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Evaluation of Oral Cavity Lesions in Tobacco Users - A Cross Sectional Clinicopathological Study

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Abstract: ***Title: Evaluation of oral cavity lesions in tobacco users- A cross sectional clinicopathological study. Aim and objective: The aim of the study is to evaluate the oral cavity changes associated with tobacco usage. Material and method: A total 50 patients with tobacco usage will be enrolled in the study. Suspicious lesions will be stained with toluidine blue, if needed biopsy will be performed for histopathological evaluation. Result: The most common diagnosis was hyperkeratosis with moderate epithelial dysplasia (50%), followed by severe dysplasia (24%). Conclusion: Tobacco usage produces visible and latent alteration in oral mucosa. Suspicious lesions should always be referred for histopathological examination to identify oral potentially malignant disorder and oral cancers, so that prompt treatment could be initiated. Patient's education is important to avoid the use of tobacco in any form.***

Keywords: Oral submucous fibrosis (OSMF); Tobacco; Leukoplakia; Oral mucosal lesions; Oral squamous cell carcinoma (OSCC); Verrucous carcinoma; Precancerous lesions; Epithelial dysplasia.

1. Introduction

Oral cancer remains a major public health challenge in India, ranking first among males and third among females. Its incidence is approximately 20 cases per 100,000 population. Tobacco use contributes significantly to mortality and morbidity, accounting for more than 1.5 million deaths annually. The oral mucosa, composed of keratinized and non-keratinized epithelium, undergoes substantial pathological alterations in response to chronic exposure to tobacco in smoked or smokeless forms.

Depending on the duration, type and frequency of tobacco exposure, epithelial cells exhibit alterations ranging from hyperkeratosis to dysplasia and malignant transformation. India has one of the highest burdens of smokeless tobacco use, contributing to potentially malignant disorders such as oral submucous fibrosis, leukoplakia, erythroplakia and tobacco pouch keratosis. Tobacco-related nitrosamines are potent carcinogens responsible for initiating oral squamous cell carcinoma. The delayed identification of asymptomatic lesions often leads to late-stage diagnosis, further worsening outcomes.

This study aims to evaluate clinicopathological alterations associated with tobacco use and correlate them with usage patterns, duration and type of habit.

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2. Material and Methods

Study Design

The present research was designed as a comparative, prospective, cross-sectional study aimed at evaluating oral cavity lesions among chronic tobacco users.

Study Setting

The study was carried out in the Department of Oral Medicine and Radiology, CSMSS Dental College and Hospital, Chh. Sambhajinagar, which routinely manages patients with deleterious oral habits such as tobacco chewing, smoking, and gutkha consumption.

Study Population

A total of 50 participants with clinically suspected oral mucosal lesions and a history of tobacco use were included. Patients were recruited from the outpatient department within the age range of 20–60 years.

Sampling Technique

A purposive sampling technique was employed. Eligible individuals who fulfilled the inclusion criteria and provided informed consent were enrolled.

Inclusion Criteria

- Male and female patients aged 20 years and above.
- History of tobacco use for a minimum of 12 consecutive months.
- Patients willing to disclose their deleterious habits and provide written informed consent for clinical examination and biopsy when required.

Exclusion Criteria
- Patients below 20 years of age.
- Individuals unwilling to disclose their habit history.
- Patients not consenting to clinical examination or biopsy.
- Patients with systemic conditions known to independently alter salivary function or mucosal health.

Examination Protocol
Each patient underwent a comprehensive evaluation consisting of:
- Case History: Documentation of demographic details, medical and dental history, and detailed tobacco habit history (form, frequency, and duration).
- Extraoral Examination: Assessment of facial symmetry, trismus, lymphadenopathy, and other relevant findings.
- Intraoral Examination: Identification of mucosal lesions such as oral submucous fibrosis (OSMF), leukoplakia, ulcerations, pigmentary changes, and keratotic patches.
- Adjunctive Diagnostic Aids: All patients underwent toluidine blue staining to highlight suspicious areas.
- Biopsy: Incisional biopsies were performed for histopathological confirmation of clinically suspicious lesions.

Ethical Considerations
Ethical approval was obtained from the Institutional Ethical Committee. Informed consent was obtained from each participant after explaining the nature, objectives, and procedures of the study. Confidentiality of patient data was ensured.

