

Original Research Article

Assessment of quality of life of patients with oral sub mucous fibrosis before and after treatment with topical curcumin

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Abstract – Background and aim: Oral Submucous Fibrosis (OSMF) is potentially pre-malignant condition of the oral cavity with a high malignant transformation rate. The condition not only affects the oral function of the patients but has a huge impact on their social and psychological wellbeing affecting the overall quality of life. To evaluate the effectivity of the treatment assessing the quality of the life of these patients before and after treatment is of utmost importance but till now has not been an integral part of the management strategy. This study was carried to assess the change in quality of life before and after treatment with curcumin in patients with OSMF. **Methods:** Quality of life was assessed before and after 3 months of treatment with topical curcumin in 50 patients with OSMF using European Organization for Research and Treatment of Cancer Quality of Life head and neck Questionnaire (EORTC QLQ35). **Results:** At the end of 3 months there was significant ($p < 0.05$) change in the quality of life of patients with OSMF as suggested by assessment of the multi-item and single item scale used in the questionnaire. **Conclusion:** The study emphasizes the use of assessing Quality of life as an integral part of treatment strategy for OSMF and suggests curcumin as a promising treatment modality for patients with OSMF.

Introduction

Oral Sub Mucous Fibrosis (OSMF) is considered as one of the most frequently encountered Oral potentially malignant Disorders (OPMD) [1]. In 1966, Pindborg and Sirsat defined OSMF as “An insidious chronic disease affecting any part of the oral cavity and sometimes the pharynx. Although occasionally preceded by and/or associated with vesicle formation, it is always associated with a juxta-epithelial inflammatory reaction followed by a fibro-elastic change of the lamina propria, with epithelial atrophy leading to stiffness” [2]. The patients of OSMF present with symptoms like burning sensation, ulceration, xerostomia, restricted mouth opening which are bothersome and interfere with the patients quality of life [3]. The management approach for OSMF mainly consists of supportive treatment which includes multivitamin, antioxidants and iron supplements and a diet rich with fruits and green leafy vegetables in combination with medicinal treatment for mild to moderate stages like topical steroids, intra-lesional injections with steroids or steroids in combination with

hyaluronidase, placental extract, interferon gamma and surgical interventions for severe cases which include intraoral and extra oral flaps, split skin grafts, laser surgery, fibrotomy with coronoidectomy etc. [4]. Though a extensive variety of treatment options are available for OSMF, most of them are only symptomatic and do not provide substantial long lasting results, and hence a search of better treatment modality is always a topic of research [5]. Curcumin has been a focus of exploration in the management of OSMF owing to its potent anti-oxidant, anti-inflammatory, fibrinolytic, anticancer and antitumor properties and its potential use in OSMF has been backed by many studies [5,6].

Quality of Life (QOL) as defined by WHO is an individual's perception of his or her position in life in the context of the culture and value systems in which the patient lives and in relation to his or her goals, expectations, standards and concerns [7]. There has been increase in the importance of using QOL as an outcome measure and as survival rate criterion in head and neck oncology [8].

Keeping in view the increasing number of cases of OSMF and considering its premalignant nature and complexity of management approaches the following study was undertaken

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Table I. Showing mean & SD (descriptive statistics) of numerical variable.

	N	Minimum	Maximum	Mean	Std. Deviation
Age	50	21	64	40.92	11.110
Duration of habit in yrs	50	2	25	8.40	6.220
Frequency of habit	50	2	4	2.80	.782

to assess the quality of life in patients with OSMF before and after treatment.

Aims and objectives

- Compare quality of life in patients with OSMF to that with healthy patients.
- Compare pre-treatment and post treatment change in Quality of life of patients.

Methods

The study was approved by the institutes ethical committee (vide registration ECR/457/Inst/MH/2013/RR-20). For the study 50 patients with clinically diagnosed stage I and Stage II OSMF based on functional classification given by Kerr *et al.* [9] and 50 healthy controls without any habit or lesion or any dental problems at present were selected. Stage III, IV, V patients were not included in the study as patients belonging to this category with less than 25 mm of mouth opening are indicated for surgical treatment rather than medicinal treatment. As topical curcumin was used as an intervention, only stage I and II patients who would benefit from medicinal treatment were selected [10].

