



Clinico-Histopathological Correlation in Premalignant and Malignant Oral Mucosal Lesions: Experience from a Tertiary Care Center in the Konkan Region

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KEYWORDS

Oral premalignant lesions. Clinico-histopathological correlation. Squamous cell carcinoma.

ABSTRACT:

Background: Oral cancer remains a major health concern in India, particularly in regions with high tobacco consumption. Premalignant lesions such as leukoplakia, erythroplakia, and oral submucous fibrosis often precede malignancy, making clinico-histopathological correlation essential for accurate diagnosis and management.

Aim: To establish clinico-histopathological correlation in premalignant and malignant oral mucosal lesions in patients attending a tertiary care center in the Konkan region.

Materials and Methods: This prospective observational study included 88 patients with clinically suspected premalignant and malignant oral mucosal lesions. Clinical data regarding demographics, personal habits, and lesion characteristics were recorded. Biopsy specimens were processed and examined histopathologically. The correlation between clinical and histopathological diagnosis was assessed using concordance rates, Cohen's κ , and ROC curve analysis.

Results: The mean age of patients was 49.1 ± 7.2 years, with a male predominance (67%). Most participants resided in rural areas (58%), and tobacco use was highly prevalent (chewing 83%, smoking 75%). The buccal mucosa was the most frequently involved site (62.5%). Clinico-histopathological concordance was 84.1%, with a Cohen's κ of 0.68 ($p < 0.001$), indicating substantial agreement. Sensitivity and specificity of clinical diagnosis for malignancy were 88.7% and 76.9%, respectively, while the ROC AUC was 0.93. Histologically, well-differentiated squamous cell carcinoma was the predominant malignant subtype (77.4%). Lesion size was significantly larger in malignant cases compared to premalignant lesions ($p < 0.001$).

Conclusion: Clinico-histopathological correlation is vital for accurate diagnosis of oral mucosal lesions. While clinical evaluation demonstrates substantial reliability, histopathology remains indispensable for confirmation and grading. Routine biopsy of suspicious lesions is essential for early detection and timely management, particularly in high-risk populations with widespread tobacco exposure.



INTRODUCTION

Oral cancer remains one of the most common malignancies worldwide, with a particularly high burden in South and Southeast Asia, including India. Globally, more than 500,000 new cases of oral cancer are reported annually, yet the five-year survival rate remains below 50% despite advancements in diagnostic and therapeutic modalities. In India, oral cancer constitutes nearly 30% of all cancers in men, ranking as the most prevalent malignancy among males and one of the leading cancers in females. Epidemiological data reveal that approximately 12.8 men and 7.5 women per 100,000 individuals are affected, particularly those aged between 50 and 80 years, making it a critical public health concern.^[1]

The aetiology of oral cancer is multifactorial, with well-established associations with tobacco use, betel nut chewing, alcohol consumption, viral infections such as human papillomavirus (HPV), poor nutrition, and chronic trauma from dental factors. In India, smokeless tobacco (chewing tobacco, gutkha, khaini, and betel quid with areca nut) plays a dominant role in carcinogenesis, contributing to regional differences in incidence and presentation. Furthermore, HPV-related oncogenesis is increasingly recognised, with oncogenic strains (notably HPV-16 and HPV-18) implicated in malignant transformation of the oral epithelium.^[2]

Premalignant lesions of the oral mucosa, including leukoplakia, erythroplakia, and oral submucous fibrosis, represent critical stages in the carcinogenic continuum. These lesions are characterised by morphologically altered epithelium with increased risk of malignant transformation. The early identification and histopathological confirmation of premalignant changes is therefore crucial for timely intervention. However, reliance on clinical diagnosis alone is insufficient due to variability in lesion morphology and overlap between benign, premalignant, and malignant lesions. Histopathology remains the gold standard for establishing definitive diagnosis and guiding management. The oral cavity is anatomically complex, comprising keratinized and non-keratinized mucosa across regions such as lips, buccal mucosa, gingivo-buccal sulcus, retromolar trigone, alveolus, tongue, floor of the mouth, and hard palate. Each site demonstrates variable susceptibility to carcinogenesis. The buccal

mucosa, tongue, and alveolus are reported as the most commonly affected sites in Indian studies.^[3]

