

RESEARCH ARTICLE

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Prevalence of Oral Premalignant Lesions and Its Risk Factors among the Adult Population in Udupi Taluk of Coastal Karnataka, India

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Abstract

Objective: Globally oral cancer is one of the ten most common cancers with prevalence being high in Central and South East Asian countries. This survey was conducted to estimate the prevalence of oral pre-malignant lesions (OPML) and to identify their risk factors. **Methods:** A community based cross-sectional study was carried out among 2033 individuals aged ≥ 18 years. A questionnaire was administered to collect socio-demographic characteristics, various risk factors for oral cancer and presence of its symptoms. Oral cavity of all the participants was examined in detail by the study investigator as per WHO guidelines for the early diagnosis of oral neoplasia. **Result:** The prevalence of OPML was found to be 3.73%. Among those with OPML, all were ever tobacco consumers and had poor oral hygiene. A significant association was observed between OPML and younger age group (OR=2.56, 95% CI 1.08-6.02), males (OR=26.76, 95% CI 8.40-85.19) and low socio-economic status (OR = 1.91, 95% CI 1.20-3.02). Tobacco (p<0.001), alcohol (OR= 7.92, 95% CI 4.77-13.14) and areca nut consumption (OR = 5.48, 95% CI 3.42-8.77) were strongly associated with OPML. On multivariate analysis among ever tobacco users, OPML was associated with younger individuals, males and those using smokeless forms of tobacco (p <0.05). The study showed that the participants with OPML were more likely to be never married (OR=1.6, 95% CI 0.92-2.96), to be unskilled workers (OR= 1.45, 95% CI 0.61-3.43), to have suffered from oral trauma (OR =1.30, 95% CI 0.75-2.26), to have consumed hot and spicy food frequently (OR=1.53, 95% CI 0.96-2.24), to have consumed fruits infrequently (OR=1.53, 95% CI 0.90-2.59) and to report family history of any cancer (OR = 1.29, 95% CI 0.58-2.87) . However, these associations were statistically insignificant. **Conclusion:** The study reinforces that use of substances such as tobacco, alcohol and areca nut are the modifiable risk factors for OPML.

Keywords: Oral premalignant lesions- screening- risk factors- tobacco use

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Introduction

Globally, among all cancers, oral cancer is one of the ten most common cancers with prevalence being high in Central and South East Asian countries (Globocan, 2012). The incidence of oral cancer ranges from 1 to 10 cases per 100,000 people in most countries. The prevalence is relatively higher among men, in older people, and among people with low literacy level and low income, with tobacco and alcohol consumption being the major causal factors (WHO, 2012). In India in the year 2012, about 53,842 oral cancer cases were diagnosed with an incidence rate of 10.1 cases per 100,000 population and 36,436 deaths were reported due to oral cancer with a mortality rate of 6.7 per 100,000 population making it a major public health problem (Globocan, 2012).

Epidemiological studies from the USA, India,

Pakistan, and Sweden provide evidence that use of smokeless tobacco is strongly associated with oral cancer (Cogliano, 2004). Oral cancers are preceded by oral pre-malignant lesions such as oral leukoplakia, oral submucous fibrosis (OSMF), and oral erythroplakia which can be easily detected by visual inspection or palpation by health care professionals (WHO- IARC). Malignant transformation rate of oral leukoplakia ranges from 0.13 to 17.5% and that of OSMF varies from 4.5% -7.6% (Amagasa et al., 2011; Pindborg et al., 1984; Murti et al., 1985). Thus, early detection and evaluation of these oral pre-cancers can play a major role in preventing their progression into invasive oral cancer (WHO- IARC).

Visual inspection of the oral cavity under adequate light is the most widely used screening method for oral neoplasia. It has been proven efficacious in preventing deaths from oral cancer, particularly among those having

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risk factors such as tobacco (in any form) or alcohol use or both (Sankaranarayanan et al., 2005). A study done by I-How Chang et al reported the sensitivity and specificity of the visual screening test to be 98.9% and 98.7% respectively (Chang et al., 2011).

