

Study Protocol

Correlation of periodontal status and salivary flow in patients with oral submucous fibrosis in Central India population: A Study Protocol

Abstract:

Background: One of the commonest premalignant condition is Oral Submucous Fibrosis. The main etiology is consumption of areca nut and its products which leads to reduced mouth opening (Trismus) and reduction in the salivary flow (Xerostomia). Both these conditions eventually result in periodontal destruction.

Objectives: The purpose of this research is to see if there is a link between periodontal health and salivary flow in OSMF patients.

Methodology: 50 patients each clinically diagnosed as chronic periodontitis with and without OSMF will be enrolled in test and control group respectively. Plaque Index, Papillary Bleeding Index, Probing Pocket Depth, Clinical Attachment Loss (CAL), Gingival Recession (REC) will be compared in both the group for assessment of the result. Saliva that has not been stimulated will be collected using a funnel in a calibrated beaker in both the groups.

Results: Patients with OSMF and chronic periodontitis will have reduced salivary flow and a compromised periodontal status whereas chronic periodontitis patients without OSMF will have normal salivary flow and comparatively less periodontal destruction.

Conclusion: OSMF is precancerous condition which leads to xerostomia and may result in periodontal destruction and therefore OSMF condition should be identified and treated as early as possible.

Keywords: Oral submucous fibrosis(OSMF), salivary flow, periodontal status, chronic periodontitis, xerostomia, trismus.

Introduction:

Human beings have been subjected to physical and mental stress as a result of the rapid rise of industry and urbanisation in the previous century. Humans use things like alcohol, cigarettes, areca nut and its derivatives to reduce stress, which have detrimental effects on the body. One of the degenerative illnesses caused by these practises is “oral submucous fibrosis” (OSMF).^[1] “OSMF is a chronic, progressive, scarring condition mainly affecting people of South-East Asian origin.”^[2]

In India, prevalence of OSMF is 0.2-2.3 percent and 1.2-4.6 percent in males and females respectively within the age range of 11 to 60 years.^[3] The malignant transformation rate is estimated to be between 7 - 13 percent.^[4] Areca nut and its derivatives such as Guthka, betel quid, paan masala and others are the most prominent causes of OSMF. Nutritional deficiency and genetic predisposition are two other causes of OSMF.^[5, 6] Along with reduced mouth opening (trismus) and inability to eat, OSMF patients present with white fibrous bands, inability to whistle and blow candle, palatal ulceration and dryness of mouth. As the OSMF patients present with trismus and xerostomia, it would lead to compromised oral hygiene practices and reduced salivary flow respectively. These conditions together may act as a predisposing factor for plaque accumulation and further may result into compromised periodontal status of the patient.

Despite the fact that studies have indicated a link between decreased salivary flow and periodontal status in OSMF patients on their own, there has been no clinical examination of the association between periodontal condition and salivary flow in OSMF patients. Therefore, the current study is undertaken to look into the relationship between salivary flow and severity of periodontitis in individuals with and without OSMF in Central India.

Objectives:

The goal of this study is to see if there is a link between salivary flow and severity of periodontitis in individuals with and without OSMF with following objectives:

1. To evaluate periodontal status in chronic periodontitis patients with and without oral submucous fibrosis.
2. To evaluate the salivary flow in chronic periodontitis patients with and without OSMF.
3. To correlate salivary flow and periodontal status in chronic periodontitis patients with and without oral submucous fibrosis.

Methods:

Total 100 patients will be selected from the outpatient Department of Oral Medicine and Diagnosis and Department of Periodontics, Sharad Pawar Dental College and Hospital, Sawangi (M), Wardha, Maharashtra and will be categorized into test and control group as: 50 patients clinically diagnosed as OSMF and having chronic periodontitis (Test group) whereas control group will be comprised of 50 patients of similar age clinically diagnosed as chronic periodontitis without OSMF. Patients will be chosen based on following criteria listed below:

Inclusion criteria:

1. Individual should be systemically healthy.
2. Subjects should have minimum 20 teeth present in their oral cavity.

Exclusion criteria:

1. Subjects with aggressive periodontitis.

2. Subjects undergoing treatment for Oral Submucous fibrosis.
3. Subjects who had periodontal therapy in the six months prior to the evaluation.
4. Previous history of antibiotic therapy or usage of anti-inflammatory drugs within 3 months prior to study.
5. Subjects physically, mentally, or legally incapacitated.
6. Pregnant women and lactating mothers.

The study will be carried out at outpatient Department of Periodontics, Sharad Pawar Dental College and Hospital, Sawangi (M), Wardha, Maharashtra. Institutional Ethical Committee (DMIMS, DU) approval will be obtained before the study commences. Risk and consent form will be signed by each participant. All the information regarding salivary flow, gingival and periodontal status will be recorded in well-designed questionnaire and periodontal chart with the help of mouth mirror, tweezers, calibrated periodontal probe (UNC-15 probe).

A) Periodontal examination will include:

1. Plaque Index (Turesky-Gilmore and Glickaman's Modification of Quigley-Hein 1970).^[9]
2. Papillary bleeding index (Muhlemann H.R. 1977)^[10]
3. Probing pocket depth (PPD) –“distance from the gingival margin to the base of the pocket”.
4. Clinical attachment loss (CAL) –“distance between cemento enamel junction and the base of the pocket”
5. Gingival Recession (REC)-“distance between cemento enamel junction and gingival margin”

Diagnosis of chronic periodontitis will be made following the classification given in American Academy of Periodontology 1999.^[11] “Chronic periodontitis is defined as common oral condition characterised by long-term inflammation of the periodontal tissues caused by the deposition of large amounts of dental plaque”.