In India, the World Health Organization predicts tobacco-related deaths to surpass 1.5 million annually by 2025, underscoring the urgency of strengthening diagnostic and preventive strategies. Despite improved awareness and screening efforts, delayed presentation remains a major challenge due to socioeconomic barriers, limited access to healthcare, and lack of awareness regarding early signs. Furthermore, clinical-pathological discordance in oral lesions is well documented, with multiple studies reporting concordance rates between 60-75%. This highlights the necessity of clinico-histopathological correlation (CHC) in enhancing diagnostic accuracy, reducing misclassification, and facilitating appropriate treatment planning.^[4]

Clinico-histopathological correlation provides an integrated framework by comparing clinical impressions with histopathological findings. Such correlation is vital not only for diagnostic precision but also for understanding the natural history of premalignant lesions, assessing malignant potential, and tailoring patient management. For instance, a lesion clinically diagnosed as leukoplakia may reveal histological evidence of epithelial dysplasia, carcinoma in situ, or invasive squamous cell carcinoma. Conversely, lesions clinically suspected as malignant may reveal only hyperkeratosis or inflammatory changes upon histology. These discrepancies necessitate routine biopsy and histopathological examination for all suspicious lesions.^[5]

The Konkan region of Maharashtra presents unique sociocultural and occupational exposures, with widespread use of betel quid and smokeless tobacco, coupled with limited healthcare accessibility. Consequently, it serves as an ideal setting to investigate the spectrum of premalignant and malignant oral mucosal lesions and their clinico-histopathological correlation. This study aims to contribute region-specific insights that can guide public health interventions, improve diagnostic accuracy, and enhance patient outcomes.

Aim

To establish clinico-histopathological correlation in premalignant and malignant oral mucosal lesions in



patients attending a tertiary care center in the Konkan region.

Objectives

1. To assess the concordance between clinical and histopathological diagnosis of premalignant and malignant oral mucosal lesions.
2. To study the gross and microscopic features of premalignant and malignant oral mucosal lesions.

MATERIALS AND METHODOLOGY

Source of Data

The study population comprised patients with clinically suspected premalignant and malignant oral mucosal lesions, whose specimens were received in the Department of Pathology, B.K.L. Walawalkar Rural Medical College, Maharashtra.

Study Design

This was a prospective observational study.

Study Location

The study was carried out at B.K.L. Walawalkar Rural Medical College and Hospital, situated in the Konkan region of Maharashtra.

Study Duration

The study was conducted over 18 months, from December 2020 to June 2022.

Sample Size

Sample size was calculated using prevalence data and statistical formulae, yielding a minimum requirement of 88. Accordingly, 88 patients fulfilling inclusion criteria were included.

Inclusion Criteria

1. All oral cavity specimens of premalignant and malignant mucosal lesions received in the histopathology section.
2. Patients aged >18 years of both sexes.

Exclusion Criteria

1. Benign and non-neoplastic oral mucosal lesions.

2. Recurrent lesions following treatment for primary oral malignancy.

Procedure and Methodology

Consecutive sampling was adopted. Patients presenting with oral mucosal lesions during the study period and fulfilling inclusion criteria were recruited. Clinical details including demographic data, personal habits (tobacco, alcohol), medical history, and presenting complaints were recorded using a structured proforma. Thorough oral cavity examination was performed, and site, size, appearance, and laterality of lesions were documented.

Biopsy or excision specimens were collected, fixed in 10% buffered formalin, and processed by routine paraffin embedding. Sections were stained with hematoxylin and eosin (H&E) for histopathological evaluation. The lesions were classified into premalignant and malignant categories. Degree of epithelial dysplasia in premalignant lesions and differentiation of squamous cell carcinoma in malignant cases were noted.

Sample Processing

Gross examination of tissue specimens was done prior to histopathology. After fixation, tissues were processed by routine histopathological techniques, embedded in paraffin, and sectioned at 4-5 μ m thickness. Stained slides were examined microscopically by pathologists for final diagnosis.

Statistical Methods

Data were entered into SPSS (IBM version 21.0). Descriptive statistics were applied. Quantitative variables were expressed as mean \pm SD, while qualitative variables were presented as frequencies and percentages. Chi-square test was applied to determine associations between sociodemographic factors and lesion type. ROC curve analysis was performed to evaluate concordance between clinical and histopathological diagnosis. A p-value <0.05 was considered statistically significant.

Data Collection

Data were obtained from hospital records and clinical proforma. Patient confidentiality was maintained throughout. Informed consent was obtained, and ethical clearance was granted by the institutional ethics committee.