Several studies have been done in other parts of India determining the prevalence of oral premalignant lesions (OPML) and its risk factors but limited data is available regarding the same from this region. Hence, this survey was undertaken in Udupi taluk to estimate the prevalence of OPML and to identify their association with various factors.

Materials and Methods

A community based cross-sectional study was carried out in Udupi taluk, coastal Karnataka among individuals aged ≥ 18 years of age residing in the study area for more than 6 months. The study period was for a total of two years from August 2015 - September 2017.

Anticipating an estimated prevalence of OPML of 5.0% as per published literature (Narasannavar et al., 2004). with relative precision of 20% and at 95% confidence interval, the calculated minimum sample size was 1,826. Considering a non-response rate of 10%, 2033 individuals needed to be recruited into the study.

The study protocol was approved by the Institutional Ethics Committee (IEC 515/2015). The survey was initiated from one of the randomly selected villages of Udupi taluk. Starting from one locality of the village the investigator moved from house to house towards the right, recruiting eligible individuals. All the individuals living in a house, who met the eligibility criteria and consented to participate in the study were evaluated. Details regarding their socio-demographic characteristics, various risk factors for oral cancer and presence of its symptoms were collected through a questionnaire. Socio-economic status of the participants was assessed using modified Udai-Pareek scale (Pareek et al., 1981).

Oral cavity of all the participants was examined for OPML as per WHO guidelines (WHO-IARC) and the findings were documented using a pre-designed proforma.

Data analysis

Data was analysed using SPSS version 15.0 and was summarized as frequencies and percentages. Association between socio-demographic and clinical characteristics and tobacco use and oral lesions was expressed as odds ratio with 95% confidence intervals. Multiple logistic regression was carried out to determine the risk factors for oral premalignant lesions among tobacco users.

Results

A total of 2033 individuals were recruited into the study. Table 1 shows the socio-demographic details of the study population. Almost half of the participants (54.0%) were in the age group of 18 - 45 years, were males (49.4%) and had declared up to 10 years of schooling (54.4%). The study also revealed that 44.7% of the participants

to be unskilled workers, majority being Hindus (86.0%) and married (86.8%) while 38.7% belonged to low socio-economic status.

On assessing tobacco and alcohol use among the study participants, it was observed that 649 (32.0%) were ever consumers of tobacco in any form. The study further demonstrated that 468 (23.02%) participants were ever users of smokeless tobacco, indicating it to be the primary form of tobacco use in this population and one fifth of the study population were current alcohol users.

Of the total study population, 3.73% were identified with OPML with the prevalence of leukoplakia, erythroplakia and OSMF being 2.60%, 0.04%, and 1.22% respectively. Four participants were found to have both leukoplakia and OSMF.

It was observed that the number of participants in the age category of 18 - 45 years were proportionately higher (63.2%) in the OPML category and this was found to be statistically significant (OR = 2.56, 95% CI, 1.08-6.02). Additionally, participants in the OPML category were more likely to be males as compared to females (OR = 26.76, 95% CI 8.40-85.19).

Majority of those with OPML (89.5%) were Hindus and more than half had five or more years of schooling

Table 1. Baseline Characteristics of the Study Participants (N= 2033)

Baseline characteristic	Number	Percentage
Age group (in years)		
18-45	1097	54.0
46-60	595	29.3
>60	341	16.8
Gender		
Males	1005	49.4
Females	1028	50.6
Religion		
Hindu	1748	86.0
Muslim	207	10.2
Christian	78	03.8
Marital status		
Ever Married	1765	86.8
Never married	268	13.2
Literacy status (years of schooling)		
<5	400	19.6
5-10	1105	54.4
>10	528	26.0
Occupation		
Professional/White collar job	123	06.1
Unskilled	909	44.7
Housewife	752	37.0
Others	249	12.2
Socio economic status		
Low	786	38.7
Middle	1242	61.1
High	5	00.2

Table 2. Association of Various Risk Factors with Oral Pre-malignant Lesion (n=2033)

