https://doi.org/10.32394/pe/208234

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# PREVALENCE OF ORAL LEUKOPLAKIA, ERYTHROPLAKIA, AND ORAL SUBMUCOSUS FIBROSIS IN PATIENTS CONSUMING TOBACCO AND ARECANUT: A HOSPITAL-BASED OBSERVATIONAL STUDY

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## ABSTRACT

**BACKGROUND.** In 2022, global oral squamous cell carcinoma (OSCC) incidence was 389,846 cases, with 188,438 deaths (GLOBOCAN). In India, it ranked 2nd with 143,759 cases and 79,979 deaths, and a 5-year prevalence of 370,106 cases. High OSCC rates are associated with oral leukoplakia, erythroplakia, and oral submucous fibrosis (OSMF), with malignant conversion rates of 1.1%-40.8% for leukoplakia, 19.9%-45% for erythroplakia, and 6% for OSMF. Central India has the highest oral cancer incidence, 19.2% in males and 7.6% in females. Limited research highlights the need for public health interventions; our study offers key epidemiological insights from a tertiary care center.

**OBJECTIVE.** The study investigates the prevalence and epidemiology of oral leukoplakia, erythroplakia, and OSMF among tobacco and areca nut users.

**MATERIAL AND METHODS.** This prospective observational study was conducted at the Govt Dental Institute, of Central India, from September 2022 to March 2023, with ethical clearance (No. 161/IEC/SS/2022). A purposive sampling approach targeted individuals with smokeless tobacco, smoking, or areca nut consumption. Oral cavity screenings were conducted, classifying leukoplakia, erythroplakia, and OSMF using established clinical criteria. The data were analyzed using SPSS 25.0, with significance set at $p < 0.05$.

**RESULTS.** Among 28,736 patients, 5,428 had a history of tobacco or areca nut consumption, and 411 were diagnosed with OPMDs (Oral Potentially Malignant Disorders), yielding an overall prevalence of 7.57%. OSMF was the most common disorder (5.30%), followed by oral leukoplakia (2.22%) and erythroplakia (0.036%). The most prevalent habit was areca nut and smokeless tobacco consumption (71.53%). OSMF Grade IV had the highest prevalence (36.79%).

**CONCLUSIONS.** The prevalence of Oral Potentially Malignant Disorders in this study (7.57%) exceeds global averages, highlighting the impact of tobacco and areca nut consumption in Central India. OSMF, particularly Grade IV, is more prevalent, underscoring the need for targeted public health interventions and rigorous screening for early detection and management.

**Keywords:** *oral submucous fibrosis, erythroplakia, oral leukoplakia, prevalence*

## INTRODUCTION

Oral squamous cell carcinoma (OSCC) of the lip and oral cavity had a significant global impact in 2022, ranking 16th in incidence with 389,846 new cases and 188,438 deaths (GLOBOCAN 2022). In India, the situation is more severe, with oral cancer ranking 2nd in incidence (10.2%; 143,759 cases), mortality (8.7%; 79,979 deaths), and 5-year prevalence (11.4%; 370,106 cases). Among Indian males, oral cancer is the most prevalent cancer by site (1). OSCC arises from Oral Potentially Malignant Disorders (OPMDs), including oral leukoplakia, erythroplakia, and oral submucous fibrosis (OSMF). Malignant conversion rates for oral leukoplakia range from 1.1% to 40.8% (2), erythroplakia from 19.9% to 45% (3-5), and OSMF at 6% (6). Early detection is crucial, as advanced-stage OSCC has a 5-year survival rate of 15% to 50% (7), while early-stage diagnosis (stage I/II) improves survival rates to over 80% (8,9). Globally, oral leukoplakia, erythroplakia, and OSMF prevalence is 4.11%, 0.17%, and 4.96%, respectively (10), with

higher rates in India at 6.7%, 2.5%, and 4.5% (11). In Central India, 37 cancer registries report the highest incidence of mouth and tongue cancers in the country. Among males, these cancers account for 19.2% of all cases (19.2 cases per 100,000 population), while in females, they account for 7.6% (7.6 cases per 100,000 population) (12).

