

A Study on Proportion of Oral Premalignant Lesions and Its Associated Risk Factors Among Adult Population Attending Cancer Screening Outpatient Department at Tertiary Care Cancer Centre in Western Region, India

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Abstract:

Introduction: In India, Oral cancer is the third most common cancer. In recent years, studies on the cancer focuses on early detection and timely intervention in Oral premalignant conditions because it plays a pivotal role for cancer prevention and improved patient outcomes. **Objectives:** To determine the proportion of individuals with suspected oral potentially malignant lesions detected through opportunistic visual oral screening among patients attending a tertiary care cancer screening outpatient department, and to evaluate the associated risk factors and clinical characteristics of these lesions. **Methods:** A Hospital based cross-sectional study was conducted among 501 individuals aged ≥ 18 years attending Cancer Screening OPD at GCRI, Ahmedabad. All participants underwent visual inspection of the oral cavity. A pre-validated questionnaire was used to obtain information regarding socio-demographic characteristics, behavioural risk factors, and symptoms suggestive of oral cancer. **Results:** The proportion of Oral Premalignant Lesion (OPML) in study population was 30.5%. Significant association was observed with older age group (OR=1.67, 95% CI 1.07-2.6), Males (OR=13.1, 95% CI 4.74-36.63) and illiterates (OR=3.32, 95% CI 2.23-4.9). Tobacco consumption ($\chi^2=345.6$, $p<0.001$) and poor oral hygiene ($\chi^2=210.4$, $p<0.001$) showed strong associations with OPML. On binary logistic regression, males were 20 times likely to show OPML compared to females (AOR= 20.42, 95% CI 7.15-58.3) and Illiterates were 4 times likely to affected by OPML compared to literates (AOR= 4.15, 95% CI 2.67-6.42). **Conclusion:** A high burden of OPML was detected through opportunistic screening, particularly among tobacco users and socio-demographically vulnerable groups. Strengthening community-level screening and risk reduction strategies is essential for early diagnosis and prevention of malignant transformation.

Keywords: Early Detection of Cancer, Oral premalignant lesions, Risk factors, Screening, Tobacco use.

Introduction:

Oral cancer, including malignancies affecting the lips, tongue, floor of the mouth, and other oral cavity structures, constitutes a significant public health issue. In

South-Central Asia, oral cavity cancer is the third most common type of cancer.^[1] In India, the age-standardized incidence rate of oral cancer is 12.6 per 1,00,000 populations.^[1] Oral cancer may be preceded by clinically

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detectable non-malignant lesions, commonly referred to as oral potentially malignant disorders. Among these, Leukoplakia, Erythroplakia, and oral sub mucous fibrosis are the most frequently encountered lesions.^[2]

The prevalence of leukoplakia in India ranges from 0.2% to 5.2%.^[3] The prevalence of oral sub mucous fibrosis (OSMF) in India varies between 0.03% and 3.2%.^[3] The incidence and prevalence of oral cancer have shown a concerning upward trend globally, necessitating a deeper understanding of its aetiology, pathogenesis, and optimal management.

In India, the prevalence of premalignant lesions varies with the screening setting, such as hospitals, communities, and primary care facilities. This variation in the prevalence of premalignant lesions can be attributed to regional, life style practices and cultural differences.^[4, 5] Lifestyle-related practices such as tobacco smoking, alcohol consumption, chewing of tobacco or pan masala, and paan chewing are widely prevalent across various regions of the world. In South Asian countries, smokeless forms of tobacco account for a substantial proportion of overall tobacco consumption.^[6]

Oral potentially malignant disorder and its sequelae may cause heavy impairment in quality of life; the disease is also highly costly for society. Primary prevention is considered the most cost-effective strategy, as it focuses on lowering the occurrence of potentially malignant disorders through modification of risk factors.^[2] Although several studies from different regions of India have assessed the prevalence of oral potentially malignant lesions and their associated risk factors, evidence from the present region remains limited.

Objectives:

The present study was conducted to determine the proportion of suspected oral potentially malignant disorders detected through opportunistic visual oral screening among individuals attending the cancer screening outpatient department of a tertiary care oncology centre in Western India. The study also aimed to describe the socio-demographic and behavioural

characteristics of individuals detected with suspected oral lesions, assess the distribution and clinical pattern of lesions according to anatomical site and appearance, examine the association of established risk factors such as tobacco and alcohol use with the presence of oral lesions, and determine the proportion of individuals requiring referral for further diagnostic evaluation and management following screening.

