



Evaluating the Quality of Life in Oral Sub Mucous Fibrosis Patients by WHOQLF-Brief Questionnaire: A Study Protocol

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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Study Protocol

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ABSTRACT

Background: - Oral Submucous fibrosis (OSMF) is a chronic insidious inflammatory disease which presents with the clinical presentation of burning sensation, fibrosis which ultimately leads to reduced mouth opening. The quality of life is the perception of an individual on their oral health as well as their well-being. The assessment of quality of life in the patients with OSMF plays an important role in the cessation of the habit.

Aim: - To analyse the quality of life in patients diagnosed with Oral Submucous Fibrosis (OSMF).

Study Design: - Cross-Sectional Study

Methodology: This is a cross-sectional study will be conducted on 300 diagnosed patients of OSMF. Selection of patients will be done as per the inclusion criteria. The nature and Purpose of

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the study will be explained to the patients before the data collection.

Results: The results will be evaluated by the statistician after the data collection and the results will be published in the peer reviewed journals.

- Improvement in the quality of life in OSMF patients.
- Knowledge and awareness regarding the consequences of betelnut in the population of Central India.

Keywords: Oral Submucous fibrosis; quality of life; WHOQOL-brief.

1. INTRODUCTION

Oral submucous fibrosis (OSMF) is a potentially malignant condition of the oral cavity characterized by juxta-epithelial inflammatory reaction and progressive fibrosis of the lamina propria and deeper connective tissues of the upper digestive tract involving the oral cavity, oropharynx and frequently the upper third of the oesophagus [1]. It is most common in the South East Asia and the Indian Subcontinent, whereas Central India being the most commonly affected [2]. Arecanut plays an important role in the etiology of OSMF [3]. Arecanut contains alkaloids which are responsible for the stimulation of fibroblasts and production of collagen and flavonoids [4]. The collagenase enzyme is inhibited by the collagen and flavonoids leading to reduced collagen degradation, which finally results into fibro-elasticity of the oral tissues [5].

It can occur at any age but most commonly the 3rd – 4th decade of life is affected. The initial clinical symptoms are burning sensation, hypersalivation, or hyposalivation and blanching of the oral mucosa which gives the mucosa a marble like appearance [6]. In the advanced stages, the consistency of the mucosa changes to leathery and becomes less elastic due to presence of fibrous bands which eventually leads to reduced mouth opening [6,7,8]. Other clinical features are difficulty in deglutition, nasal twang, reduced gustatory sensation, difficulty in speech, tongue movements. The Buccal mucosa, labial mucosa, retromolar region, hard and soft palate and floor of the mouth are most commonly affected sites. The malignant transformation of OSMF is 7.6% [8].

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 [9,10,11,12]. The objective of this study is to know the quality of life in OSMF patients and evaluate the physical and

psychological health for more effective counselling which in order will help the patients in cessation of the habit.

Rationale of Study: As Oral Submucous fibrosis is a chronic disorder it needs constant pharmacological therapy if the habit is not discontinued. The patient needs regular follow-up, self-care and support from the family and friends and people associated with their social circle.

2. METHODOLOGY

2.1 Study Place

The Study will be conducted in the department of Oral Medicine & Radiology, Swargiya Dadasaheb Kalmegh Smruti Dental College & Hospital, Nagpur after obtaining ethical approval from the Institutional Ethical Committee.

2.2 Armamentarium for Clinical Diagnosis

- Dental chair with artificial illumination
- Face mask
- Disposable pair of surgical gloves
- Sterile plain mouth mirror
- Sterile explorer
- Sterile tweezer
- Sterile cotton and guaze pieces.

2.3 Study Procedure

- The investigator will explain the patients about the procedure and purpose of this study.
- A detailed case history including the demographic details, habit history and the clinical examination will be performed.
- After the clinical diagnosis of OSMF the WHOQOL-BREF will be filled after explaining the procedure to the patients.
- The data then will be entered in the structured proforma for further reference.

