Burden and Epidemiological Profile of Oral Potentially Malignant Disorders in India: A Systematic Review and Meta-Analysis

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Abstract:
Background: Oral potentially malignant disorders (OPMDs) are a group of oral mucosal conditions with an increased risk of progression to oral squamous cell carcinoma (OSCC). India carries one of the highest global burdens of oral cancer, largely due to the widespread use of smokeless tobacco, areca nut, and smoking products. Although several epidemiological studies on OPMDs have been conducted across different regions of India, the true national burden remains unclear because of variations in study design, sample size, and population characteristics. A comprehensive synthesis of the available evidence is therefore essential to understand the epidemiological profile of OPMDs in India. **Objective:** To estimate the pooled prevalence of major oral potentially malignant disorders in India and describe their epidemiological distribution through systematic review and meta-analysis. **Methods:** A systematic literature search was conducted in PubMed, EMBASE, Web of Science, IndMED, Google Scholar, WHO South-East Asia reports, MOHFW India publications, Science Citation Index, WHO Index Medicus, Reference Citation Analysis, and OpenGrey from inception. Observational studies reporting prevalence data on OPMDs in Indian populations were included. Study quality was assessed using standardized tools. Random-effects meta-analysis was used to calculate pooled prevalence estimates with 95% confidence intervals (CI). Subgroup analyses were performed based on study setting and type of lesion. **Results:** A total of **eligible studies** providing **162 prevalence estimates** and including **823,845 participants** met the inclusion criteria. Of these, 52 were of high quality, 71 of moderate quality, and 7 of low quality. Among community-based studies, pooled prevalence was **4.3%** for leukoplakia, **2.7%** for oral submucous fibrosis, **5.8%** for palatal lesions/nicotine stomatitis, **1.2%** for erythroplakia, and **1.1%** for oral lichen planus. Hospital-based studies showed higher prevalence, particularly for leukoplakia (6.7%), oral submucous fibrosis (4.5%), lichen planus (7.5%), erythroplakia (2.5%), and palatal lesions (11.5%). Tobacco use, areca nut chewing, male gender, diabetes, and low body mass index were consistently associated with increased risk. **Conclusion:** OPMDs pose a major public health burden in India. Early detection, habit cessation, and community-based screening are essential to reduce malignant transformation and oral cancer incidence.

Keywords: Oral potentially malignant disorders; Prevalence; Epidemiology; Systematic review; Meta-analysis; India

1. Introduction

Oral cancer is a major global health challenge and represents one of the leading causes of cancer-related morbidity and mortality in low- and middle-income countries. South and South-East Asia contribute a disproportionately high share of the global oral cancer burden, with India accounting for a substantial proportion of cases[1]. The high incidence in India is closely linked to the widespread use of smokeless tobacco, areca nut preparations, smoking products, and alcohol, which are deeply embedded in social and cultural practices. Despite advances in diagnosis and treatment, most patients continue to present at advanced stages, leading to poor survival rates, increased treatment costs, and reduced quality of life[2].

Oral potentially malignant disorders (OPMDs) are a group of clinically recognizable mucosal alterations that carry a risk of malignant transformation into oral squamous cell carcinoma (OSCC). The concept of OPMDs was introduced to emphasize the dynamic nature of these lesions and their potential to progress to cancer over time. Commonly reported OPMDs in India include leukoplakia, erythroplakia, oral submucous fibrosis (OSMF), oral lichen planus, and palatal lesions related to reverse smoking and nicotine stomatitis. The rate of malignant transformation varies across these conditions, but all require early detection and long-term surveillance[2,3].

India's large population, diverse cultural habits, and uneven access to healthcare have resulted in considerable geographic and demographic variation in the occurrence of OPMDs. While numerous epidemiological studies have been conducted in community and hospital settings, most are limited by small sample sizes, regional focus, and inconsistent diagnostic criteria. Consequently, the true magnitude and distribution of OPMDs at the national level remain uncertain.

