlying problem and hence their diet was unsatisfactory. Further it was also evident that OSMF patients felt tense because of the underlying disease condition. The OSMF patients were mainly concerned about their reduced mouth opening further reducing the QOL in these patients. Further it was also noted that the OSMF patients experienced altered sense of taste and were self-conscious about their condition especially in advanced cases.

**Table 3 Comparison of OSMF and RAS groups with OHIP-14 and its sub scales scores by Mann-Whitney U test**

Variable	Groups	Mean	SD	Sum of ranks	U-value	Z-value	p-value
Total quality of life	OSMF group	17.45	9.95	1418.00	578.00	-1.9637	0.0500*
	RAS group	20.83	7.14	1822.00			
Functional limitation	OSMF group	2.38	1.19	1217.00	397.00	-3.8779	0.0001*
	RAS group	3.93	1.87	2023.00			
Physical Pain	OSMF group	3.40	1.53	1289.50	469.50	-3.1802	0.0015*
	RAS group	4.63	1.53	1950.50			
Psychological Discomfort	OSMF group	3.60	2.07	1623.00	797.00	-0.0289	0.9770
	RAS group	3.65	1.41	1617.00			
Physical Disability	OSMF group	3.30	1.99	1552.00	732.00	-0.6543	0.5129
	RAS group	3.60	1.69	1688.00			
Psychological Disability	OSMF group	1.65	1.81	1514.50	694.50	-1.0152	0.3100
	RAS group	1.90	1.57	1725.50			
Social Disability	OSMF group	1.70	1.83	1572.00	752.00	-0.4619	0.6442
	RAS group	1.80	1.57	1668.00			
Handicap	OSMF group	1.43	1.53	1629.00	791.00	-0.0866	0.9310
	RAS group	1.33	1.38	1611.00			

We evaluated the correlation of the subscales among the study population using Mann-Whitney U test. Our study demonstrated a significant positive correlation among the subscales which include functional limitation and physical pain of OHIP-14 profile as outlined in Table 3.

**Table: 4 Correlations among sub scales of OHIP-14 scores by Karl Pearson’s correlation coefficient method in OSMF group**

Variables	Functional limitation	Physical Pain	Psychological Discomfort	Physical Disability	Psychologic al Disability	Social Disability	Handicap
Functional limitation	-						
Physical Pain	0.5195*	-					
Psychological Discomfort	0.6955*	0.5359*	-				
Physical Disability	0.6435*	0.6407*	0.6453*	-			
Psychological Disability	0.6586*	0.5153*	0.6331*	0.7367*	-		
Social Disability	0.5590*	0.5106*	0.4816*	0.7372*	0.8529*	-	
Handicap	0.6260*	0.6348*	0.6837*	0.5620*	0.7866*	0.695*	-

There was a significant positive correlation between handicap and all the other subscales of OHIP-14 profile shown in Table 4 (Handicap vs Functional disability, R= 0.6260; Physical pain, R= 0.6348; Psychological discomfort, R= 0.6837. Physical disability, R= 0.5620; Psychological disability, R= 0.7866; social disability, R=0.695, all P value < 0.05).

**Table: 5 Correlations among sub scales of OHIP-14 scores by Karl Pearson’s correlation coefficient method in RAS group**

Variables	Functional limitation	Physical Pain	Psychologic- al Discomfort	Physical Disability	Psychologic al Disability	Social Disability	Handicap
Functional limitation	-						
Physical Pain	0.3298*	-					
Psychological Discomfort	0.2819	0.6523*	-				

<b>Physical Disability</b>	0.2331	0.5149*	0.3277*	-			
<b>Psychological Disability</b>	0.3647*	0.6473*	0.4263*	0.5557*	-		
<b>Social Disability</b>	0.0383	0.1811	0.2807	0.0174	0.3146*	-	
<b>Handicap</b>	0.3162*	0.3372*	0.2575	0.2211	0.3820*	0.1720	-

\*p<0.05

In relation to patients of RAS, Pearson’s correlation between the sub scales showed positive correlation in most of the subscales except between functional limitation & social, physical disability, psychological discomfort. Physical Pain, Psychological Discomfort. Physical Disability were also not affecting the social disability of the patients which inturn indicated that quality of life in all aspects was affected more in patients of OSMF than RAS( Table 5).

