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Quality Of Life Assessment In Factory Workers With Oral Submucous Fibrosis: A Cross Sectional Study Of 424 Patients

Running Title: Quality Of Life Assessment In Factory Workers With Oral Submucous

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ABSTRACT

Oral submucous fibrosis (OSMF) is a precancerous disorder prevalent in the Southeast Asia and Indian sub continent. It can happen at any age, although young people and adults between the ages of 25 and 35 are most frequently affected (2^{nd} to 4^{th} decade). Its clinical presentation is such that it leads to a significant deterioration in the cultural emotional, social and physical aspect of life. Therefore, In this study, the World Health Organization Quality of Life-BREF (WHOQOL-BREF) questionnaire was used to assess the quality of life (QoL) and gather data of patients with oral submucous fibrosis (OSMF). This cross-sectional study was conducted among factory workers of Ahmedabad, Gujarat. We used the consecutive sampling technique to recruit patients who were clinically diagnosed with OSMF (n = 424). The first two inquiries, which pertained to general QoL and general health status, were assessed independently. The remaining inquiries (3-26), which included the physical, psychological, social, and environmental health areas, were assessed independently. In order to evaluate the validity of the WHOQOL-BREF domains, Cronbach's Alpha was utilised. The OSMF patients' quality of life was generally very low, and the majority of them were not happy with the state of their oral health. Among these, domains I and II were affected more than Domains III and IV.

KEYWORD: Oral submucous fibrosis (OSMF), World Health Organization Quality of Life-BRE (WHOQOL-BREF), human papilloma virus (HPV), quality of life (QOL)

INTRODUCTION

OSMF is a pre malignant condition with a prevalence of 0.2–2.3% in males and 1.2–4.6% in females, with a broad age range from 11 to 60 years.(1–3) While betel nut chewing is considered as the main contributing factor for this disease, (4) other synergistic factors include insufficiency of vitamin B, C, and iron; persistent chewing of smokeless tobacco; abundant intake of spicy foods; genetic mutations; and human papilloma virus (HPV) infection.(6–10)

Plasma's powerful antioxidants include albumin, uric acid, and serum total protein. It is convincing enough to be utilised as a valid indicator of oxidative stress in the body as a form of protection. It might be useful for detecting oral submucous fibrosis early on (OSMF). (5)

It is an undisputed fact that chronic diseases like oral submucous fibrosis (OSMF) have a profound affect on the quality of life (QOL) of all individuals diagnosed with the same irrespective of age, profession and other qualitative and quantitative data. World Health Organisation (WHO) has defined quality of life (QOL) as an individual's perception of his position in life in the context of the culture and value system in which he lives and in relation to his goals, expectations and standards and concerns (11)

Assessing the QOL of an individual is a complex task as there are various factors like culture, psychology and social interactions involved and each may vary at an individualistic level. (12,13) A healthy person may fulfil their social obligations and achieve their goals without experiencing any physical, mental, or social discomfort, as opposed to a sick person who may find it difficult to communicate with others or eat because of pain or discomfort.(14,15)

The Chronic Oral Mucosal Disease Questionnaire (COMDQ), the Oral Impacts on Daily Performances (OIDP), the Oral Health Impact Profile (OHIP), the University of Washington Quality of Life Questionnaire (UWQOL), the World Health Organization Quality of Life-BRE (WHOQOL-BREF), and the Oral Health Related Quality of Life-UK (OHRQoL-UK). One of them, the WHOQOL-BREF questionnaire, is regarded as a reliable, valid, and multi-cultural measuring tool of quality of life (QoL), and it includes four areas of life: overall QoL and general health status, as well as physical, psychological, environmental, and social interactions.(17,18). This questionnaire can be easily translated into the native language of our industrial workers i.e. Gujarati and hence was adopted in the current study for data collection. Numerous studies have been conducted in the last 5 years to assess the effect of OSMF on QOL all over India using various data collection methods. (19–26) However, no study has been conducted solely on industrial workers in any part of the country to the best of our knowledge. The current study's objective is to rate OSMF patients' QOL. We employed the WHOQOL-BREF survey in the locals' mother tongue for this purpose. The current study's hypothesis is that if QOL is significantly impacted by OSMF, patients with OSMF will score lower on the WHOQOL-BREF and experience a variety of problems with social, mental, physical, and emotional functioning as healthy individuals.

