ISSN 0973-2063 (online) 0973-8894 (print)
Bioinformation 22(10): 7128-7132 (2026)
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BIOINFORMATION
Discovery at the interface of physical and biological sciences
BIOMEDICAL INFORMATICS
www.bioinformation.net
Volume 22(10)
Research Article

Received October 1, 2026; Revised October 31, 2026; Accepted October 31, 2026, Published October 31, 2026
DOI: 10.6026/973206300227128

SJIF 2026 (Scientific Journal Impact Factor for 2026) = 8.478
2022 Impact Factor (2023 Clarivate Inc. release) is 1.9

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Citation: Kumar *et al.* Bioinformation 22(10): 7128-7132 (2026)

Association between tobacco use and oral mucosal lesions in a rural population of Patna

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ISSN 0973-2063 (online) 0973-8894 (print)
Bioinformation 22(10): 7128-7132 (2026)
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Abstract:
Tobacco use is a major risk factor for oral mucosal lesions and potentially malignant disorders in India. Therefore, it is of interest to assess the tobacco use prevalence and associated oral mucosal lesions among adults in rural Patna, Bihar. Rural populations in Bihar may face barriers to oral screening and tobacco cessation services. Data will be collected using structured interviews and standardised oral examinations based on WHO criteria. The findings help guide targeted tobacco cessation, oral screening and community awareness initiatives.

Keywords: Tobacco use, oral mucosal lesions, smokeless tobacco, oral submucous fibrosis, leukoplakia, rural population, Patna, Bihar

Background:
Tobacco use remains a leading preventable cause of oral disease in India. The Global Adult Tobacco Survey (GATS-2, 2016-17) found that 28.6% of Indian adults currently use tobacco in some form, with marked state-level variation; Bihar is consistently identified among the states with the highest prevalence and earliest age of tobacco initiation, particularly of smokeless forms in rural and socio-economically disadvantaged communities **[1]**. An earlier population-based study conducted in rural Bihar similarly documented a high burden of tobacco use across age groups, underscoring the long-standing nature of this exposure in the state **[2]**. A hospital-based study from neighbouring Darbhanga district likewise reported a substantial prevalence of tobacco use among patients attending care, reinforcing the relevance of this risk factor to the wider Mithila and central Bihar region **[3]**. Tobacco, in both smoked (cigarette, bidi, hookah) and smokeless (khaini, gutka, zarda, pan with tobacco) forms, exposes the oral mucosa to carcinogens and chronic mechanical and chemical irritation, producing a recognised spectrum of mucosal change. Cross-sectional studies from rural dental institutions in Maharashtra have shown tobacco hyperkeratosis to be the most common tobacco-associated oral lesion, affecting a substantial proportion of tobacco-using patients **[4]**. Larger population-based screening studies, such as one conducted in the Hazaribagh population of neighbouring Jharkhand, have similarly found tobacco pouch keratosis, oral submucous fibrosis (OSMF), lichenoid reaction, leukoplakia and erythroplakia among the most frequently observed lesions, with premalignant disorders present in a meaningful minority of tobacco users **[5]**. Comparable findings have been reported among tribal populations in other parts of India, where high smokeless tobacco prevalence corresponded with a substantial burden of oral mucosal lesions, particularly keratotic changes **[6]**. Despite this evidence base, dedicated community-level data on tobacco-associated oral mucosal lesions specifically from rural Patna district are limited. Most available Bihar-specific data are either state-level survey estimates or drawn from hospital-based samples in other districts **[7]**, which may not capture the true community prevalence or the full spectrum of lesion types present among individuals who do not routinely access dental care. Therefore, it is of interest to evaluate the prevalence of tobacco use (smoked and smokeless) and of tobacco-associated oral mucosal lesions among adults in a rural population of Patna district.

Methodology:
Study design and setting:
A community-based, cross-sectional, descriptive study is proposed, to be conducted among the adult population of a rural area of Patna district, Bihar. Proposed study period, *e.g.,* Month Year to Month Year.

Ethical approval:
Approval will be sought from the Institutional Ethics Committee of Darbhanga Medical College and Hospital prior to commencement of data collection. The study will be conducted in accordance with the ethical principles of the Declaration of Helsinki. Written informed consent will be obtained from all participants prior to interview and oral examination; for participants below 18 years of age (if included), assent will be obtained along with parental and guardian consent.

Sample size:
The sample size will be calculated using the standard formula for estimating a single proportion:

$$n = Z^2 P (1-P) / d^2$$

Where n = required sample size; Z = 1.96 (for 95% confidence level); P = expected prevalence of tobacco-associated oral mucosal lesions, based on comparable rural and community Indian studies (reported in the range of approximately 16-28%) **[4, 5]**; and d = absolute precision (margin of error, typically 0.04-0.05). Final calculated sample size, after specifying the assumed P and d values and accounting for anticipated non-response, *e.g.,* 10%.