**DISCUSSION:**

Oral Submucous Fibrosis is one of the high risk potentially malignant disorder that progress into cancer with high malignant transformation rate. The presence of other PML and oral ulcers on OSMF can further deteriorate the QOL of the patient. Pain is the major symptom seen in RAS that starts in the first 24 hours as tingling and mild irritating sensation and then ascends and peaks during the first 3-4 days. Although the disease is of self-limiting in nature, pain associated with this leads to impaired oral food and fluid intake and results in dehydration may be debilitating.<sup>25</sup> the recent years QOL assessment has established as a substantial concept and target for several researches and in treatment of many chronic conditions. QOL assessments aid in achieving symptom relief and also in improving the care and rehabilitation of patients.<sup>26</sup>In the modern health research and practice, QOL is considered as a valid, appropriate and significant tool of service need and intervention outcomes. The OHIP-14 questionnaire used in the present study is designed to measure self-reported dysfunction, discomfort and disability attributed to oral diseases and also supply valuable information regarding the patient’s perspective on his or her disease, which helps the clinician to modify the treatment provided following this in depth evaluation. The OHIP-14 questionnaire is very reliable and sensitive to changes and also to exhibit suitable cross cultural consistency.<sup>27</sup> There are limited studies assessing the QOL in OSMF patients. As there is no OSMF- specific questionnaire, we chose OHIP-14, a generic questionnaire for our study. OHIP-14 is a well-known questionnaire that is available in many languages and allows comparisons between the different population groups and disease conditions.<sup>19,28,29</sup> As OSMF is a premalignant condition that has negative impact on overall general health, a generic questionnaire was chosen for our study. Subjects were given the questionnaire in Canada and in English.

In our study, the mean QOL was 17.45 ± 9.95. Similar to our results, Jena et al reported a QOL of 19.10 ± 7.66 in OSMF patients.<sup>30</sup>The mean QOL was 20.83 ± 7.14 in RAS patients, BijinaRajan et al reported a

QOL of 45.69 ± 20.18 and also stated that recurrent aphthous ulcer and pemphigus adversely affects QOL more than the other chronic oral mucosal diseases.<sup>31</sup> Further they reported lower QOL because of physical pain and psychological discomfort which were similar to the findings of our study.<sup>31</sup> Physical pain in the study group may due to burning sensation or limited mouth opening and hence deteriorating the diet. The psychological discomfort is usually due to limited mouth opening and difficulty in speech. An increase in physical pain and psychological discomforts have also been reported in other conditions including temporomandibular disorders,<sup>32</sup> oral cancers, precancerous lesions<sup>33</sup> and oral mucosal diseases.<sup>34</sup> Maximum effect of OSMF and RAS was seen on QOL because of physical pain and psychological discomfort. The more physical pain was noted in both OSMF and RAS is because of burning sensation while taking spicy food and hot beverages which ultimately cause problem in eating. Stomatitis is a significant feature of OSMF, which is secondary to the epithelial atrophy of oral mucosa. Considering the characteristics and multiplicity of signs and symptoms of OSMF and RAS, discomfort during eating is first function to be affected. OSMF might cause social trauma particularly if the lesion has involved lips and tongue. Further, it physical pain and psychological discomfort has been reported in elderly patients in North-East Poland mainly due to poor dental status.<sup>35</sup> Compared to the other diseases, OSMF patients had slightly lower OHRQoL. Contrary to our results, Chaudhry and colleagues reported no increased physical pain or psychological discomfort in their study group involving 300 OSMF patients. In their study, Chaudhry et al used WHOQOL-BREF questionnaire to assess the overall quality of life.<sup>12</sup> Further, the patients in our study complained mainly about their unsatisfactory diet and discomfort in eating certain food due to burning sensation. The results of our study with comparable with that of Husain and Tatengkeng. Study, wherein they reported negative impact of unsatisfactory diet and discomfort as the leading causes for poor OHRQoL in urban and rural population of KutaiKartanegara Regency area.<sup>19</sup> In our study we observed that pain, physical status,

and patient's psychological status were equally affected in patients with RAS and OSMF.

## CONCLUSION

To conclude the results of our study demonstrated reduced OHRQoL in patients with OSMF and RAS predominantly because of physical pain and psychological discomfort. Further studies with larger sample size evaluating the association of QOL with disease stages and different therapies are warranted. We also recommend developing disease specific questionnaires for OSMF and other chronic oral diseases so as to validate the QOL in these patients.

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