MATERIALS AND METHODS

After receiving approval from the institutional research ethics committee, this cross-sectional study was carried out in the Department of Oral and Maxillofacial Surgery, Karnavati College of Dentistry in Ahmedabad, Gujarat, India. Prior to starting this investigation, ethical approval was requested from the university's research ethics committee. Before being enrolled, patients were told of the study's goals and procedures. Prior to the study's start, participants were asked to sign a written consent form in the local language. A sequential sampling method was used to select all patients meeting the inclusion criteria. The following inclusion criteria were used to choose study participants: Patients with OSMF whose mouth opening is between 15 and 35 mm, who are at least 18 years old. The patients were enrolled after consensus was achieved by both of the clinicians, who were experts in the field of oral and maxillofacial surgery and had more than five years' clinical experience. Demographic information was recorded on the designed proforma. A detailed history of the disease was recorded. A thorough clinical examination was performed on all recruited participants. Measurements of mouth opening (inter-incisal mouth opening) were performed following the guidelines described by Dijkstra et al. (27) Briefly, the patients were asked to open their mouths as wide as possible without feeling any discomfort or pain while keeping their heads in an upright resting position. The mouth opening was measured (in mm) from the incisal edge of the upper central incisor to the incisal edge of the lower central incisor using a vernier caliper. The staging of OSMF was done as per the classification proposed by Lai et.al. There are 26 questions in the WHOQOL-BREF questionnaire. The subsequent questions, from 3 to 26, comprise four domains, while the first two pertain to the evaluation of overall QoL and overall health condition. The domains of "physical health" and "psychological health" are respectively. "Environment = Domain 4" and "Social Relationships = Domain 3" (29,30). The questions were first thoroughly conveyed to each patient in their own language. The patients were asked to answer questions for a specific score based on the events of the previous two weeks. A Likert-type scale was used to record the responses for each question, with 1 and 5 representing the least and highest effects, respectively. A higher QoL in the relevant domain is indicated by a bigger sum of points earned.Qualitative variables, such as age group, gender, duration of chewing habits, and stages of OSMF, were calculated as frequency and percentage. Quantitative variables, such as QoL score, satisfaction with health, and domains of life, were presented as mean and standard deviation. Gender, age categories, functional staging, and habit duration were analyzed with physical, psychological, social, and environmental domains of life using an independent t-test to highlight their statistical significance. The reliability of the WHOQOL-BREF domains were assessed using Cronbach"s Alpha.

RESULT

In the present study the age of the patients ranged from 21 to 64 years with a mean age of 40.92. A total of 424 participants were included in the study The duration of the habit of eating any form of betel nut ranged from 2 years to 25 years with a mean duration of 8.40 and frequency of the habit was 2 to 4 times a day with a mean of 2.80. Of the total participants 96% were males and 4% were females. Chewing Gutkha was the most common habit

amongst the participants with 42% of the participants using it while mishri (7%) was the next most common habit.

On examination, patients with stage I, II, III and IV were 144, 188, 56 and 36 respectively. Questionnaire was prepared using WHOQoL-BREF TOOL. A Total of 26 questions were included in the questionnaire and were divided among various domains of life i.e., physical, psychological, social and environmental as shown in table 1.

In order to check the reliability statistically, Cronbach's Alpha reliability test was conducted for each of four domains of life which gave result for Domain I, II, III, and IV as 0.663, 0.798, 0.728, 0.716 respectively which suggested that the study was statistically significant (Table 2).