Characteristic		OPML		Crude odds ratio (95% CI)	P value
		Present no. (n=76) (%)	Absent no. (n=1957) (%)		
*Ever user of tobacco	Yes	76 (100)	573 (29.3)	---	<0.001
	No	0	1384 (70.7)	1	
*Ever user of alcohol	Yes	54 (71.1)	463 (23.7)	7.92 (4.77-13.14)	<0.001
	No	22 (28.9)	1494 (76.3)	1	
**Repeated oral trauma	Yes	17 (22.4)	355 (18.1)	1.30 (0.75-2.26)	0.350
	No	59 (77.6)	1602 (81.9)	1	
Frequent consumption of hot and spicy food	Yes	34 (44.7)	678 (34.6)	1.53 (0.96-2.24)	0.071
	No	42 (55.3)	1279 (65.4)	1	
History of frequent oral ulcers	Yes	02 (2.6)	77 (3.9)	0.66 (0.16-2.73)	0.564
	No	74 (97.4)	1880 (96.1)	1	
Areca nut consumption	Yes	34 (44.7)	252 (12.9)	5.48 (3.42-8.77)	<0.001
	No	42 (55.3)	1705 (87.1)	1	
***Irregular consumption of fruits	Yes	57 (75)	1296 (66.2)	1.53 (0.90-2.59)	
	No	19 (25)	661 (33.8)	1	0.112
***Irregular consumption of vegetables	Yes	46 (60.5)	1200 (61.3)	0.96 (0.61- 1.54)	
	No	30 (39.5)	757 (38.7)	1	0.889
Family history of oral cancer	Yes	01 (1.3)	35 (1.8)	0.73 (0.09-5.42)	0.759
	No	75 (98.7)	1992 (98.2)	1	
Family history of any cancer	Yes	07 (9.2)	142 (7.3)	1.29 (0.58-2.87)	0.51
	No	69 (90.8)	1815 (92.7)	1	
Good oral hygiene	No	76 (100)	1603 (81.9)	---	<0.001
	Yes	0	354 (18.1)	1	

*, Ever user of tobacco/alcohol is a participant who is a current or ex user of tobacco/ alcohol; **, History of repeated oral trauma included trauma while cleaning the tongue forcefully or history of tongue bite/cheek bite/ lip bite or wearing poorly fitting dentures; ***, Irregular consumption is defined as having consumed fruits and vegetables less than daily in the past seven days.

(65.8%). Nearly 83% of those detected with OPML were unskilled workers, who were more likely to be unmarried (OR = 1.65, 95% CI 0.92-2.96). and from the low socio-economic strata (OR=1.91, 95% CI 1.20-3.02).

Table 2 shows the association of various risk factors with OPML. All the participants with OPML were ever tobacco consumers and on oral cavity examination it was observed that all had poor oral hygiene. Similarly, on univariate analysis a statistically significant association was found with alcohol consumption (OR=7.9, 95% CI:4.77-13.14) and areca nut consumption (OR=5.48, 95% CI: 3.42-8.77) and OPML. The participants with OPML were 1.3 times more likely to have suffered from oral trauma, 1.5 times more likely to have consumed hot and spicy food frequently and 1.3 times more likely to report family history of any cancer. However, these associations were statistically insignificant.

Among those with OPML, most common complaint was inability to open the mouth (19.7%) followed by burning sensation in the mouth on eating (7.9%), a sore or a patch in the oral cavity persisting for > 3 weeks (6.6%), discomfort while swallowing (5.3%), and recent alteration in taste (3.9%).

Of the total study population all those with progressive inability to open their mouth were identified with OPML.

On univariate analysis, a significant association was noted between burning sensation in the mouth while eating and OPML (OR =4.33, 95% CI: 1.77-10.57).

Lesions in the oral cavity persisting for ≥3 weeks was reported by 6.6% of the participants and found to have significant association with OPML though with a wide confidence interval. This is indicative of lesser number of events in the study population.

The factors showing an association with OPML at a p<0.2 on univariate analysis were further included in the final model for multivariable regression model, and the results are shown in Table 3.