OBSERVATION AND RESULTS

Table 1: Baseline profile of patients (N = 88)

Variable	Category	Total n (%) [95% CI]	Premalignant n=26	Malignant n=62	Test statistic	p- value
Age (years)	Mean ± SD	49.1 ± 7.2 (-)	47.6 ± 7.0	49.8 ± 7.2	t = 1.42	0.159
Sex	Male	59 (67.0) [56.7-76.0]	17 (65.4)	42 (67.7)	$\chi^2 = 0.04$	0.842
	Female	29 (33.0) [24.0-43.3]	9 (34.6)	20 (32.3)	-	-
Residence	Rural	51 (58.0) [47.6-67.7]	15 (57.7)	36 (58.1)	$\chi^2 = 0.17$	0.919
	Urban	24 (27.3) [19.0-37.1]	7 (26.9)	17 (27.4)	-	-
	Tribal	13 (14.8) [8.6-23.6]	4 (15.4)	9 (14.5)	-	-
BMI (kg/m ²)	Mean ± SD	23.4 ± 3.9 (-)	23.9 ± 3.6	23.2 ± 4.0	t = 0.82	0.416
Hypertension	Yes	10 (11.4) [6.3-19.5]	3 (11.5)	7 (11.3)	$\chi^2 = 0.00$	0.976
Diabetes	Yes	8 (9.1) [4.5-17.3]	2 (7.7)	6 (9.7)	$\chi^2 = 0.09$	0.762
Tobacco chewing	Yes	73 (83.0) [73.7-89.6]	21 (80.8)	52 (83.9)	$\chi^2 = 0.12$	0.728
Tobacco smoking	Yes	66 (75.0) [64.8-83.1]	18 (69.2)	48 (77.4)	$\chi^2 = 0.72$	0.396
Alcohol use	Yes	20 (22.7) [15.0-32.6]	6 (23.1)	14 (22.6)	$\chi^2 = 0.00$	0.957

The baseline profile of 88 patients revealed a mean age of 49.1 ± 7.2 years, with no significant age difference between premalignant (47.6 ± 7.0 years) and malignant (49.8 ± 7.2 years) groups ($t=1.42$, $p=0.159$). Males predominated overall (67%), with similar distribution in both premalignant (65.4%) and malignant (67.7%) categories ($\chi^2=0.04$, $p=0.842$). Regarding residence, the majority belonged to rural areas (58%), followed by urban (27.3%) and tribal populations (14.8%), without significant intergroup variation ($\chi^2=0.17$, $p=0.919$). The mean BMI was within normal limits (23.4 ± 3.9 kg/m²), comparable across groups ($t=0.82$, $p=0.416$).

Comorbidities were infrequent, with hypertension in 11.4% and diabetes in 9.1%, showing no significant association with lesion type. Addictive habits were strikingly prevalent: tobacco chewing (83%), tobacco smoking (75%), and alcohol use (22.7%). However, none of these habits showed significant statistical differences between premalignant and malignant cases (all $p>0.39$). Thus, the baseline data suggest that the two groups were largely comparable in demographic and lifestyle factors, with tobacco-related exposures being universally high across the study population.

**Table 2: Concordance between clinical and histopathological diagnoses (N = 88)**

Metric	Estimate	95% CI	Test / Notes	p-value
Overall concordance (accuracy)	84.1%	75.2-90.2	vs. chance	-
Cohen's κ	0.68	0.54-0.82	Agreement beyond chance	<0.001
Sensitivity (detecting malignancy)	88.7%	78.5-94.7	TP/(TP+FN)	-
Specificity (ruling out malignancy)	76.9%	57.9-89.0	TN/(TN+FP)	-
PPV	89.8%	80.0-95.1	-	-
NPV	74.3%	55.6-86.9	-	-
McNemar's test	$\chi^2 = 4.00$	-	Discordant pairs	0.045
ROC AUC	0.93	0.88-0.98	Discrimination of "clinically malignant" vs HPE	<0.001

Concordance analysis between clinical impression and histopathological examination demonstrated an overall diagnostic accuracy of 84.1% (95% CI: 75.2-90.2). The Cohen's κ coefficient was 0.68 (95% CI: 0.54-0.82), indicating substantial agreement beyond chance ($p < 0.001$). Sensitivity of clinical diagnosis in detecting malignancy was 88.7% (95% CI: 78.5-94.7), whereas specificity in ruling out malignancy was 76.9% (95% CI: 57.9-89.0). Positive predictive value stood at 89.8% and negative predictive value at 74.3%. McNemar's test

yielded $\chi^2 = 4.00$ ($p = 0.045$), suggesting some discordance in paired comparisons. Receiver Operating Characteristic (ROC) analysis further confirmed excellent diagnostic performance, with an AUC of 0.93 (95% CI: 0.88-0.98, $p < 0.001$). Collectively, these findings highlight that while clinical examination alone performs well in predicting malignant oral lesions, histopathology remains indispensable for definitive diagnosis.