A comprehensive synthesis of available evidence is essential to bridge this knowledge gap. By pooling data from multiple studies and analyzing epidemiological patterns, a systematic review and meta-analysis can provide robust national estimates. Such evidence is critical for guiding public health policy, strengthening early screening programs, and designing targeted tobacco and areca nut cessation strategies aimed at reducing the future burden of oral cancer in India[4,5].

2. Objectives

The present systematic review and meta-analysis was undertaken to generate comprehensive national-level evidence on oral potentially malignant disorders (OPMDs) in India. The specific objectives were:

- **To determine the pooled national prevalence of major oral potentially malignant disorders in India** by synthesizing data from community-based and hospital-based epidemiological studies, thereby providing a reliable estimate of the overall burden of OPMDs across diverse populations and regions.
- **To compare the prevalence patterns between community-based and hospital-based settings**- in order to assess differences in disease detection, severity, and healthcare-seeking behavior, and to highlight potential gaps in early diagnosis and access to care.
- **To explore and summarize the key demographic, behavioral, and clinical risk factors associated with OPMDs**- including tobacco use, areca nut consumption, gender, metabolic conditions, and nutritional status, to better understand high-risk groups and inform targeted prevention strategies.

3. Materials and Methods

3.1 Study Design and Reporting Framework

This systematic review and meta-analysis was conducted to synthesize epidemiological evidence on oral potentially malignant disorders (OPMDs) in India. The methodology followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines to ensure transparency, reproducibility, and methodological rigor. A predefined protocol was developed outlining the objectives, eligibility criteria, search strategy, data extraction, and statistical analysis methods.

3.2 Data Sources and Search Strategy

A comprehensive and systematic literature search was carried out across multiple electronic databases and grey literature sources to identify relevant studies. The databases searched included PubMed, EMBASE, Web of Science, IndMED, Google Scholar, Science Citation Index, WHO Index Medicus, Reference Citation Analysis, and OpenGrey. In addition, official reports and documents from the World Health Organization (WHO) South-East Asia Regional Office and the Ministry of Health and Family Welfare (MOHFW), Government of India, were screened to capture unpublished or government-supported epidemiological data.

The search strategy combined controlled vocabulary terms (MeSH and EMTREE) and free-text keywords related to oral potentially malignant disorders and India. Key terms included: *"oral potentially malignant disorders," "leukoplakia," "oral submucous fibrosis," "erythroplakia," "oral lichen planus," "nicotine stomatitis," "palatal lesions," "prevalence," "epidemiology,"* and *"India."* Boolean operators (AND/OR) were used to refine the search, and reference lists of relevant articles were manually screened to identify additional studies.

3.3 Eligibility Criteria

Inclusion Criteria

- Observational studies (cross-sectional, cohort, or baseline data from surveys)
- Conducted in India
- Reported prevalence data for at least one OPMD
- Included adult or mixed-age populations
- Published in English

Exclusion Criteria

- Case reports, case series, reviews, editorials, and conference abstracts
- Studies without prevalence data
- Duplicate publications
- Studies on oral cancer without specific OPMD data

3.4 Study Selection

Two independent reviewers screened titles and abstracts for relevance. Full-text articles of potentially eligible studies were then assessed against the inclusion criteria. Discrepancies were resolved through discussion or consultation with a third reviewer.

3.5 Data Extraction

A standardized data extraction form was used to collect information on author, year, study location, study design, sample size, age group, type of OPMD, prevalence estimates, diagnostic criteria, and reported risk factors.

3.6 Quality Assessment

The methodological quality of included studies was assessed using standardized critical appraisal tools for observational studies. Each study was categorized as high, moderate, or low quality based on risk of bias, sampling method, diagnostic clarity, and statistical reporting.

4. Results

4.1 Study Selection and Characteristics

The literature search identified a large number of studies from multiple databases and grey literature sources. After removing duplicates and screening titles and abstracts, full-text articles were evaluated. A total of **162 prevalence estimates from 130 eligible studies**, including **823,845 participants**, were included in the meta-analysis.

The studies spanned diverse regions of India and comprised both community-based surveys and hospital-based clinical investigations. Sample sizes varied widely, from

localized community screenings to large population-based studies. This variation highlights the heterogeneous nature of OPMD research in India.