Study significantly shows the quality of life adversely affected as the disease progresses. Among all the aspect of the questions asked, it was found that the scoring was gradually decreased among most of the aspects. The only domain which did not significantly showed greater deviation with the group stages (i.e., stage I, II,III,IV) was DOMAIN 3 i.e., social. The standard deviation between stage I, II, III, IV in were 0.37, 0.33, 0.98 and 1.26 respectively. With this result it can be concluded that social aspect of life is though affected by is less compared with other DOMAINS analyzed. Also 95% Confidence interval and p value for the test are also favorable and have been mentioned in the respective tables

TABLE 1: : DOMAINS OF LIFE

Sr. No	Domain	Questions
1.	Physical	Physical Health
		Medical Treatment
		Enough Energy
		Get Around
		Sleep Satisfaction
		Daily Living Activities
		Capacity Of Work
2.	Psychological	Life Enjoyment
		Meaningful Life
		Able To Concentrate
		Bodily Appearance
		Self Satisfaction
3.	Social	Negative Feelings
		Personal Relationship
		Sex Life
4.	Environmental	Support From Friends
		Feeling Of Safety
		Physical Environment
		Money For Needs
		Information In Daily Life

		Leisure Activities
		Satisfaction With Living Place

TABLE 2: Cronbach's alpha reliability test

SR. NO.	Domain	Cronbach's alpha reliability test
1	I	0.663
2	II	0.798
3	III	0.728
4	IV	0.716

TABLE 3: Descriptive test for DOMAIN 1

Descriptives									
		N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
						Lower Bound	Upper Bound		
PHYSICAL HEALTH	STAGE 1	144	3.83	0.374	0.031	3.77	3.89	3	4
	STAGE 2	188	3.87	0.335	0.024	3.82	3.92	3	4
	STAGE 3	56	3.43	0.499	0.067	3.29	3.56	3	4
	STAGE 4	36	2.56	0.695	0.116	2.32	2.79	2	4
	Total	424	3.69	0.556	0.027	3.64	3.74	2	4
MEDICAL TREATMENT	STAGE 1	144	3.33	1.084	0.09	3.15	3.51	1	4
	STAGE 2	188	3.53	0.944	0.069	3.4	3.67	1	4
	STAGE	56	3	0.934	0.12	2.75	3.25	2	4

	3				5				
	STAGE 4	36	2.44	1.081	0.18	2.08	2.81	1	4
	Total	424	3.3	1.049	0.051	3.2	3.4	1	4
ENOUGH ENERGY	STAGE 1	144	3.72	0.56	0.047	3.63	3.81	2	4
	STAGE 2	188	3.51	0.501	0.037	3.44	3.58	3	4
	STAGE 3	56	3.29	0.456	0.061	3.16	3.41	3	4
	STAGE 4	36	2.78	0.797	0.133	2.51	3.05	2	4
	Total	424	3.49	0.603	0.029	3.43	3.55	2	4
GET AROUND	STAGE 1	144	4	0	0	4	4	4	4
	STAGE 2	188	4	0	0	4	4	4	4
	STAGE 3	56	4	0	0	4	4	4	4
	STAGE 4	36	4	0	0	4	4	4	4
	Total	424	4	0	0	4	4	4	4
SLEEP SATISFACTION	STAGE 1	144	4	0	0	4	4	4	4
	STAGE 2	188	3.81	0.395	0.029	3.75	3.87	3	4
	STAGE 3	56	3.64	0.483	0.065	3.51	3.77	3	4
	STAGE 4	36	3.22	0.637	0.106	3.01	3.44	2	4
	Total	42	3.8	0.422	0.02	3.76	3.84	2	4

		4							
DAILY LIVING ACTIVITIES	STAGE 1	144	3.83	0.374	0.031	3.77	3.89	3	4
	STAGE 2	188	4	0	0	4	4	4	4
	STAGE 3	56	4	0	0	4	4	4	4
	STAGE 4	36	4	0	0	4	4	4	4
	Total	424	3.94	0.231	0.011	3.92	3.97	3	4
CAPACITY OF WORK	STAGE 1	144	4	0	0	4	4	4	4
	STAGE 2	188	3.83	0.377	0.027	3.78	3.88	3	4
	STAGE 3	56	3.43	0.499	0.067	3.29	3.56	3	4
	STAGE 4	36	2.44	0.504	0.084	2.27	2.61	2	3
	Total	424	3.72	0.546	0.027	3.66	3.77	2	4