This table demonstrates the association between types of tobacco use and OPML among ever tobacco users. After adjusting for the baseline characteristics and risk factors, type of tobacco (smoke, smokeless or both), age group and gender came significant among ever tobacco users. Among ever tobacco users, those with OPML are almost six times more likely to be smokeless tobacco users and this was a significant association [Adj OR=6.151, 95% CI, 2.158-17.537, p<0.01]. Additionally, it was also observed that those with OPML were 5 times more likely to be using a combination of smoke and smokeless forms of tobacco [Adj OR=5.689, 95% CI, 1.713-18.898, p= 0.005] and this was found to be significant.

Table 3. Multivariate Logistic Regression among Ever Tobacco Users (n=649)

Particular		OPML		Crude odds ratio (95% CI)	Adjusted odds ratio (95% CI)	P value
		Present no. (n=76) (%)	Absent no. (n=573) (%)			
Age Group	18-45	48 (63.2)	205 (35.8)	5.97 (2.49-14.31)	3.70 (1.51-9.09)	0.004
	46-60	22 (28.9)	215 (37.5)	2.61 (1.03-6.58)	2.51 (0.97-6.49)	0.057
	>60	06 (7.9)	153 (26.7)	1	1	---
Gender	Male	73 (96.1)	390 (68.1)	11.42 (3.55-36.71)	12.22 (3.71-40.22)	<0.001
	Female	03 (3.9)	83 (31.9)	1	1	---
Type of tobacco	Smokers	04 (5.3)	114 (19.9)	1	1	---
	Smokeless tobacco users	61 (80.3)	407 (71.0)	4.27 (1.52-11.99)	6.15 (2.16-17.54)	<0.001
	Smoker +	11 (14.5)	52 (9.1)	6.03 (1.83-19.83)	5.68 (1.71-18.89)	0.005
	Smokeless tobacco users					

Those detected to have OPML were also more likely to be in the 18-45 years age group [Adj OR =3.704, 95% CI 1.510-9.088] and males [Adj OR = 12.216, 95% CI,3.711-40.217].

The wide CIs are indicative of the lesser number of events in the study population.

Discussion

The overall prevalence of OPML was 3.73% with the prevalence of leukoplakia, erythroplakia and OSMF being 2.60%, 0.04%, and 1.22% respectively. This is comparable with the findings observed by Burungale et al. (2014) in Jaitala, in which the prevalence of OPML was 3.25%. However, prevalence of OSMF in the study was found to be higher (2.62%) and that of leukoplakia was lower (0.63%) compared to the present study. However, it is in contrast to the findings reported by Narasannavar A et al. (2014) in Belgaum in which the prevalence of OPML was higher (5.0%). Of these lesions OSMF was the most commonly observed OPML (4.4%) followed by erythroplakia (0.47%), leukoplakia (0.23%) and lichen planus (0.11%). In a similar study by Kumar et al., (2015) in Indore, Madhya Pradesh, a higher prevalence of OSMF (8.06%), leukoplakia (4.02%) and lichen planus (1.38%) were reported while erythroplakia was found to be the least common OPML (0.24%). Our study also showed a low prevalence of erythroplakia (0.04%). Saraswathi et al., (2000) in a hospital based study from Chennai reported a lower prevalence of OPML (1.29%) as well as all forms of OPML.

Difficulty in swallowing i.e. dysphagia was reported by 2.1% of the participants which was slightly higher as compared to the study done by Burungale et al., (2014) in which 0.87% of the population had this symptom. Burning sensation in the mouth on eating something and alteration in the taste sensation was experienced by 2.2% of the participants each which is in contrast to the findings by Mehrotra et al., (2010) (14.0% and 3.0% respectively) and Burungale et al., (2014) (6% and 4.1% respectively) with a higher proportion of the participants to be having these symptoms. In the present study, progressive inability to open mouth was experienced by 0.7% of the participants whereas Burungale et al., (2014) and Mehrotra et al.,

(2010) reported it to be 3.4% and 14.0% respectively in their studies.

A study by Pimple et al., (2012) observed that all those with OPML were found to be tobacco users which is in agreement with the present study. Similar association with tobacco use was also observed in studies by Burungale et al., (2014) and Kumar et al., (2015) (OR=2.06, p=0.030).