Despite the alarming oral cancer statistics, research on the prevalence of oral leukoplakia, erythroplakia, and oral submucous fibrosis (OSMF) in Central India remains scarce. As the region's only government dental tertiary care center, our diverse and representative sample provides crucial insights into the epidemiological landscape of OPMDs, laying the groundwork for targeted public health interventions and preventive strategies.

## AIM AND OBJECTIVES

The study aims to investigate the prevalence of oral leukoplakia, erythroplakia, and oral submucous fibrosis among individuals habitually consuming tobacco and areca nut, presenting at Government Dental College in Indore, Madhya Pradesh. It also seeks to analyze the epidemiological profiles of patients diagnosed with these conditions within this specific population group.

## MATERIAL AND METHODS

This prospective observational study was conducted in the Department of Oral Medicine and Radiology, Government Dental College, Central India, after obtaining ethical clearance from the Institutional Ethics Committee (IEC) in its meeting held on 27 August 2022, as recorded in Certificate No. 161/ IEC/SS/2022 dated 24 March 2023, which explicitly mentions the date of approval. The study employed a purposive sampling approach among patients visiting the outpatient department from September 1, 2022, to March 31, 2023, focusing on individuals with tobacco and areca nut consumption habits. Oral cavity screenings were conducted to detect occurrences of oral leukoplakia, oral erythroplakia, and oral submucous fibrosis, providing valuable insights into oral medicine and radiology. Participants of both genders were categorized into six age groups (11-15 years, 16-35 years, 36-45 years, 46-55 years, 56-65 years, and 66-75 years), with inclusion criteria requiring informed consent and exclusion criteria excluding individuals unable to participate due to health conditions. The methodology utilized in this investigation is depicted through a comprehensive flowchart illustrated in Figure 1.

Oral leukoplakia was meticulously classified according to Warnakulasuria S.'s system (2018) (13), distinguishing between homogeneous (Figure 2. A and B) and non-homogeneous types, including nodular, speckled, and verrucous variants, aiding accurate diagnosis and supporting ongoing research in oral pathology depicted in Figure 2. C, D, and E. The clinical diagnosis followed Warnakulasurya S. et al.'s clinical criteria (2020) (14), focusing on persistent white patches with well-demarcated borders, while excluding conditions such as white sponge nevus, frictional keratosis, candidal infection, leukoedema, chemical burns, and oral hairy leukoplakia. Similarly, the clinical diagnosis of erythroplakia was based on characteristic clinical features with the exclusion of similar-looking conditions (Figure 2. F).

Clinical diagnosis and staging of oral submucous fibrosis (OSMF) patients followed the criteria proposed by Passi D et al. (2017) (15), which categorizes OSMF into stages 1 to 4 based on distinct clinical features and the extent of oral cavity involvement (Figure 3, Figure 4).

Clinical diagnoses, including leukoplakia, erythroplakia, and oral submucous fibrosis (OSMF), alongside demographic and habit details, were meticulously recorded using a predesigned proforma.

## STATISTICAL ANALYSIS

Statistical analysis involved data entry into Excel and analysis using SPSS 25.0. Descriptive statistics were utilized, presenting data as numbers and percentages. The Chi-square test was employed to compare the prevalence of oral leukoplakia, erythroplakia, and OSMF, along with related habits, age, duration, and frequency of habits among study groups, with significance set at $p < 0.05$.

## RESULTS

During the study, 28,736 patients were reported to the Department of Oral Medicine and Radiology, Govt dental college of central India. Of these, 5,428 subjects had a history of smokeless tobacco, smoking, or areca nut use. Among them, 411 individuals had oral submucous fibrosis (5.30%), oral leukoplakia (2.22%), or oral erythroplakia (0.036%), resulting in an overall combined prevalence of 7.57%.

