



Clinicopathological Study of Clinically Diagnosed Potentially Malignant and Malignant Lesions in the Oral Cavity in a Tertiary Care Hospital

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KEYWORDS

Oral cavity, potentially malignant disorders, squamous cell carcinoma, tobacco habits, histopathology.

ABSTRACT:

Background: Potentially malignant disorders (PMDs) of the oral cavity carry a significant risk of malignant transformation, particularly in populations with high prevalence of tobacco- and alcohol-related habits. Early clinical recognition and histopathological confirmation are essential for timely intervention and improved prognosis.

Objectives: To study the clinicopathological profile of clinically diagnosed potentially malignant and malignant lesions of the oral cavity and to evaluate their association with demographic factors and adverse oral habits.

Materials and Methods: This observational cross-sectional study was conducted over 18 months in the Department of Otorhinolaryngology at a tertiary care hospital. A total of 100 patients with clinically suspected oral cavity lesions persisting for more than two weeks were included. Detailed demographic data, habit history, clinical findings, and lesion characteristics were recorded. Incisional biopsy was performed in all cases, and histopathological examination was considered the gold standard. Data were analysed using SPSS version 21.0, and associations were assessed using the Chi-square test.

Results: Among the study participants, 67% were males, and the most affected age group was 21–40 years. Buccal mucosa was the most common site involved. Histopathological evaluation revealed 48% potentially malignant disorders and 52% malignant lesions. Oral lichen planus was the most common PMD (35.41%), while squamous cell carcinoma accounted for 75% of malignant cases. Significant associations were observed between smoking, tobacco consumption, duration of habits, and the occurrence of malignant lesions ($p < 0.05$).

Conclusion: Oral cavity lesions show strong associations with adverse oral habits and their duration. Histopathological assessment is vital for definitive diagnosis. Early identification of PMDs, habit cessation, and routine oral screening can reduce the burden of oral cancer and improve patient outcomes.



INTRODUCTION

Oral cancer constitutes a major public health problem worldwide, particularly in developing countries, and is associated with significant morbidity and mortality. It ranks among the top ten most common cancers globally and is one of the leading causes of cancer-related deaths in South and Southeast Asia, including India. The high prevalence in this region is largely attributed to widespread use of tobacco in various forms, betel quid chewing, areca nut consumption, and alcohol intake, along with poor oral hygiene and low socioeconomic status [1,2].

Oral squamous cell carcinoma (OSCC) accounts for more than 90% of all malignant neoplasms of the oral cavity. Most oral cancers are preceded by clinically identifiable lesions known as potentially malignant disorders (PMDs), previously referred to as premalignant lesions and conditions. The World Health Organization (WHO) defines oral potentially malignant disorders as “clinical presentations that carry a risk of malignant transformation to oral cancer” [3]. Common PMDs include leukoplakia, erythroplakia, oral lichen planus, oral submucous fibrosis (OSMF), and erythroleukoplakia.

Leukoplakia is the most frequently encountered potentially malignant lesion of the oral cavity, with a reported malignant transformation rate ranging from 1% to 20%, depending on clinical subtype and degree of epithelial dysplasia [4]. Erythroplakia, although less common, carries a much higher risk of malignant transformation and is often associated with severe dysplasia or carcinoma in situ at the time of diagnosis [5]. Oral lichen planus is a chronic inflammatory condition with a controversial but documented malignant transformation potential, particularly in its erosive and atrophic variants [6]. Oral submucous fibrosis is a chronic, progressive condition strongly associated with areca nut chewing and is recognized as a high-risk PMD with reported malignant transformation rates between 7% and 13% [7].

Early detection and accurate diagnosis of oral PMDs and malignant lesions are critical for improving patient outcomes. Clinical examination plays a vital role in the initial identification of suspicious lesions; however, clinical diagnosis alone may not always correlate with histopathological findings. Histopathological

examination remains the gold standard for definitive diagnosis, grading of epithelial dysplasia, and classification of malignancies. The degree of epithelial dysplasia is considered one of the most important predictors of malignant transformation in PMDs [8].

Several demographic and behavioral factors influence the development and progression of oral PMDs and malignancies. Age, gender, occupation, and adverse oral habits such as smoking, smokeless tobacco use, and alcohol consumption have been shown to significantly impact the risk of malignant transformation. Prolonged duration and combined exposure to these habits further increase the likelihood of progression from PMDs to invasive carcinoma [9,10].