TABLE 4: Descriptive test for DOMAIN 2

		N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
						Lower Bound	Upper Bound		
LIFE ENJOYMENT	STAGE1	144	4	0	0	4	4	4	4
	STAGE2	188	3.87	0.335	0.024	3.82	3.92	3	4
	STAGE 3	56	3.36	0.616	0.082	3.19	3.52	2	4

	STAGE 4	36	2.56	0.695	0.116	2.32	2.79	2	4
	Total	424	3.74	0.555	0.027	3.68	3.79	2	4
MEANINGFUL LIFE	STAGE1	144	4	0	0	4	4	4	4
	STAGE2	188	3.85	0.357	0.026	3.8	3.9	3	4
	STAGE 3	56	3.5	0.505	0.067	3.36	3.64	3	4
	STAGE 4	36	2.67	0.676	0.113	2.44	2.9	2	4
	Total	424	3.75	0.511	0.025	3.71	3.8	2	4
ABLE TO CONCENTRATE	STAGE1	144	3.86	0.347	0.029	3.8	3.92	3	4
	STAGE2	188	3.87	0.335	0.024	3.82	3.92	3	4
	STAGE 3	56	3.5	0.505	0.067	3.36	3.64	3	4
	STAGE 4	36	2.78	0.637	0.106	2.56	2.99	2	4
	Total	424	3.73	0.506	0.025	3.68	3.77	2	4
BODILY APPEARANCE	STAGE1	144	3.75	0.548	0.046	3.66	3.84	2	4
	STAGE2	188	3.64	0.6	0.044	3.55	3.72	2	4
	STAGE 3	56	2.93	0.806	0.108	2.71	3.14	2	4
	STAGE 4	36	2.22	0.929	0.155	1.91	2.54	1	4
	Total	424	3.46	0.792	0.038	3.39	3.54	1	4
SELF SATISFACTION	STAGE1	144	4	0	0	4	4	4	4
	STAGE2	188	3.64	0.482	0.035	3.57	3.71	3	4
	STAGE 3	56	3.36	0.483	0.065	3.23	3.49	3	4
	STAGE 4	36	2.89	0.747	0.125	2.64	3.14	2	4

	Total	424	3.66	0.531	0.026	3.61	3.71	2	4
NEGATIVE FEELINGS	STAGE1	144	3.83	0.442	0.037	3.76	3.91	2	4
	STAGE2	188	3.91	0.28	0.02	3.87	3.96	3	4
	STAGE 3	56	3.36	0.483	0.065	3.23	3.49	3	4
	STAGE 4	36	2.89	0.747	0.125	2.64	3.14	2	4
	Total	424	3.73	0.524	0.025	3.68	3.78	2	4

TABLE 5: Descriptive test for DOMAIN 3

Descriptives									
		N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
						Lower Bound	Upper Bound		
PERSONAL RELATIONSHIP	STAGE 1	144	3.83	0.374	0.031	3.77	3.89	3	4
	STAGE 2	188	3.87	0.335	0.024	3.82	3.92	3	4
	STAGE 3	56	3.29	0.456	0.061	3.16	3.41	3	4
	STAGE 4	36	2.67	0.676	0.113	2.44	2.9	2	4
	Total	424	3.68	0.542	0.026	3.63	3.73	2	4
SEX LIFE	STAGE 1	144	4	0	0	4	4	4	4
	STAGE 2	188	4	0	0	4	4	4	4

	STAGE 3	56	3.57	0.499	0.067	3.44	3.71	3	4
	STAGE 4	36	3.22	0.637	0.106	3.01	3.44	2	4
	Total	424	3.88	0.356	0.017	3.84	3.91	2	4
SUPPORT FROM FRIENDS	STAGE 1	144	4	0	0	4	4	4	4
	STAGE 2	188	4	0	0	4	4	4	4
	STAGE 3	56	3.71	0.456	0.061	3.59	3.84	3	4
	STAGE 4	36	3.44	0.504	0.084	3.27	3.61	3	4
	Total	424	3.92	0.279	0.014	3.89	3.94	3	4