The mean age of the subjects was 14.9 ± 13.905 years. The majority of the subjects belonged to the age group of 16-35 years, followed by 36-45 years, followed by 46-55 years, followed by 56-65 years, more than 65 years, followed by 6-15 years. The number of male subjects was greater than the number of female subjects (78.10% vs. 21.89%). The most commonly noticed OPMDs were OSMF (70.07%), followed by leukoplakia (29.44%), followed by erythroplakia (0.48%). The most

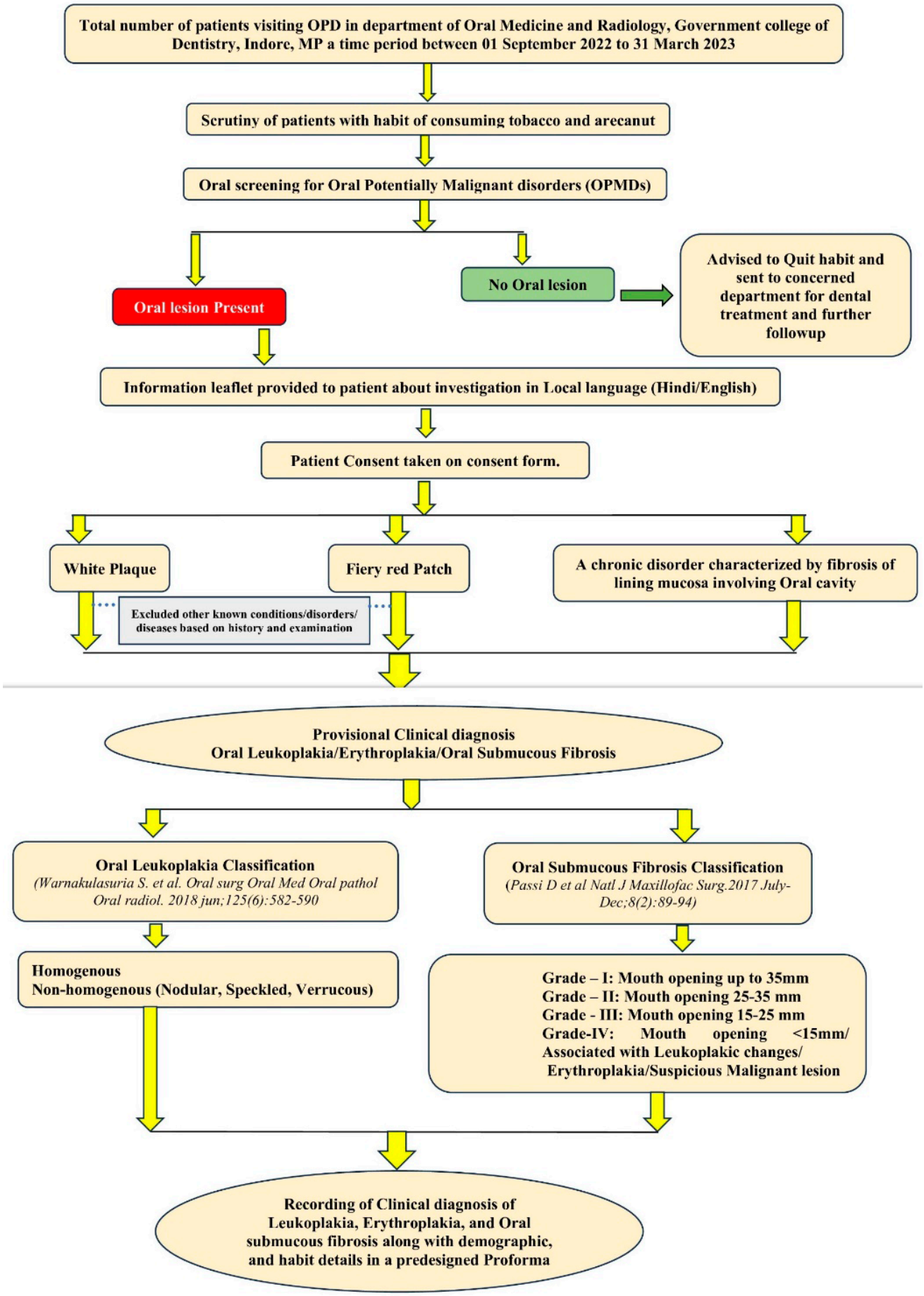


Figure 1. Methodology utilized in the investigation.

