

Impact of Oral Submucous Fibrosis on Quality of Life: A Cross-Sectional Study

Kirti Chaudhry¹ · Rishi Bali² · Arun Kumar Patnana¹  · Sukhvinder Bindra³ · Gaurav Jain¹ · Prem Prakash Sharma⁴

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Abstract

Background Oral submucous fibrosis (OSMF) is a chronic disease of the oral cavity which presents clinically with burning sensation, leathery consistency of oral mucosa with palpable fibrous bands leading to reduced mouth opening. Though the evaluation of quality of life (QOL) in health care is gaining importance, researches regarding the evaluation of QOL in OSMF individuals are very sparse. **Aim** The aim of the present study is to evaluate the QOL assessment in OSMF patients through WHOQOL-BREF questionnaire.

Methodology The study includes a total of 300 participants recruited from the outpatient department. The quality of life was assessed using the WHOQOL-BREF questionnaire. The raw scores for the physical health, psychological health, social relationships and environmental health domains were done on 4–20 scale suggested by the WHOQOL procedural manual. The analysis of variance (ANOVA) was used for the simultaneous comparison of mean scores for the four domains, and independent *t* test was used for the comparison of two means of domain scores.

Results The participants with OSMF have a significant negative impact on the quality of life when compared with the participants without OSMF ($P = 0.002$). The environmental factors in the WHOQOL-BREF have shown a significant difference in the QOL of participants with OSMF than without OSMF ($P = 0.001$).

Conclusion The oral submucous fibrosis has a negative impact on the quality of life in participants with OSMF specifically in social and environmental domains of the WHOQOL-BREF questionnaire.

Keywords Oral submucous fibrosis · Quality of life · WHOQOL-BREF · Oral premalignant condition · Environmental health

Introduction

Oral submucous fibrosis (OSMF) is a chronic disease of the oral cavity which is more commonly found in patients of Indian subcontinent and South East Asia [1]. Epidemiological and in vitro experimental studies have shown that areca nut chewing is the major etiological factor for the development of OSMF [2, 3]. The alkaloids in the areca nut stimulate the fibroblasts to produce collagen and flavonoids. The collagen and flavonoids inhibit collagenase enzyme and reduce the collagen degradation which finally results in the alteration of fibro-elasticity of oral tissues [4].

The common sites affected are buccal mucosa, labial mucosa, retromolar pads, soft palate and floor of the mouth. Early clinical features of OSMF include burning sensation, hypersalivation or xerostomia and mucosal blanching with marble like appearance [5, 6]. In later stages, the mucosa changes to leathery consistency and becomes inelastic with palpable fibrous bands [7]. Eventually, OSMF leads to

✉ Arun Kumar Patnana
arun0550@gmail.com

¹ Department of Dentistry, AIIMS, Jodhpur, Rajasthan, India

² PG Department of Oral and Maxillofacial Surgery, DAV Centenary Dental College and General Hospital, Yamunanagar, Haryana, India

³ ARMY Dental College and Hospital, Hyderabad, Andhra Pradesh, India

⁴ Department of Public Health Dentistry, AIIMS, Jodhpur, Rajasthan, India

reduced mouth opening, difficulty in swallowing, speech, hearing defects and reduced gustatory sensation [8]. OSMF also can transform into cancerous lesions, particularly oral squamous cell carcinoma, with a malignant transformation rate of 7.6% [9]. Evaluating the quality of life in health care has been acknowledged as very important in recent times. Health-related quality of life (HRQOL) is defined as individual's perceptions 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 [10].

Though, there is an extensive literature available regarding etiology, epidemiology, clinical features and different treatment modalities for OSMF, the effect of this premalignant condition on the quality of life still has not been properly investigated. Hence, the primary objective of the study was to evaluate the quality-of-life assessment in OSMF patients through WHOQOL-BREF questionnaire. The null hypothesis states that there would not be any alteration of quality of life in individuals affected with OSMF in comparison with healthy controls.