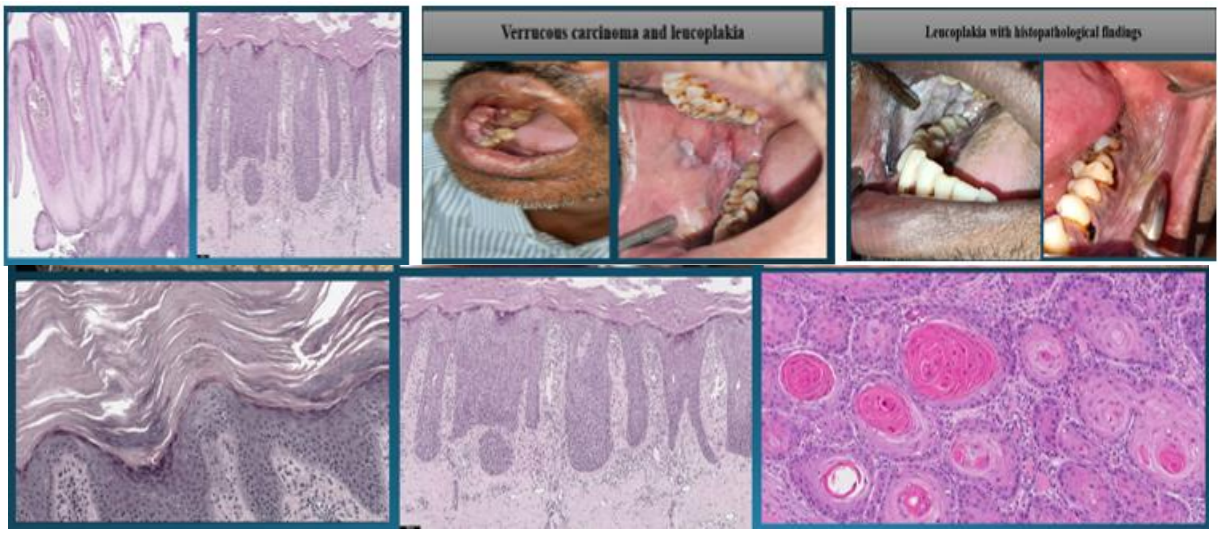
Statistical Analysis
Data were analyzed using SPSS version 21 (SPSS Inc., Chicago, IL, USA).
- Descriptive statistics: Mean ± SD for continuous variables, and frequencies/percentages for categorical variables.
- Inferential statistics: Chi-square test for categorical variables, and unpaired t-test for mean differences.
- Level of significance: $p < 0.05$ with a 95% confidence interval.

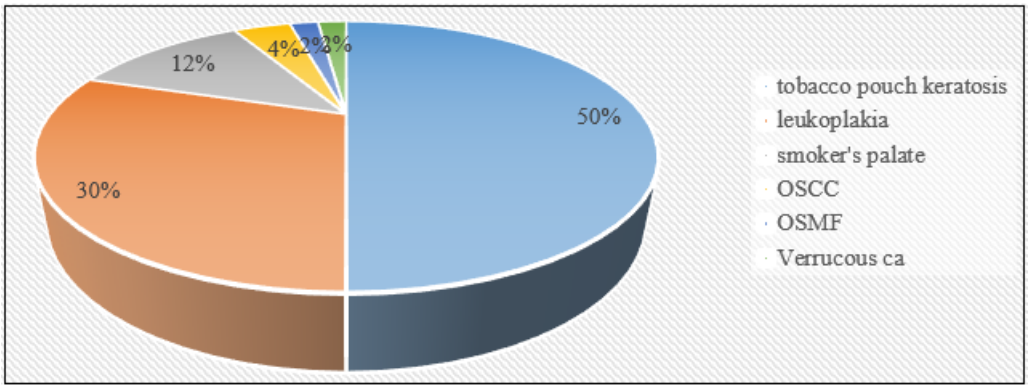
3. Results

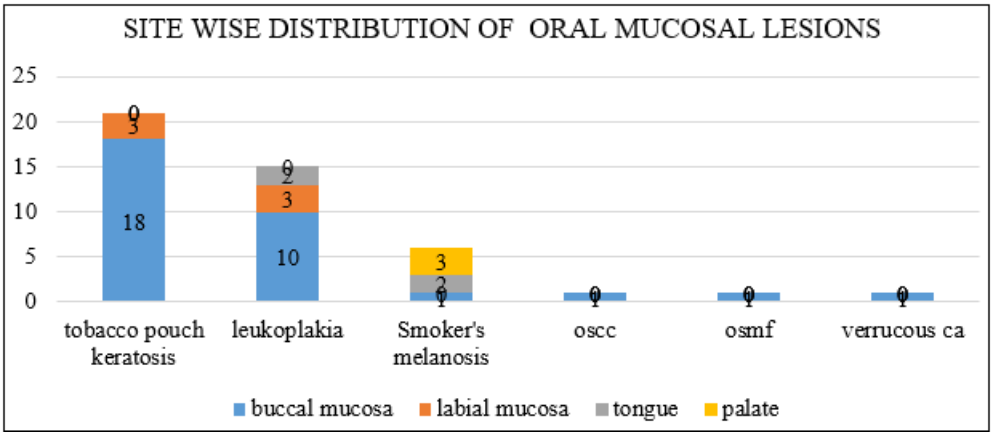
A total of **50 patients** with a history of tobacco use and clinically suspected mucosal lesions were evaluated. All patients underwent toluidine blue staining and biopsy.