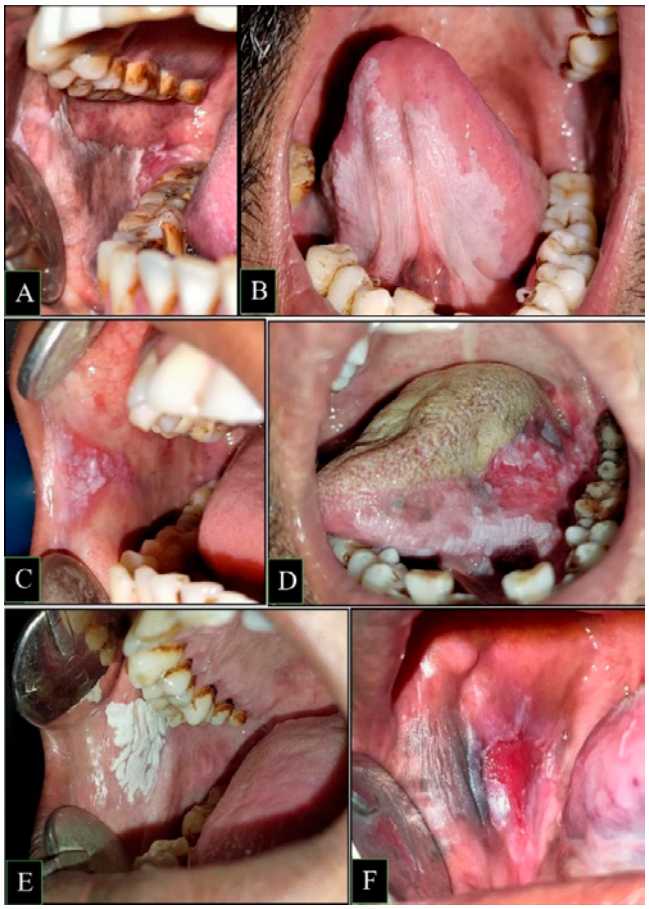


Figure 2. A photograph illustrating the diverse demographics of homogenous leukoplakia, non-homogenous, and erythroplakia. Homogenous leukoplakia is present over the most common site buccal mucosa. A. Etrocommisure to the retromolar region over right buccal mucosa. B. Ventral surface of the tongue: The lesions appear uniformly flat and thin, featuring a smooth surface that exhibits shallow cracks, with well-delineated peripheral boundaries adjacent to normal mucosa. C. Nodular leukoplakia: Multiple small polypoid outgrowths over the right retrocommisural and buccal mucosa that appear rounded and display red and white colors. D. Speckled leukoplakia: Over the right retrocommisural region and left lateral and ventral regions of the tongue, showing a mix of white and red coloration (also termed erythroleukoplakia), with white predominance. E. Verrucous: Right buccal mucosa showcases a wrinkled or corrugated surface appearance. F. Erythroplakia: A fiery red, flat patch with a smooth surface over the right buccal mucosa.