TABLE 6: Descriptive test for DOMAIN 4

Descriptives									
		N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
						Lower Bound	Upper Bound		
FEELING OF SAFETY	STAGE1	144	3.92	0.277	0.023	3.87	3.96	3	4
	STAGE2	188	3.87	0.335	0.024	3.82	3.92	3	4
	STAGE 3	56	3.57	0.499	0.067	3.44	3.71	3	4
	STAGE 4	36	3.11	0.747	0.125	2.86	3.36	2	4
	Total	424	3.78	0.456	0.022	3.74	3.83	2	4

PHYSICAL ENVIRONMENT	STAGE1	144	4	0	0	4	4	4	4
	STAGE2	188	3.83	0.377	0.027	3.78	3.88	3	4
	STAGE 3	56	3.36	0.483	0.065	3.23	3.49	3	4
	STAGE 4	36	2.67	0.676	0.113	2.44	2.9	2	4
	Total	424	3.73	0.524	0.025	3.68	3.78	2	4
MONEY FOR NEEDS	STAGE1	144	3.81	0.397	0.033	3.74	3.87	3	4
	STAGE2	188	4	0	0	4	4	4	4
	STAGE 3	56	3.21	0.414	0.055	3.1	3.33	3	4
	STAGE 4	36	2.56	0.695	0.116	2.32	2.79	2	4
	Total	424	3.71	0.55	0.027	3.66	3.76	2	4
INFORMATION IN DAILY LIFE	STAGE1	144	3.89	0.315	0.026	3.84	3.94	3	4
	STAGE2	188	3.57	0.709	0.052	3.47	3.68	2	4
	STAGE 3	56	3.64	0.483	0.065	3.51	3.77	3	4
	STAGE 4	36	3.56	0.504	0.084	3.39	3.73	3	4
	Total	424	3.69	0.573	0.028	3.63	3.74	2	4
LEISURE ACTIVITIES	STAGE1	144	3.61	0.681	0.057	3.5	3.72	2	4
	STAGE2	188	3.34	0.782	0.057	3.23	3.45	2	4
	STAGE 3	56	2.71	0.803	0.107	2.5	2.93	2	4
	STAGE 4	36	2.67	0.828	0.138	2.39	2.95	2	4
	Total	424	3.29	0.825	0.04	3.21	3.37	2	4
SATISFACTION	STAGE1	144	3.69	0.571	0.048	3.6	3.79	2	4

WITH LIVING PLACE	STAGE2	188	3.34	0.808	0.059	3.22	3.46	2	4
	STAGE 3	56	2.71	0.803	0.107	2.5	2.93	2	4
	STAGE 4	36	2.89	0.575	0.096	2.69	3.08	2	4
	Total	424	3.34	0.789	0.038	3.26	3.41	2	4
SATISFACTION WITH HEALTH SERVICES	STAGE1	144	3.72	0.449	0.037	3.65	3.8	3	4
	STAGE2	188	3.81	0.395	0.029	3.75	3.87	3	4
	STAGE 3	56	2.86	0.749	0.1	2.66	3.06	2	4
	STAGE 4	36	3.56	0.504	0.084	3.39	3.73	3	4
	Total	424	3.63	0.572	0.028	3.58	3.69	2	4
SATISFACTION WITH TRANSPORT	STAGE1	144	3.83	0.374	0.031	3.77	3.89	3	4
	STAGE2	188	3.89	0.309	0.023	3.85	3.94	3	4
	STAGE 3	56	3.07	0.71	0.095	2.88	3.26	2	4
	STAGE 4	36	3.44	0.504	0.084	3.27	3.61	3	4
	Total	424	3.73	0.506	0.025	3.68	3.77	2	4

The internal consistency of WHOQOL-BREF among domain I, II, III, and IV have been mentioned in table 3, table 4, table 5 and table 6 respectively.

The First domain includes physical health factors, in which the factor which is affected the most is physical health of patient. The mean difference between the stages is 1.27. The other factors are less affected comparatively. Also the patient when asked about getting around frequency, it is not affected at interpreted by data given in table 3

The Second domain includes psychological factors amongst which almost all the factors are affected. The factor which is severely affected is the patients' apprehension about life enjoyment with the mean difference of 1.44 as interpreted I table 4.