Materials and Methods

The cross-sectional study was conducted in the Department of Dentistry, All India Institute of Medical Sciences, Jodhpur, Rajasthan, India, during the time period of February 2017–October 2017 after obtaining clearance from Institutional Ethics Committee. In the present study, a total of 184 clinically diagnosed OSMF patients were screened, all 150 patients who gave consent were assessed for quality of life using WHOQOL-BREF questionnaire and a detailed proforma including the patients demographics, habitual, clinical features, and quality-of-life features was filled. Healthy individuals with minor dental problems, patient attendants and hospital staff who gave consent were included in the control group, and their quality of life was assessed through the same questionnaire. Both the group individuals with chronic, morbid diseases and severe medical illnesses with ASA 4 and 5 were thoroughly checked and excluded thus taking care of confounding factors in the present study. Subjects with restricted mouth opening because of odontogenic infections and temporomandibular joint disorders were also excluded from the study. An informed consent was taken from all the subjects, and complete confidentiality was assured.

The first and second questions were scored and analyzed separately for the overall quality of life and health of the participants in both the groups. The insignificant statistical difference in the overall health of the participants (inferred by second question) with and without OSMF infers the

homogeneity of participants in both the groups. This along with the patient selection ruled out the selection bias. Information bias was taken care by administering the same tool WHOQOL-BREF in both the groups by single investigator. However, the data interpretation and statistics were done by a separate trained examiner, thus minimizing the risk of assessment bias.

The copyright permission was sought for WHOQOL-BREF questionnaire in both Hindi and English languages for assessing the quality of life for individuals with and without OSMF. The WHOQOL is a 26-item instrument (WHOQOL-BREF) which includes two general questions and four domains:

1. physical health (7 items),
2. psychological health (6 items),
3. social relationships (3 items), and
4. environmental health (8 items); it also contains about individual's overall perception of quality of life and individual's overall perception of their health. Each individual question of the WHOQOL-BREF is scored from 1 to 5 on a response scale, which is stipulated as a five-point ordinal scale. Each subject was explained the question clearly and based upon the subjects response a particular score was given for a specific question.

The four domain scores denote an individual's perception of their quality of life in each particular domain. Domain scores are calculated in a positive direction where the higher scores denote the higher quality of life. The mean score of items within each particular domain was used to calculate the specific domain raw score. The raw scores developed for each domain was transformed to 4–20 scale using the tables given by WHOQOL-BREF procedural manual. If more than 20% of data were missing for an assessment, the assessment of the participant was excluded. If any one of the items was missing in the WHOQOL-BREF, the mean of other items in the domain was substituted. If more than two items were missing from the particular domain, the domain score was not calculated (with an exception for domain 3, where the domain was calculated if less than 1 item is missing).

Data Analysis and Results

The homogeneity of the cases and controls was assessed by considering the responses of the second question in WHOQOL-BREF. No statistical significant difference was observed between the overall health of the participants with and without OSMF ($P = 0.283$) (Table 1). However, a statistically significant difference was observed regarding the overall quality of life between the participants with and

Table 1 Assessment of homogeneity of cases and controls based upon the second question of WHOQOL-BREF

QOL question	Responses to the question	Participants with OSMF <i>N</i> = 150 (%)	Participants without OSMF <i>N</i> = 150 (%)	χ^2 value	<i>P</i> value*
How satisfied are you with your health?	1, 2, 3 ^a	32 (21.3)	27 (18.1)	2.5217	0.283
	Satisfied	102 (68)	97 (65.1)		
	Very much satisfied	16 (10.7)	25 (16.8)		

^a1, very dissatisfied; 2, dissatisfied; 3, neither satisfied nor dissatisfied

**P* value of more than 0.05 is considered as not statistically significant

without OSMF as assessed through the second question of WHOQOL-BREF. The second question was analyzed using the Chi-square test of association between individuals with and without OSMF. The participants without OSMF have a significantly higher quality of life in comparison with those with OSMF (15.43 ± 2.12 vs 14.33 ± 2.06 , with *P* value ≤ 0.01) (Table 2). Hence, further analysis was done to explore the statistical difference between the four domains of the WHOQOL-BREF. The four domains were compared among cases and controls by applying independent *t* test using SPSS statistical software 21. *P* value < 0.05 is considered as significant.