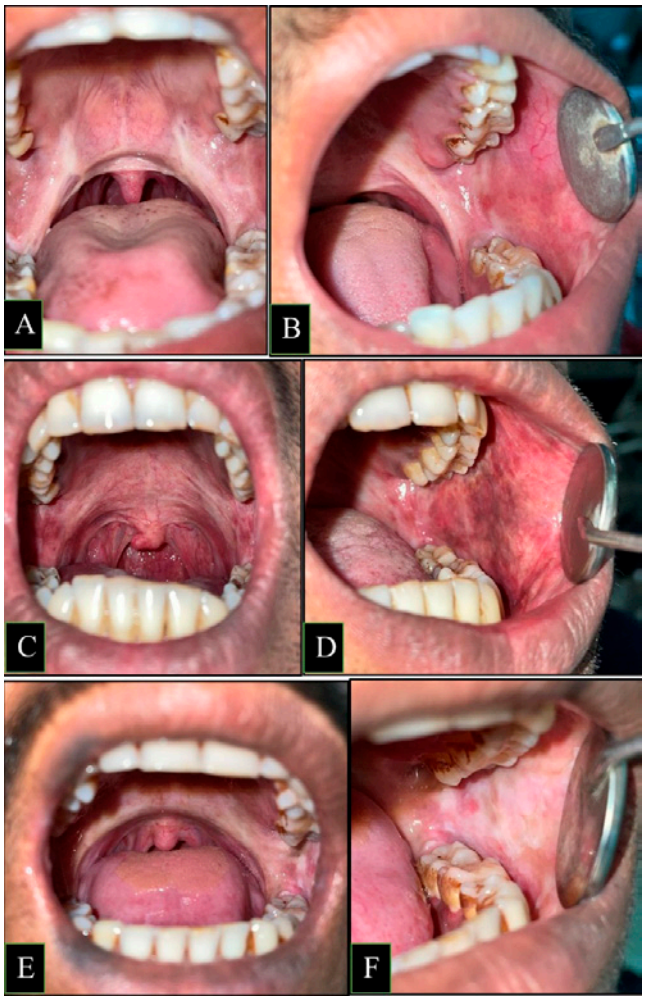


Figure 3. A and B photograph illustrating the clinical features of OSMF grade-1 (A. Normal shaped uvula with blanching of palatal mucosa. B. Erythematous atrophic mucosa without any sign of fibrosis). C and D illustrate OSMF grade-2 (C. Anteriorly everted uvula. D. Mottled and marble-like appearance of bilateral buccal mucosa with palpable fibrotic bands). E and F illustrate OSMF grade-3 (E. Severe Blanching of the soft palate and retromolar region, Bud-shaped uvula. F. Buccal mucosa with broad, thick palpable fibrotic bands)

commonly reported habit was the consumption of areca nut along with smokeless tobacco (71.53%), followed by areca nut chewing (19.70%), followed by smoked tobacco (10.46%). Followed by smokeless tobacco (5.59%). The consumption of alcohol was reported by 19.70% of the subjects. The majority of them reported to have occasional consumption of alcohol. Of the 121 subjects with leukoplakia, 100 were male and 21 were female, demonstrating a male predominance (82.64%).

Homogeneous leukoplakia was more prevalent, accounting for 87.6% of cases, with non-homogeneous types making up 12.40%. Leukoplakia predominantly affected the buccal mucosa (80.99%), followed by the tongue (4.95%) and a combination of the tongue and buccal mucosa (4.13%). Homogeneous leukoplakia was significantly associated with the age group of 55-65 years and older (p-value < .05), while non-homogeneous leukoplakia was linked to the age group of 46-55 years (p-value < .05). Erythroplakia showed a significant association with the age group of 36-45 years and male predominance (100%), predominantly affecting the buccal mucosa, and significantly associated with smokeless tobacco consumption.


Figure 4. A photograph illustrating the clinical features of OSMF grade 4 with mouth opening less than 15mm. (A. Interincisal Mouth Opening: 12 mm. B. Restricted tongue movements. C. Associated with homogenous leukoplakia of the left buccal mucosa. D. With suspicious malignancy of the left buccal mucosa)