It will be further categorised as

- a. “Mild (clinical attachment loss = 1-2 mm)”
- b. “Moderate (clinical attachment loss = 3-4 mm)”
- c. “Severe (clinical attachment loss \geq 5 mm)”

B) Patients with OSMF will be diagnosed using *Ranganathan K et al's* categorization (2006)^[12]

Groups will be as follows:

- I: “There is no evidence of a restriction in mouth opening, only symptoms are present.”
- II: “There is limited mouth opening of 20 mm and above”.
- III: “Mouth opening is less than 20 mm.”
- IV: “OSMF has advanced and there is limited. Changes in the mucosa that are precancerous or cancerous.”

C) Non-stimulated salivary flow will be measured. The non-stimulated saliva will be collected in the following manner^[13]

Materials used for collection will be Funnel and calibrated beaker

Method will be as follows:

One hour prior to the test, the patient will be asked to avoid eating or drinking anything (except water). During this time, smoking, chewing gum, and drinking tea will be prohibited. The patient will be instructed to use distilled water to rinse his or her mouth multiple times before relaxing for five minutes. Then patients will be asked to keep their mouth open in the

funnel with their eyes open for 5 minutes. Beaker will be kept under the funnel and saliva will be collected in it. Readings will be noted down in a periodontal chart.

Statistical Analysis :

Statistical analysis will be conducted using descriptive and inferential statistics, including the chi-square test, student paired and unpaired t-tests, with SPSS version 24.0 and GraphPad Prism version 7.0.

Expected Results:

This study will compare the periodontal status and salivary flow in total 100 patients with and without OSMF. All the clinical parameters (PI, PBI, PPD, CAL, GR) in the test group will be significantly higher as compared to control group.

Test group will show reduced amount of salivary flow and the periodontal status will be much more compromised in comparison to control group.

In test group, Group I will show very mild periodontal destruction, Group II will show mild periodontal destruction, Group III will show moderate periodontal destruction and Group IV will show severely compromised periodontal status.

In all the four groups salivary flow will be observed to be reduced gradually from Group I to Group IV leading to severe xerostomia in Group IV patients and hence compromised periodontal status.

Discussion:

Oral Submucous Fibrosis, also known as "Atropica idiopathica mucosae oris," is a potentially cancerous condition reported by Schwartz in 1952. Jens J Pindborg defines "OSMF as an insidious, chronic disease that affects any area of the oral cavity and occasionally the pharynx".^[14]

It causes fibroelastic changes of lamina propria atrophy of epithelium which causes stiffness of oral mucosa eventually reducing the mouth opening. Other characteristic features include reduction in salivary flow (xerostomia), mucosal blanching and a burning feeling in the mouth, depapillation of tongue causing loss of gustatory sensation and shrunken uvula.^[15-17]

The major etiological factor is Areca nut and its derivatives like Guthka, betel quid, paan masala, etc. Areca nut contains arecoline and Arecaidine nitrosation which causes DNA alkylation leading to increased fibroblast proliferation and elevated collagen synthesis causing fibrosis.^[18] Quid chewing promotes bacterial colonization and periodontal infection resulting in disruption of periodontal harmony and causing periodontitis.^[19]

Reduced mouth opening and reduced salivary flow also contribute to periodontal destruction. OSMF patients with periodontal disease had a higher plaque index than those without OSMF. This finding will be commensurate with according to *Akhter et al*^[20] and *Dodani et al*^[21].

Findings of this study were consistent with *Akhter et al.*, who found that betel quid chewers had greater mean pocket PPD and CAL. In their study, betel quid chewers had a mean pocket probing depth of 3.8 ± 0.7 mm and clinical attachment loss of 4.2 ± 1.2 mm.^[20] Moreover, *Ling et al.* discovered a strong link between habit of chewing betel quid

and severity of periodontal disease.^[22] PPD was reported by *Dodani et al.* to be 1.88 ± 0.36 mm in patients with OSMF and 1.68 ± 0.16 mm in those without OSMF.^[21] In betel quid chewers, *Chu et al.* found PPD of 1.8 ± 0.38 mm and CAL of 0.52 ± 0.76 mm.^[23] A number of related studies on oral submucous fibrosis were reported^[24-32].

Most of the patients visiting the outpatient department of Sharad Pawar Dental College and Hospital, Sawangi (Meghe), Wardha, Maharashtra are labourers and they have habit of chewing areca nut while working. Therefore, the prevalence of OSMF patients in this region is high. Also, these patients are unaware about the severity of the disease as well as maintenance of oral hygiene. OSMF is not only a pre-cancerous condition but also associated with compromised periodontal condition due to trismus and xerostomia that eventually results into early tooth loss at young age. Therefore, early diagnosis and management by motivating patient for cessation of habit and creating awareness for the maintenance of oral hygiene is a crucial part of dental professional in such a rural area of central India.^[33-40]

Conclusion:

According to the findings of this study Periodontal health is affected in patients with OSMF. A definite link between reduced salivary flow and poor periodontal health status in OSMF patients will be observed.

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