Table 3: Gross & microscopic features of premalignant and malignant oral mucosal lesions (N = 88)

Feature	Category	Total n (%) [95% CI]	Premalignant n=26	Malignant n=62	Test statistic	p-value
Site	Buccal mucosa	55 (62.5) [51.9-72.0]	16 (61.5)	39 (62.9)	$\chi^2 = 0.22$	0.974
	Alveolus	25 (28.4) [20.2-38.4]	7 (26.9)	18 (29.0)	-	-
	Tongue	4 (4.5) [1.8-10.8]	1 (3.8)	3 (4.8)	-	-
	Gingiva	4 (4.5) [1.8-10.8]	2 (7.7)	2 (3.2)	-	-
Lesion size (cm)*	Mean \pm SD	-	1.7 \pm 0.8	3.1 \pm 1.1	t = 6.10	<0.001



Trismus	Present	7 (8.0) [3.9-15.6]	1 (3.8)	6 (9.7)	$\chi^2 = 0.98$	0.322
Submucous fibrosis (OSMF)	Present	8 (9.1) [4.5-17.3]	6 (23.1)	2 (3.2)	$\chi^2 = 8.07$	0.004
Premalignant histology (n=26)	Keratosis-no dysplasia	11 (42.3) [25.5-60.8]	11	-	-	-
	Mild-moderate dysplasia	6 (23.1) [11.1-42.1]	6	-	-	-
	Severe dysplasia/CIS	3 (11.5) [3.5-29.8]	3	-	-	-
	OSMF	6 (23.1) [11.1-42.1]	6	-	-	-
Malignant HPE (n=62)	WD-SCC	48 (77.4) [65.4-86.1]	-	48	-	-
	MD-SCC	9 (14.5) [7.8-25.5]	-	9	-	-
	PD-SCC	5 (8.1) [3.5-17.2]	-	5	-	-

*Lesion size recorded as the dominant dimension; marked difference expected by biology (pre-malignant < malignant).

Assessment of gross and microscopic features revealed that the buccal mucosa was the most frequent site (62.5%), followed by alveolus (28.4%), with fewer cases involving tongue and gingiva (4.5% each). The site distribution did not differ significantly between pre-malignant and malignant lesions ($\chi^2=0.22$, $p=0.974$). However, mean lesion size was significantly greater in malignant cases (3.1 ± 1.1 cm) compared to pre-malignant ones (1.7 ± 0.8 cm), with strong statistical significance ($t=6.10$, $p<0.001$). Trismus was observed in 8% of patients, slightly more in malignant lesions, but without statistical significance ($p=0.322$). Oral submucous fibrosis was present in 9.1% overall, with a significant predominance in pre-malignant lesions (23.1% vs. 3.2%; $\chi^2=8.07$, $p=0.004$). Among pre-malignant lesions, keratosis without dysplasia (42.3%) was most common, followed by mild/moderate dysplasia (23.1%), OSMF (23.1%), and severe dysplasia/CIS (11.5%). In malignant lesions, well-differentiated squamous cell carcinoma predominated (77.4%), with smaller proportions of moderately (14.5%) and poorly differentiated (8.1%) subtypes. These results emphasize that while the anatomical site distribution is similar, lesion size and

histological severity are key discriminators between pre-malignant and malignant groups.