4.2 Quality Assessment of Included Studies

Study quality was assessed using standardized methodological tools. The distribution of studies according to quality is presented in **Table 1**.

Table 1. Study Quality Distribution

Quality	Number of Studies
High	52
Moderate	71
Low	7

- High-quality studies employed representative sampling, clear diagnostic criteria, and robust reporting of prevalence data.
- Moderate-quality studies often lacked randomization, had smaller sample sizes, or incomplete risk factor assessment.
- Low-quality studies were limited by poor diagnostic descriptions or insufficient sample sizes.

4.3 Pooled Prevalence in Community-Based Studies

Community-based surveys provide insights into the true prevalence of OPMDs in the general population. The pooled prevalence estimates are shown in **Table 2**.

Table 2. Pooled Prevalence of OPMDs in Community-Based Studies

Disorder	Prevalence (%)	95% CI
Leukoplakia	4.3	4.0–4.6
Oral Submucous Fibrosis (OSMF)	2.7	2.5–3.0
Palatal lesions/nicotine stomatitis	5.8	4.4–7.2
Erythroplakia	1.2	0.7–1.7
Oral Lichen Planus	1.1	0.9–1.2

- **Leukoplakia** was the most frequently reported lesion, indicating high prevalence of tobacco-associated epithelial changes.

- **Palatal lesions (5.8%)**, largely due to reverse smoking, were particularly common in certain regions.
- **OSMF (2.7%)** reflects habitual areca nut and gutkha consumption.
- **Erythroplakia and oral lichen planus**, while less prevalent, are clinically significant due to high malignant transformation potential.

4.4 Pooled Prevalence in Hospital-Based Studies

Hospital-based studies consistently reported higher prevalence of OPMDs **(Table 3),** likely because symptomatic or high-risk individuals seek care in clinical settings.

Table 3. Pooled Prevalence of OPMDs in Hospital-Based Studies

Disorder	Prevalence (%)	95% CI
Leukoplakia	6.7	6.0–7.3
Oral Submucous Fibrosis (OSMF)	4.5	4.2–4.9
Oral Lichen Planus	7.5	5.3–9.6
Erythroplakia	2.5	0.4–4.5
Palatal lesions/nicotine stomatitis	11.5	8.0–15.0

- The higher prevalence in clinical settings suggests that many OPMDs remain undetected in the community until they cause symptoms.
- **Palatal lesions and oral lichen planus** were notably elevated in hospitals, highlighting the need for targeted screening in high-risk groups.

4.5 Major Risk Factors Associated with OPMDs

Analysis across included studies identified consistent risk factors contributing to OPMD development, summarized in **Table 4**.

Table 4. Major Risk Factors for OPMDs

Risk Factor	Association
Tobacco use	Strong
Areca nut chewing	Strong
Male gender	Higher risk
Diabetes	Increased risk
Low BMI	Increased risk
Alcohol	Contributory

- **Tobacco and areca nut consumption** were the strongest contributors to all major OPMDs.
- **Male gender** reflects higher prevalence of harmful habits among men.
- **Metabolic conditions (diabetes, low BMI)** may impair mucosal integrity, facilitating lesion development.
- **Alcohol** acts synergistically with tobacco and areca nut to increase risk.

5. Discussion

The present meta-analysis highlights that **oral potentially malignant disorders (OPMDs) are highly prevalent throughout India**, representing a critical and persistent public health challenge. The findings underscore that **tobacco and areca nut consumption are the dominant etiological factors**, with habitual exposure leading to chronic irritation of the oral mucosa, epithelial dysplasia, and cumulative genetic and epigenetic changes that substantially elevate the risk of malignant transformation into oral squamous cell carcinoma (OSCC). The data also reveal a **striking difference between community-based and hospital-based prevalence rates**, with hospital studies consistently reporting higher frequencies of OPMDs. This disparity suggests that a large proportion of lesions remain **undiagnosed or underreported in the general population**, only coming to clinical attention when symptomatic, which delays intervention and allows progression toward malignancy. Such findings emphasize the **need for structured, community-focused screening strategies** to identify lesions at an early stage, particularly in high-risk populations.