Methodology:

This study was a hospital-based cross-sectional study conducted in Community oncology outpatient Department of the Gujarat Cancer Research Institute, a state-of-the-art cancer research facility situated in Ahmedabad from 1st May 2023 to 30th June 2023. A total 501 Individuals above 18 years of age, seeking health care services and consultation services from Cancer screening outpatient department were selected as study participants. The participants were briefed about the study objectives and procedures, following which informed consent was obtained.

In accordance with WHO–IARC guidelines, all participants underwent oral cavity examination for the detection of oral potentially malignant lesions, conditions, and oral cancer. Co-Investigators & Assistant Doctors were trained for screening of these lesions and Clinical detailed history was conducted by principal investigator and medical officers, who will record oral premalignant lesions & conditions. A pre-designed questionnaire which was validated by consultant of community oncology department were used to record the exposure of the subjects to known risk factors for oral pre cancer. Along with questions related to the type, frequency and duration of deleterious habits, the demographic information on characteristics such as age, sex, occupation, educational level, and socioeconomic status was also obtained. Visual examination of oral cavity was done using mouth mirror and probe. As a non-invasive technique, the oral cavity examination was performed quickly, is without additional diagnostic expense to the patient. The investigator looked for red and white lesions of the oral

mucosa and indurated and fixed masses through palpation. All those with oral lesions were counselled and referred to the Head and Neck Oncology Department for further management. Ethical approval obtained from Institutional Review Committee of The Gujarat Cancer and Research Institute (IRC/2024/P-18 dated 26/03/2024).

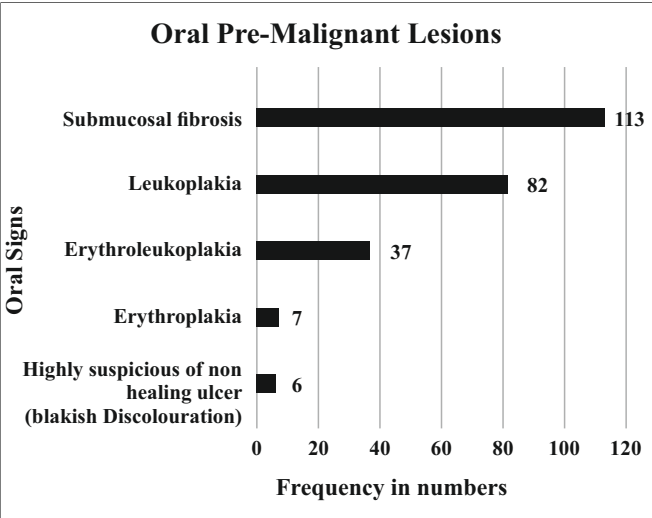
Results:

The study population comprised of 81% male and 19% female. The mean ($\pm$ SD) age of the participants was 37.5 (SD $\pm$ 11.7) years and among them majority (74.6% females and 77.9% males) belongs to 25-54 years age category. More than half of the study participants (63.5%) were literate. The study further revealed that 86.2% of the participants were employed, the majority were married (84.4%), and a substantial proportion (62.7%) had a monthly income of less than 10,000 INR. [Table 1]

Table 1: Baseline Socio-demographic Profile of Participants (N=501)

Baseline characteristics	Number	Percentage %
Age group (years)		
15-24	76	15.2%
25-54	377	75.2%
54-64	39	7.8%
>65	9	1.8%
Gender		
Males	406	81%
Females	95	19%
Marital Status		
Ever Married	423	84.4%
Never Married	78	15.6%
Literacy status		
Literate	318	63.5%
Illiterate	183	36.5%
Monthly Income		
<10000 rupees	314	62.68%
10000-20000 rupees	105	20.95%
>20000 rupees	82	16.37%

Figure 1: Frequency of different Oral Pre-Malignant Lesions (OPML)



Assessment of tobacco and alcohol use among the study participants revealed that 165 (38.9%) had consumed tobacco in any form at some point in their lifetime. Among tobacco users, 73.8% reported the use of smokeless tobacco, indicating it as the predominant form of tobacco consumption in the study population. Additionally, nearly one-tenth of the participants were current alcohol users.