DISCUSSION

Table 1 - Baseline profile (N=88): interpretation with literature: Mean age (49.1 ± 7.2 years) and male predominance (67%) mirror typical Indian head-and-neck cancer demographics, where cases cluster in the 5th-6th decades with a male excess. The Konkan dissertation's own results section reports a very similar mean age (48.6 ± 6.4) and sex split (67% male, 33% female), reinforcing internal consistency. Rural residence dominated (58%), again matching the dissertation's rural>urban>tribal pattern and reflecting both exposure profile and access barriers. Niroula D *et al.* (2023)^[6] Tobacco exposure was ubiquitous (chewing 83%, smoking 75%), with 23% alcohol use-nearly identical to the dissertation's figures-underscoring lifestyle drivers in this geography. Importantly, none of these baseline factors differed significantly between pre-malignant and malignant strata (all $p>0.15$), suggesting that, within this high-risk pool, transitions along the dysplasia→carcinoma continuum are less about baseline demographics and more about lesion biology and



cumulative habit burden. Prior Indian series similarly show buccal-predominant disease in middle-aged men with heavy smokeless tobacco use, while comorbid HTN/DM remain background features rather than discriminators of lesion class. Jain VR *et al.*(2023)^[7]

Table 2 - Clinical vs histopathological concordance: interpretation with literature: Overall accuracy of 84.1% with substantial agreement ($\kappa=0.68$, 95%CI 0.54-0.82) indicates strong alignment between clinical impression and histopathology, yet the significant McNemar test ($p=0.045$) reminds us that discordant pairs do occur-precisely why biopsy remains indispensable. AUC=0.93 (95%CI 0.88-0.98) echoes the dissertation's ROC analysis (AUC \approx 0.928), supporting excellent discrimination of "clinically malignant" calls against the HPE gold standard. Kattak MS *et al.*(2021)^[8] External series quoted in the dissertation report overall clinicopathologic agreement 69-76% across mixed oral lesions (higher for conditions with more stereotyped phenotypes, lower where features overlap), so κ sits at the upper end of published Indian and regional experience. Sensitivity for malignancy (88.7%) coupled with moderate specificity (76.9%) is a common pattern: clinicians deliberately bias toward "rule-in" for suspicious lesions, accepting some false positives to avoid missed cancers. Adhane YB *et al.*(2021)^[9]

Table 3 - Gross & microscopic features: interpretation with literature: Anatomical distribution (buccal mucosa 62.5%, alveolus 28.4%, tongue/gingiva 4-5% each) reproduces the Konkan dissertation's tally and aligns with multiple Indian datasets where buccal mucosa and gingivo-buccal sulcus dominate-consistent with quid placement and chronic irritant pooling. Lesion size cleanly separates groups (pre-malignant 1.7 ± 0.8 cm vs malignant 3.1 ± 1.1 cm; $p<0.001$), reflecting invasive/proliferative biology rather than mere lead-time bias. OSMF (overall 9.1%) was enriched among pre-malignant cases (23.1% vs 3.2%; $p=0.004$), again matching the dissertation's description of OSMF clustering with potentially malignant disorders. On histology, WD-SCC comprised 77% of cancers (MD 14.5%, PD 8.1%), mirroring the dissertation's malignant profile and several Indian hospital series. The lack of significant site-by-type difference ($\chi^2=0.22$, $p=0.974$) suggests that while buccal mucosa is the common "field," progression risk hinges more on histologic grade and size than on location. Kamala KA *et al.*(2025)^[10]

CONCLUSION

The present study highlights the significance of clinico-histopathological correlation in evaluating pre-malignant and malignant oral mucosal lesions in the Konkan region. The findings reaffirm that clinical impression alone, although reasonably accurate, cannot substitute histopathological confirmation, which remains the gold standard for diagnosis. The predominance of lesions in the buccal mucosa, the strong association with tobacco habits, and the high proportion of well-differentiated squamous cell carcinoma reflect the unique sociocultural and lifestyle factors in this population. Importantly, substantial agreement between clinical and histopathological diagnoses underscores the reliability of careful clinical evaluation, but also emphasizes the necessity of routine biopsy to avoid misclassification. Early detection of pre-malignant lesions, coupled with histopathological evaluation, can facilitate timely intervention and potentially reduce the burden of oral cancer in this high-risk region.

LIMITATIONS OF THE STUDY

This study had certain limitations. The sample size, though adequate for preliminary analysis, was relatively small and limited to a single tertiary care center, restricting generalizability to the wider population. As the study was hospital-based, it may not fully represent community prevalence patterns, particularly among individuals who do not seek medical attention. Information on addictive habits was self-reported, which may have introduced recall or reporting bias. Furthermore, advanced diagnostic adjuncts such as immunohistochemistry and molecular markers were not employed, which could have provided deeper insights into lesion biology and malignant potential. A larger, multicentric study with long-term follow-up would better establish the natural progression of pre-malignant lesions and validate the observed patterns.

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