Despite advances in diagnostic techniques, oral cancer in India is often diagnosed at an advanced stage, resulting in poor prognosis and survival rates. This underscores the importance of clinico-pathological correlation studies to assess the accuracy of clinical diagnosis, understand lesion distribution patterns, and evaluate the association of various risk factors with malignant transformation. Such studies are essential for improving early detection strategies and guiding preventive and therapeutic interventions.

The present study was undertaken to evaluate the clinical and histopathological spectrum of clinically diagnosed potentially malignant and malignant lesions of the oral cavity in patients attending a tertiary care hospital. The study aims to correlate clinical findings with histopathological diagnosis and to assess the association of demographic factors and adverse oral habits with the type and severity of oral cavity lesions.

MATERIALS AND METHODS

Place of Study

The present study was conducted in the Department of Otorhinolaryngology, Integral Institute of Medical Sciences and Research (IIMSR), Lucknow, Uttar Pradesh, India.

Study Design

This was an observational cross-sectional clinico-pathological study.

Study Duration

The study was carried out over a period of 18 months.



Study Population

The study population comprised patients presenting to the ENT outpatient department (OPD) with ulcerative, proliferative, or other suspicious lesions of the oral cavity persisting for a duration of at least two weeks.

Sample Size Calculation

The sample size was calculated using the rule-of-thumb formula:

$$n = \frac{z^2 p(1-p)}{d^2}$$

Where:

- n = required sample size
- p = anticipated prevalence (40%)
- z = Z value corresponding to 95% confidence level (1.96)
- d = margin of error (10%)

Considering a non-response rate of 10%, the final sample size was calculated to be 100 patients.

Inclusion Criteria

- Patients aged ≥ 18 years.
- Patients presenting with an ulcer, growth, or lesion in the oral cavity persisting for at least two weeks.

Exclusion Criteria

- Patients aged < 18 years.
- Patients already diagnosed with oral malignancy and receiving treatment.

Methodology

Patients presenting with clinically suspected potentially malignant or malignant lesions of the oral cavity and fulfilling the inclusion criteria were consecutively recruited for the study. Written informed consent was obtained from all participants after explaining the nature, objectives, procedures, potential benefits, and possible risks of the study.

Data were collected using a pre-designed structured proforma. Demographic details, including age, sex, occupation, education, residence, and marital status were recorded. A detailed history of the oral lesion was

obtained, including site, onset, duration, progression, and associated symptoms such as pain, burning sensation, bleeding, ulceration, and difficulty in swallowing. Information regarding adverse oral habits such as tobacco smoking, tobacco chewing, betel quid use, and alcohol consumption was also documented.

All patients underwent a thorough general physical and systemic examination, followed by a detailed ENT, head, and neck examination. Lesions were assessed for size, site, surface characteristics, mobility, induration, and the presence of regional lymphadenopathy.

An incisional biopsy was performed in all cases under aseptic conditions. The biopsy specimens were sent for histopathological examination. Histopathological diagnosis was established based on World Health Organization (WHO) criteria. Dysplastic lesions were graded as mild, moderate, severe dysplasia, or carcinoma in situ. Squamous cell carcinoma (SCC) was classified as well-differentiated, moderately differentiated, or poorly differentiated.

Histopathology was considered the gold standard, and clinical diagnosis was compared with histopathological findings to assess the accuracy of clinical evaluation in detecting potentially malignant and malignant oral cavity lesions.

Statistical Analysis

The collected data were tabulated and analyzed using Statistical Package for Social Sciences (SPSS) version 21.0 and Microsoft Excel 2019. Descriptive and comparative statistical analyses were performed using the Chi-square test and Student's *t*-test. A *p*-value of < 0.05 was considered statistically significant.

RESULT AND OBSERVATIONS;

Table 1. Distribution of study participants based on Age and Gender (n = 100)

Variable	Category	Frequency (n)	Percentage (%)
Age (years)	<20	4	4.0
	21–40	65	65.0
	41–60	23	23.0



	61–80	8	8.0
	Total	100	100.0
Gender	Male	67	67.0
	Female	33	33.0
	Total	100	100.0

Among the 100 study participants, the majority belonged to the 21–40 years age group (65%), followed by 41–60 years (23%), 61–80 years (8%), and less than 20 years (4%). With respect to gender distribution, males constituted 67% of the study population, while females accounted for 33%.