Among the various OPMDs, **leukoplakia and oral submucous fibrosis (OSMF) were the most frequently observed lesions**, reflecting the widespread and habitual use of smokeless tobacco products and areca nut in multiple forms, such as gutkha, betel quid, and pan masala? Additionally, the elevated prevalence of **palatal lesions in reverse smokers and erythroplakia** underscores the influence of region-specific practices and cultural behaviors on disease distribution. Importantly, the analysis also identified **systemic factors**, such as diabetes and low body mass index, as significant contributors to OPMD risk, suggesting that metabolic and nutritional status may modulate mucosal susceptibility to injury and dysplasia.

These findings have several important implications. Firstly, they highlight the **urgent need for public health policies** aimed at reducing tobacco and areca nut consumption, promoting awareness of early oral lesions, and providing accessible oral healthcare services in both urban and rural populations. Secondly, the observed differences between hospital- and community-based prevalence indicate that **opportunistic screening alone is insufficient**, and systematic, region-specific screening programs could significantly improve early detection. Finally, the integration of lifestyle interventions, nutritional

counseling, and management of systemic conditions alongside routine oral examinations may offer a **comprehensive preventive approach**, potentially reducing the incidence of OSCC. Overall, this meta-analysis provides compelling evidence that while OPMDs are highly prevalent and pose a substantial burden, they are largely preventable, and early detection coupled with targeted public health strategies can markedly reduce progression to oral cancer in India.

6. Public Health Implications

The high prevalence of oral potentially malignant disorders (OPMDs) in India presents a significant public health challenge. Effective prevention, early detection, and intervention strategies are essential to reduce progression to oral squamous cell carcinoma (OSCC). The following approaches, organized under specific subheadings, highlight key strategies:

6.1 Opportunistic Dental Screening

Dentists and other oral healthcare professionals play a pivotal role in the **early identification of OPMDs**. Opportunistic screening involves examining patients during routine dental visits for any oral mucosal changes, such as leukoplakia, erythroplakia, or submucous fibrosis. Early detection can lead to **timely referrals, interventions, and monitoring**, significantly reducing malignant transformation risk.

Implementation Strategies:

a. Standardized oral visual examination (OVE) protocols during check-ups.
b. Risk assessment questionnaires to identify tobacco, areca nut, or alcohol users.
c. Training programs for dentists and primary care providers on lesion recognition, referral pathways, and documentation.

Evidence Base:

Studies from India and other South Asian countries indicate that opportunistic screening is feasible, cost-effective, and can identify early-stage lesions that might otherwise go unnoticed.

6.2 Tobacco and Areca Nut Cessation Programs

Tobacco and areca nut use are the most important modifiable risk factors for OPMDs in India. Targeted cessation programs can dramatically reduce disease burden.

Key Interventions:

a. Behavioral counseling and motivational interviewing.
b. Nicotine replacement therapy or pharmacological interventions where appropriate.

c. Community campaigns emphasizing the risk of oral cancer associated with smokeless tobacco, betel quid, gutkha, and pan masala.

Policy Implications:

a. Strengthening regulations on advertising and sale of smokeless tobacco products.
b. Introducing taxation strategies to reduce affordability and accessibility.
c. School-based prevention programs targeting adolescents, a vulnerable population.

6.3 Rural and Community-Based Outreach

Rural areas, where more than 70% of India's population resides, often lack access to dental care and preventive screening. Community outreach programs are critical to address **geographic and socio-economic disparities** in oral health.

Practical Approaches:

a. Mobile dental clinics and periodic health camps in remote villages.
b. Collaboration with primary health centers, self-help groups, and local schools.
c. Training community health workers in early recognition of oral lesions and referral mechanisms.

Expected Outcomes:

a. Increased early detection of OPMDs.
b. Improved awareness of risk factors and preventive behaviors.
c. Reduced disease progression in underserved populations.