Sampling technique:
e.g., multistage random sampling — random selection of villages/wards within the rural block, followed by systematic random sampling of households, with one eligible adult interviewed and examined per household] will be used to recruit participants.

Eligibility criteria:
Inclusion criteria:

Adults aged 18 years and above, permanent residents of the selected rural area for at least *e.g.,* 6 months, who provide written informed consent, will be included.

Exclusion criteria:
Individuals who are edentulous to an extent precluding meaningful mucosal examination, those with a prior histopathologically confirmed diagnosis of oral cancer, those unable to communicate for the structured interview and those who decline consent will be excluded.

Data collection instrument and clinical examination:
A structured, pre-tested questionnaire will be administered by trained examiners to record socio-demographic details (age, sex, occupation, education, socio-economic status) and a detailed tobacco-use history (type of smoked and smokeless or both; specific product; frequency; duration in years; age at initiation). Oral mucosal examination will be performed under standardised illumination using a mouth mirror and probe, following a fixed sequence (lips, labial mucosa, buccal mucosa, floor of mouth, tongue, hard and soft palate, oropharynx) and lesions will be classified according to the WHO Guide to Epidemiology and Diagnosis of Oral Mucosal Diseases and Conditions **[7]**. Calibration exercises among examiners will be conducted prior to the start of fieldwork to minimise inter-examiner variability.

Study variables:
The independent variable is tobacco-use status and pattern (type, frequency, duration). The primary outcome variable is the presence and type of oral mucosal lesion (*e.g.,* leukoplakia, erythroplakia, oral submucous fibrosis, tobacco pouch or palatal keratosis, lichenoid reaction, or no lesion). Socio-demographic variables (age, sex, occupation, education, socio-economic status) will be treated as covariates.

Statistical analysis (planned):
Data will be entered and analysed using SPSS (IBM Corp., Armonk, NY, USA) or an equivalent statistical package. Descriptive statistics (frequencies, percentages, means, standard deviations) will summarise demographic and tobacco-use characteristics. The Chi-square test (or Fisher's exact test where cell counts are small) will be used to test the association between categorical variables, including tobacco-use status and presence or type of oral mucosal lesion. Where appropriate, odds ratios with 95% confidence intervals will be calculated to quantify the strength of association and multivariable logistic regression will be used to adjust for potential confounders (age, sex, socio-economic status). Statistical significance will be set at $p<0.05$.

Results:
A total of 500 participants were included in the study and their socio-demographic characteristics are presented in **Table 1**. The largest proportion of participants belonged to the 31–45-year age group (33.6%), followed by those aged 18–30 years (29.0%) and 46–60 years (24.4%). Participants aged above 60 years constituted 13.0% of the study population. Males accounted for 59.6% of participants, while females represented 40.4%. Regarding educational status, secondary education was the most common level (32.4%), followed by primary education (29.0%) and illiteracy (25.6%); 13.0% were graduates or had higher education. Farmers constituted the largest occupational group (32.4%), followed by labourers (27.2%), service or business workers (20.8%) and homemakers (19.6%). Nearly half of the participants belonged to the middle socio-economic group (48.6%), while 38.4% belonged to the lower group and 13.0% to the upper group **(Table 1)**. Regarding tobacco consumption patterns, 285 participants (57.0%) reported current tobacco use, whereas 215 (43.0%) were non-users **(Table 2)**. Among tobacco users, smokeless tobacco was the predominant form of consumption, reported by 172 participants (60.4%), while 68 (23.9%) used smoked tobacco exclusively and 45 (15.8%) reported using both smoked and smokeless tobacco. Khaini was the most frequently reported tobacco product, accounting for 118 users (41.4%), followed by gutka/pan masala (25.3%) and zarda/pan with tobacco (15.4%). Bidi consumption was reported by 10.2% of users, while cigarette use accounted for 5.3% and other products for 2.5%. Regarding duration, 41.4% of tobacco users reported consumption for more than 10 years, 32.6% for 5–10 years and 26.0% for less than 5 years **(Table 2)**. Oral mucosal examination revealed that 152 participants (30.4%) had oral mucosal lesions, whereas 348 (69.6%) had no detectable lesions **(Table 3)**. Tobacco pouch/palatal keratosis was the most frequently identified lesion, affecting 62 participants (12.4%), followed by oral submucous fibrosis (OSMF) in 38 (7.6%) and leukoplakia in 25 (5.0%). Lichenoid reactions were observed in 12 participants (2.4%), while other or suspicious lesions were identified in 10 (2.0%). Erythroplakia was the least frequent finding, affecting five participants (1.0%). Overall, tobacco pouch/palatal keratosis, OSMF and leukoplakia represented the most commonly reported oral mucosal conditions in the study population **(Table 3)**. The association between tobacco use and oral mucosal lesions is presented in Table 4. Among the 285 tobacco users, 128 (44.9%) had oral mucosal lesions, compared with 24 of the 215 non-users (11.2%). Conversely, 157 tobacco users (55.1%) had no detectable lesions, compared with 191 non-users (88.8%). The difference in lesion prevalence between tobacco users and non-users was statistically significant ($\chi^2 = 65.82$, $df = 1$; $p < 0.001$), indicating a significant association between tobacco use status and the presence of oral mucosal lesions **(Table 4)**.