Table 2. Distribution of study participants based on Occupation and Habits (n = 100)

Variable	Category / Sub-variable	Frequency (n)	Percentage (%)
Occupation	Businessman	14	14.0
	Farmer	15	15.0
	Homemaker	24	24.0
	Student	9	9.0
	Shopkeeper	37	37.0
	Tailor	1	1.0
	Total	100	100.0
Smoking	Yes	58	58.0
	No	42	42.0
Tobacco usage	Yes	82	82.0
	No	18	18.0
Alcohol consumption	Yes	57	57.0
	No	43	43.0

Among the study participants, the most common occupation was shopkeeping (37%), followed by homemaking (24%), farming (15%), and business (14%). With regard to habits, 58% of participants were smokers, 82% reported tobacco usage, and 57% consumed alcohol.

Table 3. Distribution of study participants based on Duration of Habits and Site of Lesion

Variable	Category	Frequency (n)	Percentage (%)
Duration of habits (n = 82)	<10 years	0	0.0
	11–20 years	35	42.68
	21–30 years	29	35.36
	31–40 years	18	21.95
	Total	82	100.0
Site of lesion (n = 100)	Left buccal mucosa	38	38.0
	Right buccal mucosa	26	26.0
	Soft palate	10	10.0
	Hard palate	9	9.0
	Lateral border of tongue	8	8.0
	Tip of tongue	5	5.0
	Gingivobuccal sulcus	2	2.0
	Floor of mouth	1	1.0
	Retromolar junction	1	1.0
	Total	100	100.0

Among the 82 participants with a history of adverse oral habits, the majority had a habit duration of 11–20 years (42.68%), followed by 21–30 years (35.36%) and 31–40



years (21.95%). Regarding the site of the lesion, the most commonly affected site was the left buccal mucosa (38%), followed by the right buccal mucosa (26%), soft palate (10%), hard palate (9%), and lateral border of the tongue (8%).

Table 4. Distribution of study participants based on Local Examination findings (n = 100)

Parameter	Sub-variable	Frequency (n)	Percentage (%)
Shape	Circular	38	38.0
	Oval	62	62.0
Colour	Red	66	66.0
	Yellow	34	34.0
Discharge	Present	5	5.0
	Absent	95	95.0
Appearance	White patch	23	23.0
	Ulcer proliferative growth	21	21.0
	Ulcer	17	17.0
	Red & white patch	14	14.0
	White striations	13	13.0
	Ulcerated growth	12	12.0
	Total		100

Table 5. Distribution of study participants based on Clinical, Histopathological, and Final Diagnosis (n = 100)

Diagnostic Category	Diagnosis	Frequency (n)	Percentage (%)
Clinical diagnosis	Erythroplakia	14	14.0
	Leukoplakia	4	4.0

	Lichen planus	18	18.0
	Malignant lesion	50	50.0
	OSMF (PMD)	14	14.0
	Total	100	100.0
Histopathological diagnosis	Leukoplakia with mild dysplasia	3	3.0
	Oral lichen planus	17	17.0
	OSMF with moderate dysplasia	14	14.0
	Severe dysplasia	14	14.0
	SCC – well differentiated	14	14.0
	SCC – moderately differentiated	13	13.0
	SCC – poorly differentiated	12	12.0
	Verrucous carcinoma	13	13.0
	Total	100	100.0
	Final diagnosis	Malignant	52
Premalignant		48	48.0
Total		100	100.0

Table 6. Distribution of study participants based on type of Potentially Malignant Lesion (n = 48)

Potentially malignant	Frequency	Percentage
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lesion	(n)	(%)
Lichen planus	17	35.41
Erythroleukoplakia	14	29.16
Oral submucous fibrosis (OSMF)	14	29.16
Leukoplakia	3	6.25
Total	48	100.00

Table 7. Distribution of study participants based on Degree of Dysplasia and Type of Malignant Lesions

Diagnostic category	Sub-category	Frequency (n)	Percentage (%)
Degree of dysplasia (n = 48)	Mild dysplasia	20	41.68
	Moderate dysplasia	14	29.16
	Severe dysplasia	14	29.16
	Total	48	100.00
Malignant lesions (n = 52)	Squamous cell carcinoma (SCC)	39	75.0
	Verrucous carcinoma	13	25.0
	Total	52	100.00

Table 8. Distribution of study participants based on Symptoms and Association of Age with Type of Oral Lesion (n = 100)

Variable	Category / Sub-category	Malignant n (%)	PMD n (%)	Total n (%)
Symptoms	Pain – Yes	—	—	52 (52.0)
	Pain – No	—	—	48