The classification by Kerr *et al.* is as follows:

Stage 1: Mild: Any features of the disease triad for OSMF (burning, depapillation, blanching or leathery mucosa) may be reported and inter-incisal opening >35 mm.

Stage 2: Moderate: Above features of OSMF and inter-incisal limitation of opening between 20–35 mm.

Stage 3: Severe: Above features of OSF and inter-incisal opening <20 mm.

Stage 4A: Above features of OSMF with other potentially malignant disorders on clinical examination.

Stage 4B: Above features of OSMF with any grade of oral epithelial dysplasia on biopsy

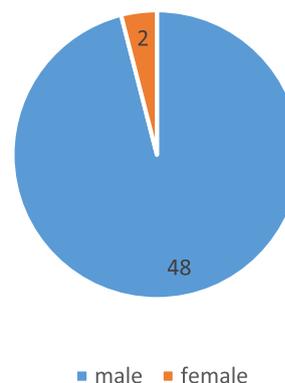
Stage 5: Above features of OSMF with oral squamous cell carcinoma.

Age group for the study was 13 years and above and patients of either gender were recruited. Patients not under any intervention for OSMF were included. Patients with stage III, stage IV and stage V OSMF and with any other Oro-mucosal lesion other than OSMF, with history of previous treatment for the same, medically compromised patients and those who were not ready to participate in the study and did not sign the informed consent were not included in the study.

Table II. Diagram 1 – Distribution as per gender.

	Frequency	Percent
Female	2	4.0
Male	48	96.0
Total	50	100.0

Gender distribution



After the patients signing the informed consent document and thus willing to voluntarily participate in the study, case history of these patients was recorded which included the demographic details, a detailed recording of the habit in regards to type of tobacco, duration, frequency was done and through clinical examination of the condition to categorise the stage of OSMF along with base line evaluation of the signs and symptoms of pain, burning sensation, ulceration, presence of fibrous bands, mouth opening was performed and recorded.

Patients were advised and counselled to discontinue all tobacco related habits. Counselling was performed at the TII (tobacco intervention centre) which is based in the dental college.

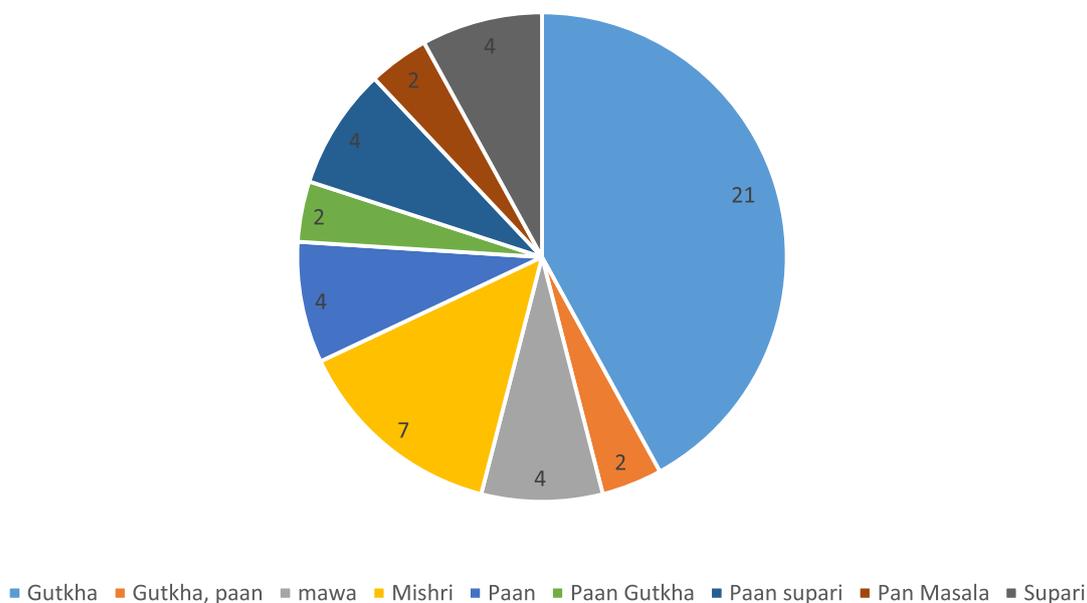
All patients were advised routine blood examination if required and were advised a through oral prophylaxis to remove all extrinsic tobacco stains present on the teeth.