2.4 Inclusion Criteria

- The patients in the age group of 18 – 60 years
- Both males and females
- Willing to participate in present study.
- Patients diagnosed with Oral Submucous fibrosis
- Patients undergoing treatment for Oral Submucous fibrosis

2.5 Exclusion Criteria

- Participants not willing to participate
- Impaired cognition, unable to follow the instructions of investigator at the time of data collection.
- Patients below the age of 18 years.

2.6 Sample Size Calculation

Cochran formula for Sample size estimation:

$$N = Z^2 \times p(1-p) / E^2$$

Where

Z=Statistic for the level of significance at 5% i.e. 95%

Confidence interval = 1.96

P= Proportion of subjects responded good for QOL = 37.50 % = 0.3750

E= Error of margin = 7% = 0.05

$$N = (1.96^2 \times 0.3750 \times (1-0.3750)) / (0.05)^2$$

$$N = 360.15$$

$$N = 360$$

Study Reference: Abdul Bari Memon et al.

Formula Reference: Cochran W.G. et al. (1977)

Power of test – 80%

Level of Significance: 5%

Software used: SPSS 27.0 version

2.7 Data Management and Statistical Analysis

Data of the patient will be recorded in the excel spreadsheet taking into consideration all the parameters related to the quality of life and the data will be analysed by the experienced statistician.

3. RESULTS

The results will be analysed according to the age distribution, gender distribution, OSMF staging for descriptive analysis. The comparative analysis will be done on the basis of the parameters of Quality of life by chisquare test, Student's t-test.

3.1 Expected Result Outcomes

- Improvement in the quality of life in OSMF patients.
- Knowledge and awareness regarding the consequences of arecanut in the population of Central India.
- Help in evaluating the physical as well as psychological status of the patient will eventually help in the counselling and cessation of the habit.

4. DISCUSSION AND CONCLUSION

OSMF is a chronic premalignant condition which is present due to inflammation of juxtaepithelium. This disorders leads to difficulty in mastication that ultimately is related to the quality of life of the patient [10,11,12,13,14]. Though there is excessive literature on OSMF, but the literature related to the quality of life is less, therefore the primary objective of this study is to evaluate the quality of life of the patients suffering with OSMF.

Kirti C had undertaken a study with the aim to assess the Quality of life in OSMF patients. They showed OSMF have a significant negative impact on the quality of life when compared with the participants without OSMF and concluded that oral submucous fibrosis has a negative impact on the quality of life in participants with OSMF specifically in social and environmental domains [1].

Gondivkar S et al conducted a study on impact of socioeconomic characteristics on oral health related quality of life (OHRQoL) in patients with oral submucous fibrosis on 300 patients by modified Kuppuswamy scale. Their results suggested that OSMF patients with low socio-economic status had worse quality of life as compared to those of middle and upper socio-economic classes. Their study concluded that the socio-economic status of the patient should play a vital role in the management of OSMF patients [15].

Chole R et al. measured quality of life in 100 patients diagnosed with Oral Submucous Fibrosis by using European Organization for Research and Treatment of Cancer Quality of Life head and neck four times: at the baseline, one month, two months and three months after the start of the treatment. The patients were divided into 2 groups. One group with Spirulina while another group containing Spirulina with Triamcinilone acetonide 0.1% their results showed that there was a significant difference in the quality of life in all the stages [3].

Gondivkar et al. conducted a systematic review to assess the most appropriate OHR-QoL instrument for OSMF with the use of Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) checklist. They stated that selecting the right instrument in routine practice was challenging, as the psychometric quality of measurement was not explored. Based on previous work according to the PRISMA guidelines three generic and one disease-specific questionnaire were selected. This review concluded that disease specific questionnaire was more effective and consistent as compared to OPMDQoL due to its superiority in recognizing disease severity and define management protocol [16-23],

CONSENT

As per international standard or university standard, patients' written consent has been collected and preserved by the author(s).

ETHICAL APPROVAL

The Study will be conducted in the department of Oral Medicine & Radiology, Swargiya Dadasaheb Kalmegh Smruti Dental College & Hospital, Nagpur after obtaining ethical approval from the Institutional Ethical Committee.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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