A total of 288 (70.071%) of the subjects had OSMF. Male = 219, Female = 69. In this study, the highest prevalence was recorded in OSMF Category Grade IV, with 106 cases (36.79%). Upon subgrouping OSMF Grade IV, there were 48 (16.6%) subjects with suspected malignant lesions alongside OSMF, 46 (15.97%) with mouth opening less than 15 mm, and OSMF with leukoplakia was present in 12 (4.16%) subjects. Age was found to have a significant association with lesion/conditions (p-value <.05). There was a significant association between OSMF grade 1 and the age group of 11-15 years (p-value <.05). OSMF grade 2 and grade 3 showed a significant association with the age group of 16-35 years (p-value <.05). Erythroplakia showed significant association with the age group of 36- 45 years (p-value <.05). Non-homogenous leukoplakia is significantly associated with age group of 46-55 years (p-value <.05). Homogenous leukoplakia is significantly associated with age group of 55-65 years and more than 65 years (p-value <.05). OSMF grade 4 with suspected malignant lesion is associated with age group of 46-55 years and 55-65 years (p-value <.05). The gender of the individuals showed no significant association with the type of lesion/condition (p-value >.05). Adverse habits are significantly associated with the significant association with lesions/conditions. Smokeless tobacco consumption was significantly associated with leukoplakia (homogenous and non-homogenous) and Erythroplakia (p-value<.05). Smokeless tobacco consumption was significantly associated with homogenous leukoplakia (p-value<.05). Areca nut chewing was found to be significantly associated with OSMF (p-value <.05).Combined use of areca and tobacco had no significant association with any specific lesion/condition (p-value >.05). Alcohol consumption had no significant association with any specific lesion/condition (p-value >.05).

## DISCUSSION

In this study, the combined prevalence of oral leukoplakia, erythroplakia, and oral submucous fibrosis (OSMF) was 7.57%, exceeding the global averages of 1-5% reported by Mello FW et al. (2018) (10). This finding aligns with various Indian studies, such as those by Shivakumar KM et al. (2022) (16) in western Maharashtra, who reported a prevalence of 1.67%, Jose C et al. (2023) (17) in Karnataka (13.28%) and Shah JS et al. (2023) (18) recorded a combined prevalence rate of 1.43% in the western Indian state of Gujarat (Table 1). One of the key factors contributing to the high prevalence (13.28%) of oral potentially malignant disorders (OPMD) in the study by Jose C et al. (2023) is the selection of a sample population predominantly composed of individuals engaged in the cultivation and processing of areca

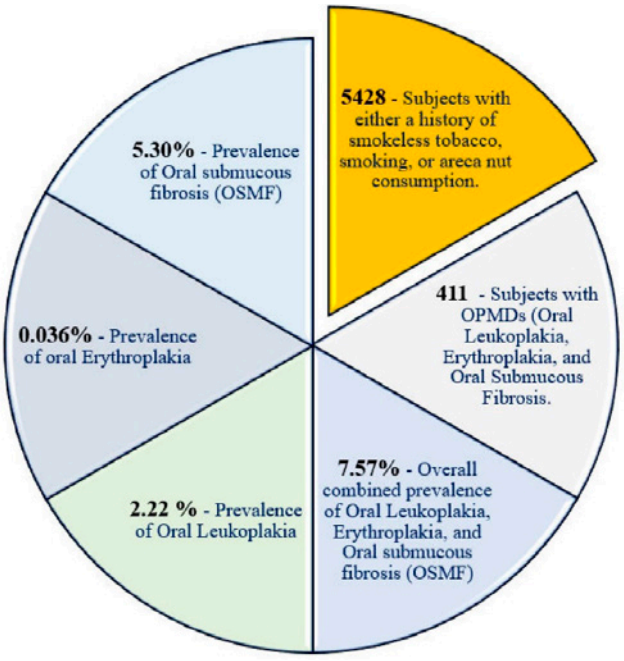


Figure 5. Prevalence of oral leukoplakia, erythroplakia, and oral submucous fibrosis(OSMF)

nut and its derivatives—well-established risk factors for the development of OPMD. In the study by Shah JS et al. (2023) (18) in Ahmedabad, Gujarat, OSMF was the most common among 552 OPMD patients, with 190 cases, followed by leukoplakia (120 cases). Similarly, Shivakumar KM et al. (2022) (16) in western Maharashtra and Kumar S et al. (2015) (19) in Indore, Madhya Pradesh, reported a high prevalence of OSMF and the lowest prevalence of erythroplakia among leukoplakia, erythroplakia, and OSMF. In contrast, Singh G et al. (2023) (20) in Hyderabad, Telangana, found leukoplakia (202 cases) and erythroplakia (71 cases) to be more prevalent than OSMF (40 cases).