Among the total study population, 30.5% were identified with oral pre malignant lesions (OPML). Of these lesions, oral sub mucous fibrosis constituted the highest proportion (73.86%), followed by Leukoplakia (53.59%) and Erythroplakia (4.58%). Additionally, 60 (12%) participants reported at least one oral symptom, with ulcerative lesions involving the oral mucosa, tongue, or palate being the most commonly observed symptom (43.3%). [Figure 1]

Significant association was observed between OPML and older age group (OR=1.67, 95% CI 1.07-2.6), Males (OR=13.1, 95% CI 4.74-36.63) and Illiterates (OR=3.32, 95% CI 2.23-4.9). Tobacco consumption ($\chi^2=345.6$, $p<0.001$) and poor oral hygiene ($\chi^2=210.4$, $p<0.001$) were also strongly associated with OPML [Table 2]

Binary logistic regression analysis revealed that males had significantly higher odds of developing oral potentially malignant lesions compared to females

Table 2: Factors associated with Oral Pre-malignant Lesion (N=501)

Characteristic	OPML		Chi-square	P-value
	Present no. (n=153) (%)	Absent no. (n=348) (%)		
Ever user of tobacco	Yes	153	42	345.6
	No	0	306	0.000
Gender	Male	149	257	38.3
	Female	4	91	0.000
Education	Illiterate	86	97	36.8
	Literate	67	251	0.000
Good oral hygiene	No	119	42	210.4
	Yes	34	306	0.000

Table 3: Binary Logistic Regression among study participants

	B	S.E.	Wald	df	Sig.	Exp(B)	95% CI for EXP(B)	
							Lower	Upper
Gender	3.017	.536	31.736	1	.000	20.428	7.151	58.354
Education level	1.423	.223	40.564	1	.000	4.149	2.678	6.428
Age	.018	.009	3.638	1	.056	1.018	1.000	1.037
Constant	-4.762	.663	51.658	1	.000	.009		

(AOR = 20.42; 95% CI: 7.15–58.3; $p < 0.001$). Similarly, illiterate participants were nearly four times more likely to have oral potentially malignant lesions compared to literate participants (AOR = 4.15; 95% CI: 2.67–6.42; $p < 0.001$). [Table 3]

Discussion:

An opportunistic screening for oral potentially malignant lesions was carried out among attendees of the Community Oncology Outpatient Department of a tertiary care cancer institute in Western India. The burden of suspected oral precancerous lesions among the participants was 30.5% (95% CI: 12.3, 16.2), which was higher to the rate found in a population-based survey conducted in Indore, India, where it was 13.7%^[7] and the prevalence observed in the present study was nearly ten times higher than that reported by Burungale SU et al. (2014), where the prevalence of oral potentially malignant lesions was 3.25%.^[8] In India, the smokeless tobacco use is common among women.^[9,10] Males had a higher prevalence ratio (PR) of suspected oral lesions after adjusting for substance use. Similar male

preponderance was noted in studies done at the Indore district of Madhya Pradesh.^[7]

In the present study, oral sub mucous fibrosis (OSMF) was the most frequently observed oral potentially malignant lesion (73.86%), with the next most common lesion being Leukoplakia (53.59%), erythroleukoplakia (24.18%), Erythroplakia (4.58%), and highly suspicious non-healing ulcer (3.92%). A similar study conducted by Kumar et al. (2015) reported oral sub mucous fibrosis as the most prevalent lesion (8.06%), followed by Leukoplakia (4.02%) and lichen planus (1.38%), whereas Erythroplakia was the least commonly observed oral potentially malignant lesion (0.24%). In the present study, a comparatively lower proportion of highly suspicious non-healing ulcers (3.92%) and Erythroplakia (4.58%) was observed. The present study also shows that 12 % of study participants suffered from at least one of the oral symptoms and among them most commonly observed were trismus i.e., difficulty in opening mouth (8%). The proportion of participants with progressive restriction in mouth

opening observed in the present study was higher compared to that reported by Burungale et al. (2014).^[8] However, it is lower compared to the study conducted at semi-urban district of Vidisha in Central India by Mehrotra et al., which reported difficulty in opening mouth to be 14% among their study participant.^[11]

A study conducted by Pimple et al. (2012) noted that all individuals with oral precancerous lesions (OPML) were tobacco users.^[12] which aligns with the findings of the current study. A similar association between tobacco use and oral potentially malignant lesions was reported by Burungale et al. (2014) and Kumar et al. (2015) (OR = 2.06, $p = 0.030$). In the present study, all participants identified with oral potentially malignant lesions were tobacco users, with smokeless tobacco being the predominant form of consumption (74.5%). A statistically significant association was observed between tobacco use and oral potentially malignant lesions ($\chi^2=345.6$, $p<0.001$). These findings are consistent with studies conducted by Thomas et al. (2003) (OR = 37.8; 95% CI: 16.2-88.1), Mehrotra et al. (2010) (OR=4.5), and Sankaranarayanan et al. (1989) ($p<0.001$), all of which demonstrated a significant association between tobacco chewing and oral potentially malignant lesions.^[11,13,14]