Patients were solely given commercially available topical curcumin gel which contains Curcuma longa extracts (10 mg) in a gel base to be used 3 times a day. They were asked to dab a small amount of paste enough to cover the affected area and

Table III. Diagram 2 - Distribution as per type of habit.

	Frequency	Percent
Gutkha	21	42.0
Gutkha, paan	2	4.0
Mawa	4	8.0
Mishri	7	14.0
Paan	4	8.0
Paan, gutkha	2	4.0
Paan, supari	4	8.0
Pan masala	2	4.0
Supari	4	8.0
Total	50	100.0

Distribution as per type of habit



hold it in the oral cavity at least for 5 min and then rinse with water to clear any residue.

The participants were evaluated for the baseline quality of life using EORTC H&N -35 questionnaire which is available in English, Hindi and Marathi. The questionnaire comprises of 35 questions assessing symptoms of the patient, social function and body image/sexuality. It has seven multi-item scales that assess pain, swallowing, senses (taste and smell), speech, social eating, social contact and sexuality. There are also eleven single items. For all items and scales, high scores indicate more problems [11]. All patients received the treatment for 3 months and were called for follow up at 1 month, 2 months and 3 months' interval and at the last follow up visit the quality of the life was re assessed. All data were entered into a computer by giving coding system, proofed for entry errors. Data obtained was compiled on a MS Office Excel Sheet (v 2019, Microsoft Redmond Campus, Redmond,

Washington, United States). Data was subjected to statistical analysis using Statistical package for social sciences (SPSS v 26.0, IBM). Descriptive statistics like frequencies and percentage for categorical data, Mean & SD for numerical data has been depicted. Intra group comparison was done using paired *t* test (up to 2 observations). Comparison of frequencies of categories of variables within the group was done using chi square test. For all the statistical tests, *p* < 0.05 was considered to be statistically significant, keeping α error at 5% and β error at 20%, thus giving a power to the study as 80%.

Results

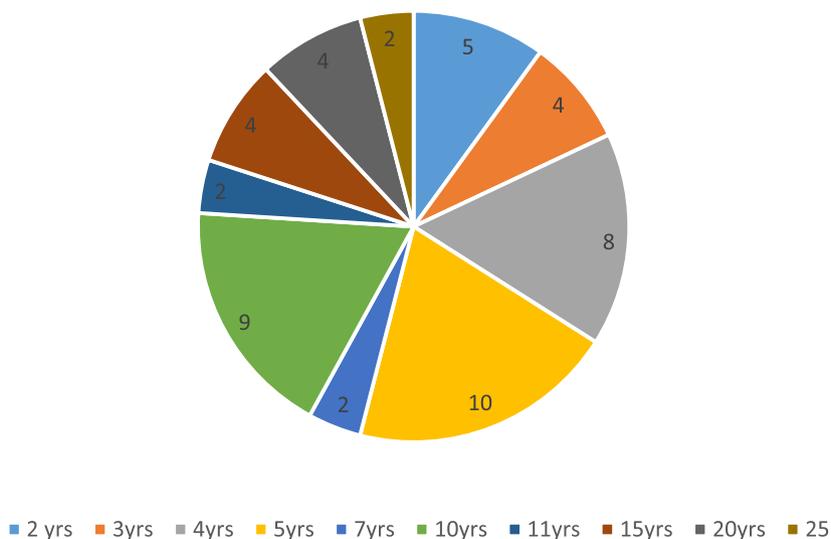
Demographic characteristics

In the present study the age of the patients ranged from 21 to 64 years with a mean age of 40.92. The duration of the habit of eating any form of betel nut ranged from 2 years to 25 years

Table IV. Diagram 3 – Distribution as per duration of the habit in years.