Table 1. Systematic review and Meta-analysis/ regional studies on the combined prevalence of oral leukoplakia, erythroplakia, and oral submucous fibrosis (OSMF)

| PREVALENCE | REGION | AUTHOR |
|---|---|---|
| 1 to 5% | Global Average | Mello FW et al. (2018) [10] |
| 6.7%: Hospital-based<br>4.3%: Community based | Indian Average | Kumbhalwar A et al. (2022) [11] |
| 1.43% | Gujrat, India | Shah JS et al. (2023) [18] |
| 13.28% | Karnataka, India | Jose C et al. (2023) [17] |
| 1.67% | Maharashtra, India | Shivakumar KM et al (2022) [16] |
| 7.57% | Madhya Pradesh, India | Present study |

Table 2. Systematic review and Meta-analysis/ regional studies on prevalence of oral leukoplakia

| PREVALENCE | REGION | AUTHOR |
|---|---|---|
| 4.11% | Global Average | Mello FW et al. (2018) [10] |
| 1.39% | Global Average | Zhang C et al. (2023) [23] |
| 7.7% | Asian average | Mello FW et al. (2018) [10] |
| 7.20% | Jharkhand, India | Choudhary et al. (2022) [22] |
| 4.02% | Madhya Pradesh, India | Rahangdale et al. (2021) [21] |
| 2.2 % | Madhya Pradesh, India | Present study |

Table 3. Systematic review and Meta-analysis/ regional studies on the prevalence of oral erythroplakia

| PREVALENCE | REGION | AUTHOR |
|---|---|---|
| 0.17 % | Global Average | Mello FW et al. (2018) [10] |
| 0.04 % to 1.14%% | Global Average | Wadde et al. (2024) [24] |
| 1.2 % | Indian Average | Kumbhalwar A et al. 2022 [11] |
| 1.3 % | Karnataka, India | Jose CB et al. (2023) [17] |
| 2.3 % | Jharkhand, India | Choudhary et al. (2022) [22] |
| 0.24 % | Madhya Pradesh, India | Kumar S et al. (2015) [19] |
| 0.036 % | Madhya Pradesh, India | Present study |

Table 4. Systematic review and Meta-analysis/ regional studies related to the prevalence of oral submucous fibrosis (OSMF) (*PP = Pooled prevalence).

| PREVALENCE | REGION | AUTHOR |
|---|---|---|
| 4.96 % | Global Average | Mello FW et al. (2018) [10] |
| 0.03% to 30%<br>(PP* 5% in arecanut users) | Global Average | Yuwanti M et al. (2023) [25] |
| 2.7 % | Indian Average | Kumbhalwar A et al. (2022) [11] |
| 6.21% | Karnataka | Jose CB et al. (2023) [17] |
| 1.6 % | Maharashtra | Chauhan R et al. (2021) [26] |
| 6.4 % | Madhya Pradesh, India | Torwane NA et al. (2015) [27] |
| 5.30 % | Madhya Pradesh, India | Present study |

The prevalence of oral leukoplakia among 411 subjects was found to be 2.2%. This rate is lower than that reported in Indore, Madhya Pradesh (5.6%) by Rahangdale et al. (2021) (21) and in Hazaribagh, Jharkhand (7.2%) by Choudhary et al. (2022) (22). Globally, Zhang et al. (2023) (23) reported a prevalence of 1.39%, while Mello et al. (2018) (10) found a meta-analysis prevalence of 4.11%, indicating significant variability worldwide (Table 2).