				(48.0)
	Ulceration – Yes	—	—	52 (52.0)
	Ulceration – No	—	—	48 (48.0)
	Induration – Yes	—	—	80 (80.0)
	Induration – No	—	—	20 (20.0)
	Node involvement – Yes	—	—	26 (26.0)
	Node involvement – No	—	—	74 (74.0)
Age group (years)	<20	4 (4.0)	0 (0.0)	4 (4.0)
	21–40	30 (30.0)	35 (35.0)	65 (65.0)
	41–60	14 (14.0)	9 (9.0)	23 (23.0)
	>60	4 (4.0)	4 (4.0)	8 (8.0)
	Total	52 (52.0)	48 (48.0)	100 (100.0)

Chi-square test: $\chi^2 = 5.32$, $df = 3$, $p = 0.150$ (Not statistically significant)

Table 9. Association of Gender and Occupation with Potentially Malignant and Malignant Lesions of the Oral Cavity (n = 100)

Variable	Category	Malignant n (%)	PM D n (%)	Total n (%)
Gender	Male	39 (39.0)	28 (28.0)	67 (67.0)



	Female	13 (13.0)	20 (20.0)	33 (33.0)
	Total	52 (52.0)	48 (48.0)	100 (100.0)
Occupation	Businessman	10 (10.0)	4 (4.0)	14 (14.0)
	Farmer	13 (13.0)	2 (2.0)	15 (15.0)
	Housewife	9 (9.0)	15 (15.0)	24 (24.0)
	Shopkeeper	0 (0.0)	9 (9.0)	9 (9.0)
	Student	20 (20.0)	17 (17.0)	37 (37.0)
	Total	52 (52.0)	48 (48.0)	100 (100.0)

Malignant lesions were more common among males (39%) compared to females (13%), whereas potentially malignant disorders were relatively more frequent in females (20%). The association between gender and type of oral lesion was statistically significant ($p = 0.05$). With respect to occupation, higher proportions of malignant lesions were observed among farmers and businessmen, while housewives and shopkeepers showed a greater prevalence of potentially malignant disorders. The association between occupation and lesion type was statistically significant ($\chi^2 = 22.25$, $df = 5$; $p = 0.01$).

Table 10. Association of Smoking, Tobacco Consumption, and Alcohol Use with Potentially Malignant and Malignant Oral Lesions (n = 100)

Habit	Category	Malignant n (%)	PMD n (%)	Total n (%)
Smoking	Present	40 (40.0)	18	58

			(18.0)	(58.0)
	Absent	12 (12.0)	30 (30.0)	42 (42.0)
	Total	52 (52.0)	48 (48.0)	100 (100.0)
Tobacco consumption	Present	31 (31.0)	26 (26.0)	57 (57.0)
	Absent	21 (21.0)	22 (22.0)	43 (43.0)
	Total	52 (52.0)	48 (48.0)	100 (100.0)
Alcohol consumption	Present	8 (8.0)	11 (11.0)	19 (19.0)
	Absent	44 (44.0)	37 (37.0)	81 (81.0)
	Total	52 (52.0)	48 (48.0)	100 (100.0)

Smoking showed a strong and statistically significant association with lesion type, with malignant lesions being markedly more common among smokers (40%) compared to non-smokers (12%). Tobacco consumption was slightly more frequent among individuals with malignant lesions (31%) than those with potentially malignant disorders (26%), and this association was statistically significant. Alcohol consumption was reported by a smaller proportion of participants, and no statistically significant association was observed between alcohol use and the type of oral cavity lesion ($p = 0.33$).



Table 11. Association between Duration of Habits and Potentially Malignant and Malignant Lesions of the Oral Cavity (n = 100)

Duration of habits (years)	Malignant n (%)	PMD n (%)	Total n (%)
<10	8 (8.0)	10 (10.0)	18 (18.0)
11–20	14 (14.0)	21 (21.0)	35 (35.0)
21–30	13 (13.0)	16 (16.0)	29 (29.0)
>30	17 (17.0)	1 (1.0)	18 (18.0)
Total	52 (52.0)	48 (48.0)	100 (100.0)

Statistical analysis: $\chi^2 = 16.02$, $df = 3$, $p = 0.01$ (statistically significant)

DISCUSSION

The present clinico-pathological study was undertaken to evaluate the demographic profile, clinical characteristics, habit association, and histopathological spectrum of clinically diagnosed potentially malignant disorders (PMDs) and malignant lesions of the oral cavity in a tertiary care hospital setting. Oral cavity lesions represent a major public health burden in India, largely attributable to widespread tobacco and areca nut use, and early identification of PMDs is crucial in preventing malignant transformation.