No statistically significant difference was observed for physical health, psychological health and social relationship domain of WHOQOL-BREF questionnaire. The quality-of-life scores are shown in Table 3. The least mean difference of QOL scores between participants with and without OSMF was observed in the psychological health domain (0.10 although statistically insignificant), whereas the highest mean difference of QOL scores was observed in the environmental health domain (1.09) and it was significant statistically (*P* value = 0.00) (Table 3).

Discussion

Quality of life is gaining a worldwide acceptance in assessing various diseases and their effect on human race as a whole. QOL is both clinically and physiologically a

meaningful endpoint, and it is best defined only from the patient's perspective [11]. Measuring QOL in OSMF has not been the focus of clinical practice and research in the past decades, but in recent times it is gaining importance and may be used as a tool for assessing treatment outcomes [12]. In a survey of MEDSCAPE, it was found that from a period 1982–1999 total of 38,371 studies have been done assessing quality of life in various diseases and in the same time span from 2000 to 2017 the number showed an almost sevenfold increase to 2, 74,147. Similarly, assessment of quality of life in various oral conditions has shown a tenfold increase from 1526 (in the time frame of 1982–1999) to 15,884 (time frame of 2000–2017). The importance of QOL is being increasingly recognized and is reflected in its use as an outcome measure in oral premalignant lesion research, in the recent times [13].

The quality of life in diseased individuals can be measured using generic, disease-specific, and discipline-specific questionnaires [14]. Generic questionnaire cannot detect the clinical changes associated with the specific disease, but they do allow the comparison between different disease conditions [15]. The disease-specific questionnaire can accurately analyze the clinical changes associated with the particular disease, but they cannot allow the comparisons between different diseases [16]. The discipline-specific questionnaire aids an improved accuracy and sensitivity to identify disease-specific changes at the same time maintaining the ability to compare QOL in different diseases [17].

Table 2 Assessment of overall quality of life between cases and controls based upon the first question of WHOQOL-BREF

QOL question	Responses to the question	Participants with OSMF (<i>N</i> = 150)	Participants without OSMF (<i>N</i> = 150)	χ^2 value	<i>P</i> value
How would you rate your quality of life?	1, 2, 3 ^a	40	23	12.2801	0.0022*
	Good	83	76		
	Very good	27	51		

^a1, very poor; 2, poor; 3, neither poor nor good

**P* value of more than 0.05 is considered as not statistically significant

Table 3 Comparison of cases and controls for four different domains of WHOQOL-BREF questionnaire

Analyzing domain	Evaluation groups (N)	Mean $\pm$ SD	Standard error mean	Mean difference ^a	95% CI	T value ^b	P value *
Physical health	With OSMF (150)	15.38 $\pm$ 2.01	0.16	0.20	– 0.27 to 0.68	0.85	0.39
	Without OSMF (150)	15.17 $\pm$ 2.22	0.18				
Psychological health	With OSMF (150)	15.50 $\pm$ 2.15	0.17	0.10	– 0.37 to 0.57	0.42	0.68
	Without OSMF (150)	15.39 $\pm$ 2.02	0.16				
Social relationships	With OSMF (150)	15.65 $\pm$ 2.23	2.53	– 0.52	– 1.06 to 0.02	– 1.89	0.06
	Without OSMF (150)	16.17 $\pm$ 2.53	0.20				
Environmental health	With OSMF (150)	14.33 $\pm$ 2.06	0.16	– 1.09	– 1.56 to – 0.61	– 4.51	0.00
	Without OSMF (150)	15.43 $\pm$ 2.12	0.17				

^aMean difference was calculated by subtracting the mean scores of participants without OSMF from mean scores of participants with OSMF

^bIndependent t test was used for the comparison of quality of life between cases and controls for the four domains

*P value of less than 0.05 was considered as statistically significant

In the absence of OSMF-specific QOL questionnaire, World Health Organization QOL-BREF (WHOQOL-BREF) questionnaire was chosen over dental specialty-based questionnaire in our study. WHOQOL-BREF is one of the best known instruments which is available in many languages and allows for cross-comparisons of QOL in different cultures and different diseases. Further, we firmly believe OSMF is an oral presentation of a premalignant condition whose effects are way beyond the boundaries of oral health. Thus, a generic questionnaire (WHOQOL-BREF) was preferred over specialty-specific questionnaire, so that the effect of different systemic diseases on the quality of life in same or different populations can be compared using this standard instrument.