Our investigation revealed a prevalence of oral erythroplakia at 0.036%, which is notably lower than the 0.24% reported by Kumar S et al. (2015) (19), the 1.3% noted by Jose CB et al. (2023) (17), and the 2.3% reported by Choudhary et al. (2022) (22). Globally, Wadde et al. (2024) (24) reported a prevalence range of 0.04% to 1.14% (Table 3).

The prevalence of oral submucous fibrosis (OSMF) among individuals with habits of smokeless tobacco and areca nut consumption was 5.30%, closely aligning with the findings of Yuvanti M. et al.'s systematic review in 2023 (25), which reported a pooled prevalence of 5% among areca nut users. Similarly, Mello FW et al. (2018) (10) found a prevalence of 4.96%, demonstrating consistency across studies. However, notable regional variations exist: Chauhan R et al. (2021) (26) reported a lower prevalence rate of 1.6% in an institutional-based study, whereas higher prevalence rates were documented by Jose CB et al. (2023) (17) at 6.21% in South India and by Torwane NA et al. (2015) (27) at 6.4% in Bhopal, Madhya Pradesh (Table 4).

Patients in our study were classified into four categories based on Passi D et al.'s (2017) (15) classification. Grade IV had the highest prevalence with 106 cases (36.79%), followed by Grade II with 98 cases (34.02%), Grade III with 47 cases (16.31%), and Grade I with 37 cases (12.84%). Upon subgrouping OSMF Grade IV, there were 48 subjects (16.6%) with suspected malignancy alongside OSMF, 46 subjects (15.97%) with mouth opening less than 15 mm, and OSMF with leukoplakia was present in 12 subjects (4.16%).

The findings of this study regarding the prevalence of OSMF contrast with other studies, which commonly report Grade 2 or Grade 1 as the most prevalent subcategories. In our study, however, the most prevalent subcategory of OSMF was Grade 4. This discrepancy may stem from our use of the Passi D et al. (2017) (15) classification, while most studies utilize classifications by Kerr 2011 and Khanna-1995 (28). In our study, Grade IV OSMF starts with a mouth opening of less than 15 mm, while studies using Kerr et al. (2011) classify Grade III OSMF with a mouth opening of less than 20 mm; Khanna et al. (1995) do not specify mouth opening criteria for Grade I. Another contributing factor to the higher prevalence of Grade IV OSMF in this study is that it was conducted exclusively at the only government dental tertiary care center in the central Indian state. Patients with advanced OSMF, marked by severe trismus (mouth opening less than 15 mm) or suspected malignant transformation, are more likely to seek affordable specialized care at this facility. As a result, the center frequently manages cases requiring oral and maxillofacial surgical interventions, such as OSMF band excision or biopsy.

A similar significant trend emerged in studies examining the prevalence of oral malignancy in OSMF patients. Gupta J et al. (2023) (29) reported that out of 630 OSMF patients, 176 (27.83%) had suspected malignant lesions at the time of clinical examination. Most studies reported a higher incidence of OSMF Grade IV, indicating suspected malignancy. This suggests potential bias in the evaluation of Grade IV OSMF patients, as many studies tend to downplay the prevalence of this category.

## CONCLUSION

In conclusion, this study reveals a combined prevalence of 7.57% for oral leukoplakia, erythroplakia, and OSMF, surpassing global averages and reflecting significant regional variations. The study highlights the increased incidence of advanced OSMF (Grade IV) and the association of areca nut use with OSMF (p-value < .05). To benefit patients and society, individuals with areca nut chewing habits and clinical features of OSMF Grade IV, along with suspected malignant lesions, should be accurately classified as Grade IV OSMF during screenings rather than prematurely categorized as chronic oral ulcers or suspected malignancies. This approach facilitates accurate diagnosis and helps elucidate the role of areca nut as a causative agent in oral cancer, paralleling tobacco's recognized risks, particularly in a society with limited awareness of areca nut's carcinogenic potential.

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**Received:** 01.02.2025
**Accepted for publication:** 14.07.2025

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