Years	Frequency	Percent
2	5	10.0
3	4	8.0
4	8	16.0
5	10	20.0
7	2	4.0
10	9	18.0
11	2	4.0
15	4	8.0
20	4	8.0
25	2	4.0
Total	50	100.0

Distribution as per duration of habit in 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% (48) were males and 4% (2) 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 (Tabs. I-V).

Pre and post treatment comparison on ECRTC questionnaire

The EORTC Questionnaire consists of seven multi item scales and 11 single item scales. The questionnaire was presented to the patients after taking their informed consent at baseline and after 3 months' post treatment. For the multi item scales namely, pain, swallowing, sense of taste, speech, social eating and social contact, comparison at baseline between the OSMF group and healthy patients showed negative impact on patients with OSMF (Tab. II). As regards to the single item

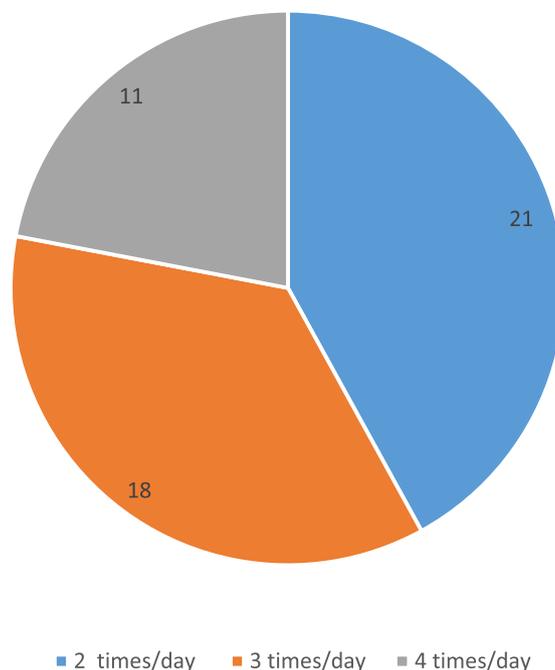
scales excluding the difference in mouth opening which was significantly affected in the OSMF group all other single items namely dry mouth, sticky saliva, coughing, sexuality, felt ill, nutritional supplements, weight issues showed non-significant difference (Tab. III).

At the end of 3 months post treatment there was significant decrease in the symptoms of pain, swallowing, sense of taste, speech issues, social eating and social contact and also in mouth opening which also became better post treatment. The statistically highly significant difference seen for values between the time intervals ($p < 0.01$) for all the variables in the multi item scale with higher values before treatment as compared to after, and for mouth opening from the single item scale suggests that post treatment the patient reported with lower scores pointing out lesser symptoms and hence better quality of life (Tab. IV).

Table V. Distribution as per frequency of the habit per day.

	Frequency	Percent
2	21	42.0
3	18	36.0
4	11	22.0
Total	50	100.0

Distribution as per frequency of Habit per day



Also post treatment the OSMF group showed statistically highly significant difference in pain in teeth, feeling of illness and dry mouth and sticky saliva with lesser score post treatment indicating lesser symptoms and thus better oral functions. There was a statistically non-significant difference seen for the frequencies between the time intervals ($p > 0.05$) for sexuality related problems and weight gain (Tab. V).

Discussion

Oral sub mucous fibrosis is a potentially pre malignant condition of the oral cavity with a complex treatment strategy and does not show significant reverting back of symptoms by any single treatment modality. Burning sensation on eating medium to spicier food and restriction in mouth opening and the main symptoms presented by the patients but surely not the only ones. The condition affects the patients eating habits, mouth opening, mandibular and tongue movements, swallowing, speech collectively affecting the quality of life of the patient functionally and socially. The fear of malignant transformation

also affects the patients psychologically. The treatment strategy for malignant and pre malignant conditions should therefore aim at not only resolving the patient's symptoms but also restoring the quality of life of the patient which has been affected severely. According to a systematic review by Gondivkar *et al.* in 2017, amongst the OPMDs, QOL has been assessed most commonly in patients with Lichen planus while very few articles assessed QOL in OSMF patients [12]. Literature shows very few studies on QOL assessment in OSMF and fewer studies where assessment of QOL has been used as a treatment outcome to assess the effectivity of the treatment strategy used.