6.4 Health Education and Awareness Campaigns

Public knowledge of OPMDs and their link to oral cancer remains low. Education initiatives can empower individuals to **seek early care and adopt preventive measures**.

Strategies:

a) Mass media campaigns using television, radio, and social media.
b) Integration of oral health education into school curricula and workplace wellness programs.
c) Community workshops to demonstrate oral self-examination techniques and healthy lifestyle practices.

6.5 Integration with National Health Policies

A coordinated national framework is needed to address OPMDs systematically.

Recommendations:

a. Include opportunistic oral screening in primary healthcare programs.
b. Develop registries for OPMDs to monitor prevalence and outcomes.
c. Integrate habit cessation programs with other non-communicable disease interventions, such as diabetes and obesity management, as these were also found to increase OPMD risk

7. Limitations

While this systematic review and meta-analysis provides a comprehensive overview of oral potentially malignant disorders (OPMDs) in India, several limitations must be considered to contextualize the findings:

7.1 Heterogeneity among Studies

One of the major limitations is the **high heterogeneity observed across included studies**. Variations in study design, sample size, geographic location, and diagnostic criteria for OPMDs contributed to inconsistencies in prevalence estimates. Some studies used clinical examination alone, while others included histopathological confirmation, which may affect accuracy. Additionally, differences in age distribution, gender representation, and inclusion criteria across studies may have influenced pooled prevalence rates. This heterogeneity highlights the challenge of generalizing results to the entire Indian population.

7.2 Under-Reporting and Publication Bias

Under-reporting of OPMDs, particularly in rural and underserved populations, is another significant limitation. Many individuals with OPMDs may not seek clinical attention due to lack of awareness, financial constraints, or geographic barriers, leading to **underestimation of true prevalence**. Furthermore, hospital-based studies likely over represent symptomatic patients, while community-based surveys may miss subclinical lesions. Publication bias is also possible, as studies with significant findings are more likely to be published, potentially skewing pooled estimates.

7.3 Limited Molecular and Etiological Data

Although epidemiological data provide valuable prevalence estimates, **molecular insights into the pathogenesis of OPMDs remain limited**. Few studies have evaluated genetic, epigenetic, or molecular markers associated with malignant transformation. Understanding the molecular mechanisms underlying OPMD progression is crucial for risk stratification, early diagnosis, and personalized

interventions. Similarly, lifestyle, dietary, and metabolic risk factors were inconsistently reported across studies, limiting the ability to perform robust subgroup analyses.

7.4 Regional and Cultural Variability

The diversity of cultural habits, such as type of smokeless tobacco, areca nut preparation, and reverse smoking practices, varies widely across Indian states. Some regions are underrepresented in the literature due to lack of local studies or cancer registries, which may affect the **national representativeness of findings**.

7.5 Need for Longitudinal Data

Most included studies were cross-sectional in nature, providing a snapshot of prevalence rather than incidence or progression over time. **Longitudinal studies** are needed to evaluate the natural history of OPMDs, rates of malignant transformation, and the impact of interventions on disease outcomes

8. Conclusion

Oral potentially malignant disorders (OPMDs) represent a major and growing public health challenge in India, largely driven by the widespread use of tobacco, areca nut, and alcohol, along with limited access to early diagnostic services. This systematic review and meta-analysis demonstrates that OPMDs are highly prevalent nationwide, with leukoplakia, oral submucous fibrosis (OSMF), palatal lesions related to reverse smoking, erythroplakia, and oral lichen planus being the most commonly reported conditions. The consistently higher prevalence observed in hospital-based studies compared to community-based surveys highlights delayed diagnosis and missed opportunities for early detection.

Strong associations with modifiable risk factors such as tobacco and areca nut use, as well as demographic and systemic factors including male gender, diabetes, and low body mass index, underscore the need for targeted preventive strategies. Early detection through routine oral examinations, opportunistic dental screening, and community outreach programs can significantly reduce malignant transformation to oral squamous cell carcinoma.

Integrating OPMD screening and habit cessation initiatives into existing public health frameworks, particularly in rural and underserved areas, is essential to reduce the oral cancer burden and improve population oral health outcomes in India.

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