In the present study, first two questions of the WHOQOL-BREF questionnaire were inferred separately wherein results of question No. 2 (Table 1) suggested that both population groups are homogenous. However, a statistically significant difference was observed in quality of life of diseased group than controls for the first question (Table 2). It infers that QOL was negatively influenced in individuals with OSMF. The present results are in agreement with those obtained in other populations as well [18–20]. Further, all the four domains, namely physical, psychological, social and environmental, were further analyzed separately to identify the specific domain in which quality of life of OSMF patients was affected.

In the present study, the OSMF patients have shown no significant difference of physical health domain of WHOQOL when compared with the control participants. The results of the present study are contradictory to the results of Villanueva et al. [19], Tadakamadla et al. [20], where they observed that the quality of the physical factors shows a significant impact on the oral health quality of life. The

contradictory results of physical health domain in the present study to the previous literature might be because of variations in the study samples analyzed, where all the participants of OSMF with no restrictions on clinical severity were included in the present study for evaluation the QOL. Use of generic questionnaire seems to be another reason to miss on the physical assessment of QOL in OSMF patients.

It was observed that the OSMF patients have no negative impact on the psychological wellbeing of the individuals in routine life. The results of no significant negative effects of QOL on the psychological health were contradictory to the earlier reports of QOL evaluation studies in premalignant lesions [19–22]. Further surprisingly QOL in diseased group was better although the effect was insignificant (Table 3). The contradictory results in the present study might be because of proven euphoric effects by certain the etiologic agents (betel nut) for the initiation and progression OSMF. [23, 24].

The present study has also observed that though the results are statistically not significant (*P* value 0.06), the individuals affected with the OSMF are negatively affected under the social relationships domain with higher mean scores of WHOQOL-BREF scale (Table 3). The present study results are in accordance with the early literature, where they observed that the oral premalignant lesions negatively affect the quality of life of individuals [20, 25]. Though the present study reports the negative QOL effects on the social domain for OSMF individuals, the exact reason behind the negative personal relationships, social support, sexual activity of OSMF individuals with others would require further research.

The environmental domain which includes the questionnaire including home environment and family

conditions has shown a significant reduction of quality of life in the OSMF patients in the present study. The classical sign of reduced mouth opening in OSMF patients has shown a direct impact on the discomfort levels of one's quality of life in the daily living [5]. The burning sensation to the spicy food needs to be considered for reduction of quality of life in OSMF individuals [6]. The significant difference of quality of life for the environmental health domain in OSMF patients to the control participants in the present study proved that the OSMF patients do compromise on the environmental factors in the daily living of life.

Throughout the commencement of this study, utmost care was taken to minimize the potential sources of various biases, confounding factors which improve the quality of our research work. However, the QOL was not assessed according to the grading in the present study which might reduce the precision of results in the present study suggesting a need of QOL assessment according to grades of progression of OSMF. Though every effort was made to evaluate the difference between QOL of OSMF patients to the normal individuals, the authors recommend further cross-sectional studies to evaluate the individual factors in each domain of WHOQOL in association with oral submucous fibrosis. The authors also recommend further researches to correlate the demographic and severity of clinical findings with the QOL in OSMF patients. Most importantly, authors strongly advocate a need of disease-specific questionnaire to completely assess quality of life in OSMF patients. Our study has systematically assessed QOL in OSMF patients using WHOQOL-BREF and has established a stepping stone for population-specific and disease-specific comparisons.

Conclusion

The present study results conclude that the oral submucous fibrosis (OSMF) has a negative impact on the quality of life specifically in the environmental domains of the WHOQOL-BREF questionnaire. The physical and psychological factors have shown no negative impact on QOL of participants with OSMF. The disease (OSMF)-specific WHOQOL-BREF questionnaire is required for the precise assessment of QOL in individuals affected by oral submucous fibrosis.

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