Demographic Profile

In the present study, the majority of patients belonged to the 21–40 years age group (65%), followed by the 41–60 years group (23%). Although oral malignancies are traditionally considered diseases of older age, recent studies have shown a rising incidence among younger individuals, particularly in developing countries, due to early initiation of deleterious oral habits such as tobacco chewing and smoking [1,2]. The relatively younger age distribution in this study highlights the shifting epidemiological trend and emphasizes the need for early screening programs.

Male predominance was observed, with males constituting 67% of the study population. This finding is consistent with several Indian and international

studies, which have reported higher prevalence of oral PMDs and malignancies among males due to greater exposure to tobacco, alcohol, and occupational risk factors [3–5]. However, a notable proportion of females (33%) were also affected, reflecting the increasing prevalence of smokeless tobacco use among women in India.

Occupational Distribution and Habits

Occupation-wise, shopkeepers (37%) and homemakers (24%) formed a significant proportion of the study population. The high prevalence among shopkeepers may be attributed to easy accessibility to tobacco products and prolonged exposure to stress-related habits. Homemakers showed a higher prevalence of PMDs, which may be related to the use of smokeless tobacco products and betel quid, a trend increasingly reported in recent literature [6].

A strong association was observed between adverse oral habits and lesion occurrence. Tobacco usage was reported by 82% of participants, smoking by 58%, and alcohol consumption by 57%. Tobacco remains the single most important etiological factor in the development of oral PMDs and malignancies, causing chronic mucosal irritation, genetic mutations, and epithelial dysplasia [7,8]. The statistically significant association between smoking and malignant lesions observed in this study corroborates findings from earlier studies [9,10].

Site and Clinical Presentation

The buccal mucosa was the most commonly affected site, with the left buccal mucosa (38%) followed by the right buccal mucosa (26%). This predilection is well documented in Indian studies and is attributed to the habitual placement of tobacco and areca nut in the buccal vestibule [11,12]. Other sites such as the palate and tongue were less frequently involved.

Clinically, oval-shaped lesions, red discoloration, and ulcerative or proliferative growth patterns were common. Induration was present in 80% of cases, a feature strongly suggestive of malignancy. These findings emphasize the importance of careful clinical examination, as certain clinical features may raise suspicion of malignant transformation even before histopathological confirmation.



Spectrum of Potentially Malignant Disorders

Among PMDs, oral lichen planus was the most common lesion (35.41%), followed by erythroleukoplakia (29.16%) and oral submucous fibrosis (29.16%). Leukoplakia constituted the least proportion (6.25%). Similar distributions have been reported by other authors, who have highlighted lichen planus and erythroleukoplakia as lesions with significant malignant transformation potential [13,14].

Histopathological examination revealed varying degrees of epithelial dysplasia among PMDs, with mild dysplasia being the most common (41.68%), followed by moderate and severe dysplasia. The presence of higher grades of dysplasia underscores the necessity of regular follow-up and early intervention in patients diagnosed with PMDs.

Malignant Lesions and Histopathology

Malignant lesions constituted 52% of the total cases, with squamous cell carcinoma (SCC) accounting for 75% and verrucous carcinoma for 25%. SCC is the most common malignancy of the oral cavity worldwide and arises from progressive dysplastic changes in the epithelium [15]. The predominance of well and moderately differentiated SCC in this study aligns with previous reports [16].

Association of Duration of Habits with Lesion Type

A statistically significant association was observed between duration of habits and lesion type ($\chi^2 = 16.02$, $p = 0.01$). Malignant lesions were more prevalent in individuals with habit duration exceeding 30 years, whereas PMDs were more frequent in those with shorter durations, particularly 11–20 years. This finding strongly supports the dose–response relationship between duration of carcinogenic exposure and malignant transformation, as documented in earlier studies [17,18].

Clinical–Histopathological Correlation

Histopathology was considered the gold standard in this study, and comparison with clinical diagnosis revealed that certain lesions clinically suspected as PMDs were confirmed as malignant on histopathological examination. This highlights the limitations of clinical assessment alone and reinforces the indispensable role

of biopsy and histopathological evaluation in definitive diagnosis [19].

CONCLUSION

This study demonstrates a high prevalence of potentially malignant and malignant oral cavity lesions, predominantly affecting males in younger and middle-aged groups. Buccal mucosa was the most commonly involved site, closely associated with tobacco-related habits. Oral lichen planus and oral submucous fibrosis were the common potentially malignant disorders, while squamous cell carcinoma constituted the majority of malignant lesions. A significant association was observed between prolonged habit duration and malignant transformation. Histopathological evaluation remains the gold standard for accurate diagnosis. Early detection, habit cessation, and regular oral screening are crucial to prevent progression to oral malignancy.

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