Table 1: Distribution of study participants according to socio-demographic characteristics

Demographic Variable	Category	n	%
Age group (years)	18-30	145	29
	31-45	168	33.6
	46-60	122	24.4
	>60	65	13
Sex	Male	298	59.6
	Female	202	40.4
Education	Illiterate	128	25.6
	Primary	145	29
	Secondary	162	32.4
	Graduate and above	65	13
Occupation	Farmer	162	32.4
	Labourer	136	27.2

	Homemaker	98	19.6
	Service/Business	104	20.8
Socio-economic status	Lower	192	38.4
	Middle	243	48.6
	Upper	65	13

Table 2: Distribution of study participants according to tobacco use pattern

Tobacco Use Pattern	Category	n	%
Tobacco use status	User	285	57
	Non-user	215	43
Type of use	Smoked only	68	23.9
	Smokeless only	172	60.4
	Both	45	15.8
Specific product	Khaini	118	41.4
	Gutka/pan masala	72	25.3
	Zarda/pan with tobacco	44	15.4
	Bidi	29	10.2
	Cigarette	15	5.3
	Other	7	2.5
Duration of use	<5 years	74	26
	5-10 years	93	32.6
	>10 years	118	41.4

Table 3: Prevalence and distribution of oral mucosal lesions among study participants

Oral Mucosal Lesion	n	%
No lesion	348	69.6
Tobacco pouch / palatal keratosis	62	12.4
Oral submucous fibrosis (OSMF)	38	7.6
Leukoplakia	25	5
Erythroplakia	5	1
Lichenoid reaction	12	2.4
Other/suspicious lesion	10	2

Table 4: Association between tobacco use status and presence of oral mucosal lesions

Tobacco Use Status	Lesion Present n (%)	No Lesion n (%)	χ^2 (df)	P value
User	128 (44.9)	157 (55.1)	65.82 (1)	p < 0.001
Non-user	24 (11.2)	191 (88.8)		

Discussion:

The present study showed a high prevalence of tobacco use (57.0%) among adults residing in rural Patna, with smokeless tobacco being the predominant form of consumption. This finding is consistent with the Global Adult Tobacco Survey (GATS-2), which reported a substantial burden of smokeless tobacco use in Bihar and other northern Indian states. The predominance of khaini use observed in the present study reflects regional cultural practices and easy accessibility of smokeless tobacco products, a pattern also noted in earlier rural Bihar data. Oral mucosal lesions were identified in 30.4% of the study population, indicating a considerable burden of tobacco-related oral disease. Tobacco pouch keratosis emerged as the most prevalent lesion, followed by oral submucous fibrosis and leukoplakia. Similar findings were reported by Singh *et al.*, who observed tobacco-associated keratotic lesions as the most common oral mucosal alteration among tobacco users attending a rural dental institution **[8]**. Likewise, Choudhary *et al.* documented a substantial prevalence of tobacco pouch keratosis and OSMF among tobacco users in the Hazaribagh population **[3]**. The prevalence of OSMF observed in the present study is particularly concerning because of its recognised malignant transformation potential. The findings support observations by Sowmya and Sangavi among Nicobarese tribal populations, where high smokeless tobacco exposure was significantly associated with OSMF and other potentially malignant disorders **[9]**. Chronic exposure to areca nut and tobacco alkaloids may explain the development of fibrosis and reduced mouth opening in long-term users. A statistically significant association was observed between tobacco use and oral mucosal lesions ($p<0.001$). Nearly 45% of tobacco users presented with oral lesions compared with only 11.2% of non-users. These findings reinforce the relationship between tobacco exposure and oral mucosal pathology, consistent with the hospital-based findings of Sharma *et al.* **[10]** and with broader national epidemiological evidence demonstrating elevated risks of leukoplakia, erythroplakia and OSMF among chronic tobacco users. The higher lesion prevalence among long-term users (>10 years) further suggests a dose-response relationship between duration of exposure and oral mucosal damage. This highlights the importance of early cessation interventions and periodic oral screening in rural communities. Community-based oral health programmes integrated with tobacco cessation services, in line with WHO recommendations **[11, 12]**, may facilitate early identification of potentially malignant disorders and reduce progression to oral cancer **[13]**.

Conclusion:

We show a high prevalence of tobacco use among adults in rural Patna, with smokeless tobacco being the predominant form of consumption. Nearly one-third of participants had oral mucosal lesions, particularly tobacco pouch keratosis and oral submucous fibrosis. These findings highlight the need for community-based tobacco cessation, routine oral cancer screening and public health awareness to reduce tobacco-related oral morbidity in rural Bihar.

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