The main objective of our study was to measure the QOL of patients with OSMF and to then assess the change in QOL before and after treatment. For the assessment of QOL we have used EORTC – QLQ-H&N35 questionnaire, and this head & neck module is meant for use among a wide range of patients with head & neck cancer. It incorporates seven multi-item scales that assess pain, swallowing, senses (taste and smell), speech, social eating, social contact and sexuality. There are also 11 single items which assess the oral functioning related to

teeth, saliva, mouth opening and general physical status of the patient related to his weight change and perception of illness. A study done for assessment of QOL and performance status in patients with OSMF stated that EORTC-QLQ-35 can be effectively used in OPMDs like OSMF [13].

In our study, at baseline the QOL of patients with OSMF was compared to that of healthy individuals in the control group which showed how negatively patients with OSMF are affected as reflected by functional, social and psychological scales. In a cross sectional study done to assess the impact of OSMF on quality of life showed that the patients with OSMF had physical impairment and functional limitations along with being affected socially and psychologically as compared to the healthy individuals [14].

In the present study discussing about the multi item scales first, the base line data showed patients with OSMF significantly complained of pain, difficulty swallowing ($p < 0.05$). Though the sense of smell was not affected the sense of taste was significantly compromised. Function of speech, social eating and social contact was also significantly affected ($p < 0.05$). Our results are in accordance with a study which analysed the impact of OPMDs on daily life activities which showed that along with pain, burning sensation, difficulty in opening mouth and swallowing which affected the physical and functional abilities of the patient, social eating and social contact were very significantly affected as the patients discouraged both due to public embarrassment [15]. Substantial alterations to taste perception with sour, salt, and bitter and then to sweet in OSMF subjects was reported in a study to evaluate the gustatory functions in patients with OSMF [16].

Though direct psychological impact has not been assessed in this questionnaire, in a study done to assess the impact of OSMF on psychological stress and as per a latest systematic review on Quality of Life in OSMF patients, conclude that OSMF has negative impact not only on social, physical but also on psychological domains thus bringing up the idea of psychological counselling for patients with OSMF [17,18]. Speech problems which are common in OSMF patients also adds to the negatively affected social life of these patients [15,19]. Though in the present study the sexual activity of patients in OSMF did not show any negative impact but we would recommend further studies on this aspect as other social domains being negatively affected could cause an indirect impact on the sexual life of these individuals.

Moving on to the 11 single items of the questionnaire, which assess the dental condition, mouth opening, salivary consistency and flow, history of medications and weight related issues restriction of mouth opening and dry mouth were significantly reported in patients with OSMF as compared to healthy individuals.

In the present study the post treatment analysis of both the multi item scales and the single items scales except for sexual issues and weight gain showed highly significant changes post treatment as compared to the baseline. This clearly suggests that the quality of life of patients definitely improved after treatment.

Conclusion

Any disease affects the patient's quality of life in some way or other. Owing to its chronicity and tendency towards malignant transformation, premalignant conditions substantially affects the individual not only functionally but also socially, psychologically, mentally and financially, all these factors being inter-related in affecting the patients' health as a whole. Though there is no universally accepted disease specific questionnaire available to assess the QOL in OSMF, EORTC-H&N-35 and similar questionnaires used in many studies have pointed out the negative effect of this condition on the QOL of these patients. The study emphasizes the use of assessing Quality of life as effect of treatment outcome for OSMF and suggests curcumin could be a promising treatment modality for patients with OSMF.

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Conflict of interest

The authors declare that they have no conflicts of interest in relation to this article.

Ethical approval

Ethical approval was not required.

Informed consent:

All the participants of the study were enrolled only after they signed an informed consent form and declared their voluntary participation in the study.

Ethical committee approval:

The study was approved by the institutes ethical committee vide registration ECR/457/Inst/MH/2013/RR-20).

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