Histopathological Findings
1) **Hyperkeratosis with epithelial dysplasia:**
   - Severe dysplasia: **12 cases (24%)**
   - Moderate dysplasia: **25 cases (50%)**
   - Mild dysplasia: **6 cases (12%)**
2) **Oral Submucous Fibrosis (OSMF) with dysplasia:**
   - OSMF with moderate epithelial dysplasia: **2 cases (4%)**
   - OSMF with hyalinized connective tissue and dysplastic epithelium: **2 cases (4%)**
3) **Malignant lesions:**
   - Superficially invasive oral squamous cell carcinoma (OSCC) with keratin pearl formation: **2 cases (4%)**
   - Verrucous carcinoma: **1 case (2%)**

Prevalence Patterns
- The **most common diagnosis** was **hyperkeratosis with moderate epithelial dysplasia (50%)**, followed by **severe dysplasia (24%)**.
- Potentially malignant disorders (PMDs) such as OSMF and leukoplakia accounted for **32% of cases**, while frank malignancies (OSCC and verrucous carcinoma) were found in **6% of patients**.
- Lesion prevalence was strongly associated with the chronicity and type of tobacco habit, with smokeless forms (gutkha, betel quid with tobacco) showing a higher correlation with OSMF and keratotic lesions.







4. Discussion

The present study investigated oral mucosal lesions among chronic tobacco users and revealed a high prevalence of potentially malignant disorders (PMDs) such as leukoplakia and oral submucous fibrosis (OSMF), as well as frank malignancies including oral squamous cell carcinoma (OSCC) and verrucous carcinoma. Among all participants, hyperkeratosis with epithelial dysplasia emerged as the most common histopathological finding, with moderate-to-severe grades of dysplasia observed in nearly three-fourths of patients.

The predominance of **hyperkeratotic lesions with epithelial dysplasia** aligns with earlier studies. Reddy et al. (2015) reported that leukoplakia accounted for the majority of lesions among chewing tobacco users, while Kumbhalwar et al. (2022), in a systematic review, confirmed that keratotic lesions and OSMF are the most prevalent PMDs in the Indian population. The high proportion of dysplasia in this study (74%) underscores the malignant potential of such lesions, consistent with the observations of Mirbod and Ahing (2000), who emphasized that epithelial dysplasia is the most important predictor of malignant transformation.

The presence of **OSMF with dysplasia** in 8% of cases corroborates findings from Pindborg et al. (1980) and Murti et al. (1995), who demonstrated that areca nut and gutkha chewing are major etiological factors in the pathogenesis of OSMF. Our results also mirror the study by Harini et al. (2022), which found that taste alteration, salivary dysfunction, and epithelial atrophy often accompany OSMF, thereby increasing susceptibility to malignant change.

Importantly, **malignant lesions** (OSCC and verrucous carcinoma) were identified in 6% of patients. This finding, though small, is significant because it reflects the malignant continuum of tobacco-associated lesions. Similar transformation rates have been highlighted in studies by Gupta et al. (2019) and Tamgadge et al. (2020), who noted that long-standing leukoplakias and OSMF cases exhibit a considerable risk of malignant change over time.

The type and duration of tobacco habit appeared to influence lesion type. Smokeless tobacco (gutkha, betel quid with tobacco) was more often associated with **OSMF and keratotic changes**, whereas smoking was more frequently linked to **hyperkeratosis and dysplastic changes**. This is in agreement with epidemiological surveys in India, which show that smokeless forms have a stronger association with OSMF, while smoked forms are more likely to cause leukoplakia and carcinoma (Rani et al., 2003; Preeti & Raut, 2012).

In this study, **toluidine blue staining** was used as an adjunctive diagnostic tool before biopsy. The dye was effective in highlighting suspicious lesions, consistent with Birur et al. (2018), who validated its role in early detection of PMDs and OSCC. While not a substitute for histopathology, toluidine blue remains a valuable chairside aid in community and clinical screening programs, particularly in resource-limited settings.

5. Clinical Implications

- Early detection of dysplastic lesions offers an opportunity for preventive interventions.

- Regular oral examinations, especially among high-risk groups, should be incorporated into public health programs.
- Habit cessation counseling must be prioritized to reduce disease progression and malignant transformation risk.

6. Conclusion

The study revealed a high frequency of oral mucosal lesions among tobacco users, with the majority exhibiting moderate-to-severe epithelial dysplasia. Potentially malignant disorders such as leukoplakia and OSMF were highly prevalent, while invasive carcinomas were also identified in a small but significant proportion of patients. These findings emphasize the urgent need for early detection, routine biopsy of suspicious lesions, and robust cessation programs to mitigate the burden of oral cancer.

7. Future Perspectives

1) Community Screening: Expansion of chairside screening methods (toluidine blue, brush cytology, autofluorescence) in community and primary health settings.
2) Longitudinal Studies: Long-term follow-up of dysplastic lesions to better quantify rates of malignant transformation.
3) Molecular Research: Exploration of salivary, genetic, and epigenetic biomarkers for predicting malignant potential.
4) Integrated Care Models: Collaboration between dentists, oncologists, and public health professionals for comprehensive prevention and management.
5) Tobacco Control: Stronger legislative measures, taxation, and education campaigns targeting smokeless and smoked tobacco users.
6) Patient Awareness: Continuous educational efforts to improve awareness regarding early symptoms and the necessity of routine oral check-ups.

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Conflict of interest:
The authors declare no conflict of interest related to this study.

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