The third domain is tabulated in table 5 describing the social aspect of patient which does not show any significant difference though till some extent, patients have admitted that their personal relationships are affected when compared with staging of OSMF.

The fourth domain, depicted in table 6 includes the environmental factors which if affected were asked to the patients. Results have been found that only money needs of the patients are affected as they were not satisfied with it and has the mean difference between stage 1 and stage 4 of 1.44. Other factors were affected slightly or none at all.

DISCUSSION

OHRQoL is a newly emerging field of research in the last few decades and has an important role in clinical practice research. Furthermore, it is firmly believed that OSMF is a chronic disease that affects oral health and thus the impact of OSMF on the OHRQoL of many patients is evident (31–34). This area demands more study, particularly in South Asian countries, due to the greater prevalence of habit-related OSMF.

The mean age of the 424 participants in the study was found to be 40.92 years. Of these 96% were males and 4% were females. Mathew AL, Cherian SA, James M in 2019 conducted a cross sectional study in south kerala where the mean age of patients with OSMF was 48.63+14.2 with a male predilection of 78.9% and 21.1% females. The higher age group emphasizes the chronicity of the disease as seen in both the studies and the male predilection is further highlighted in our study as it has been conducted on factory workers where men receive more employment than women. (35)The duration of the habit of eating any form of betel nut ranged from 2 years to 25 years with a mean duration of 8.40 years and frequency of the habit was 2 to 4 times a day with a mean of 2.80. Jasper M, Srivastava A, Yadav S, Kiran Verma in 2018 corelated the duration of betel nut chewing along with presence and absence of fibrous bands in the oral cavity stated that maximum cases developed clinical presentation of OSMF after consuming betel nut for 5.1 years or more. (36) This is in conjunction with our findings as our mean duration of habit is 8.40 years.

Domain I shows no statistically significant changes in QOL. This shows direct correlation with the study conducted by Memon et al in 2021 (25)while it contradicts with the results of Chaudhary et. al in 2019 (20) stated significant changes in the oral cavity and subsequently QOL as severity of the disease progressed. Since our study was majorly on factory workers, our findings could be attributed to lack of awareness, lack of pain in functional movements of the mouth and priority of continuation of habit over health changes.

Domain II shows the maximum changes as per our analysis where the participant is conscious about his/her lifestyle and experiences mental and emotional trauma due to the same. Memon in 2021(25) and Chaudhary in 2020(19) stated low scored for this domain whereas Sagtani, R.A., Thapa, S. & Sagtani, A. in 2020 conducted a similar study on 125 smokers and 125 non smokers and observed that there was a statistically significant impact on domain II. (37) This could be due to occupational stress, social and family responsibilities, peer pressure, financial difficulties and lack of validation in their day to day life.

No significant changes were seen in Domain III in our study although as disease progresses, the hampering of social roles was voiced by the participants. This was more in females than males thereby stating that females have a better QOL than males with OSMF. Rao in 2015 observed that females are usually shy about their sexual needs and culturally bound to avoid personal relationships. (38) It was also observed that as the disease progresses, this domain gets more affected thereby affecting overall QOL. When OSMF as a disease progresses, the mouth opening becomes more and more restrained leading to speech problems also. Thus social and personal interactions get reduced and the individual tends to avoid social gatherings.

In domain IV, overall environmental factors did not show any analytically significant changes. Only the need for money was affected the most. This could be due to poor managements of finances as participants spend more money for continuation of habit than other requirements. Satisfaction with living peace was affected the least because the patient shows little to no change in domains I and III. Conundrum to these observations Memon in 2021 (25) noted the highest significant score for domain IV. He attributed this to the limited resources of the people puruse social, leisurely and recreational activities. Inspite of this, the sense of physical safety and security was found to be present and unaffected by the presence of OSMF.

CONCLUSION

424 participants were asked a total of 26 questions were asked to the patients and were divided into 4 different domains. Among these, domains I and II were affected more than Domains III and IV. Thus we can conclude that as the stage of OSMF increases, the quality of life is also affected.

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