Studies conducted by Kumar et al., (2015) (OR=2.09, 95% CI=1.45–3.00) and Pimple et al., (2012) ($p<0.001$) showed that male gender was significantly associated with OPML.^[7,12] These results are consistent with the present study, where among individuals who have ever used tobacco, those with oral precancerous lesions (OPML) had higher odds of being male compared to female (AOR= 20.42, 95% CI 7.15-58.3, $p<0.0010$). The association observed in the present study was stronger than that reported by Pahwa et al. (2018), where male ever-tobacco users had higher odds of developing oral potentially malignant lesions compared to females (AOR = 12.22; 95% CI: 3.71–40.22).^[15]

Interestingly, the results of the study also shows that a significant association was observed between OPML and older age group (OR=1.67, 95% CI 1.07-2.6), Males (OR=13.1, 95% CI 4.74-36.63) and Illiterates

(OR=3.32, 95% CI 2.23-4.9). The study further demonstrated that illiterate participants had significantly higher odds of developing oral potentially malignant lesions compared to literate individuals (AOR = 4.15; 95% CI: 2.67–6.42; $p < 0.001$), which may be attributed to limited awareness, inadequate health education, and reduced access to preventive healthcare services. Illiteracy often correlates with lower socioeconomic status, which can result in poor nutrition, lack of awareness about the risks of tobacco and alcohol use, and limited access to regular health check-ups. Additionally, illiterate individuals may be less likely to recognize the early signs of OPML or seek timely medical advice, thereby contributing to a greater burden of the condition.

Among participants with OPML, only 3% reported being ever alcohol users, which is considerably lower than the findings reported by Pahwa et al. (2018), Juntanong et al. (2016), and Fioretti et al. in their respective studies (1999).^[15,16,17] In the present study, individuals with oral precancerous lesions (OPML) did not have good oral hygiene ($\chi^2=210.4$, $p<0.001$). This finding is in agreement with a study conducted by Oji et al. (2012) in Nigeria, which reported a significant association between poor oral hygiene, particularly irregular tooth brushing and oral cancer ($p<0.001$).^[18] Similarly, a study conducted by Rosenquist et al. (2005) demonstrated a comparable association between poor oral hygiene and OPML, reporting an odds ratio of 5.3.^[19]

The Occurrence of suspected oral mucosal lesions rises with age, with individuals aged over 60 years being 12.2 times more likely to have these lesions.^[20] The present study also showed similar patterns, with majority of participants (>45 years) were significantly associated with OPML (OR=1.67, 95% CI 1.07-2.6). The National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Disease, and Stroke (NPCDCS) recommend screening for oral cancers in individuals aged 30 years and above. This strategy is considered efficient as it improves the yield during screening.^[21]

Screening patients attending the outpatient department of a tertiary care hospital opportunistically is

a cost-effective and practical approach requiring minimal training. Screening can be conducted by visually inspecting the oral cavity using a torchlight and disposable tongue depressors. However, staining of the participant's mucous membrane by tobacco and Areca nut presented a challenge in diagnosing the lesions.

One potential limitation of the study could be social desirability bias, where participants, both male and female, might have underreported their tobacco and alcohol consumption frequency to conform to social expectations. Another limitation is the cross-sectional design, which raises questions about the temporal relationship between potentially malignant oral disorders and their associated risk factors. Additionally, it is recognized that other unmeasured or unaccounted risk factors may contribute to the development of these disorders, underscoring the need for further research in this area.

Conclusion:

Although the study indicated prevalence of 30.5% oral potentially malignant lesions (OPML) in this population, a high proportion of individuals among them found to use tobacco in various forms and they do not have any oral symptoms with their long history of tobacco usage. This underscores the need to strengthen existing health programmes by integrating timely opportunistic screening of all suspected individuals at the community level. Such screening efforts can facilitate early diagnosis and preventive interventions for neoplasia, ultimately leading to improved public health outcomes. By strengthening screening programmes and enhancing awareness regarding the harmful effects of tobacco use, the burden of oral potentially malignant disorders may be substantially reduced, along with improvement in overall population health outcomes.

Statements and Declarations

Conflict of Interests

No conflict of interests have been declared by the authors. Authors declare no financial support or relationships that may pose conflict of interests.

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