Among ever tobacco users, those with OPML were almost six times more likely to be smokeless tobacco users [Adj OR=6.15, 95% CI, 2.16-17.54, p<0.01] and five times more likely to be using a combination of smoke and smokeless forms of tobacco [Adj OR=5.69, 95% CI, 1.71-18.90, p= 0.005]. This is similar to the findings from studies done by Thomas et al., (2003) in Trivandrum (OR=37.8, 95% CI=16.2, 88.1), Mehrotra et al., (2010) in Vidisha (OR = 4.5), Sankaranarayanan et al., (1989) (p<0.001) where tobacco chewing had a significant association with OPML.

Among ever tobacco users, those detected to have OPML were also around 4 times more likely to be in the 18-45 years age group [Adj OR =3.70 95% CI, 1.51-9.09]. However, according to the study done by Thomas et al., (2003) in Trivandrum multiple oral pre-malignant lesions were more likely in the age group of 45-54 years. In the study by Pimple et al., (2012) highest prevalence of OPML was found in the age group of 35-45 years .

The studies done by Kumar et al., (2015) (OR=2.09, 95% CI=1.45-3.00) and Pimple et al., (2012) (p<0.001) showed that male gender was significantly associated with OPML. These findings are corroborating with that of our study in which among, ever tobacco consumers, those with OPML were 12.22 times more likely to be males as compared to females [Adj OR = 12.22, 95% CI 3.71- 40.22].

Those with OPML were 1.9 times more likely to be from low socio-economic status as compared to high socioeconomic status and this was found to be statistically significant [OR=1.91, 95% CI 1.20 – 3.02]. In the study by Hashibe et al., (2003) high socio-economic status was protective with an OR of 0.6 for development of OPML.

In the present study alcohol consumption was found to be significantly associated with OPML and it is comparable with the findings of the previous studies (Pimple et al., 2012; Burungale et al., 2014).

Among those with OPML, 71.1% were ever alcohol

users and it was seen that those with OPML were 7.9 times more likely to have consumed alcohol which is higher as compared to the studies done by Juntanong et al., (2016) in Thailand (Adjusted OR: 4.57) and by Fioretti et al., (1999) (OR: 3.0).

The present study showed that the participants with OPML were 1.3 times more likely to have suffered from oral trauma though the association was statistically insignificant. However, a meta-analysis done by Manoharan et al., (2014) showed a significant association between oral cancer and oral mucosal trauma due to ill-fitting dentures (OR =1.42, 95% CI 1.01-1.99).

It was observed that those with OPML were 1.5 times more likely to have consumed hot and spicy food frequently. Similar results were obtained in a study done by Ahmad et al., (2006) in which OSMF was associated with frequent consumption of chillies and other spices.

Of the 76 participants with OPML, majority were infrequent consumers of fruits (75.0%) and vegetables (60.5%). This association was however, not significant and a detailed diet assessment among this population may yield more information in this regard. The study by Gupta et al., (1999) in Kerala had also concluded that consumption of vegetables and fruits are helpful in preventing the development of pre-malignant lesions of the oral cavity. In the study by Kumar et al., (2015), 47.6% of the participants with OPML infrequently consumed fruits and vegetables.

A study by Garavello et al., (2008) reported that the family history of oral cancer is a strong determinant for developing oral cancer (OR =3.10, 95% CI 2.00 -3.10). In the present study, among those with OPML, one participant (1.3%) had family history of oral cancer.

In our study it was found that none of those with OPML had good oral hygiene. This is agreeing with the study by Oji et al., (2012) in Nigeria in which poor oral hygiene due to not brushing the teeth regularly was significantly associated with oral cancer (p<0.001). Another study by Rosenquist et al., (2005) in Sweden also found a similar association between poor oral hygiene and OPML with an odds ratio of 5.3.

The study revealed an overall OPML prevalence of 3.75% in this population, which is lesser than elsewhere in the country. The prevalence of leukoplakia was found to be the most common morbidity. Among the tobacco users, use of smokeless tobacco, male gender and younger age (18-45 years) were found to be the significant predictors for OPML.

Our study being a community based survey provides the baseline data regarding the prevalence of OPML and its risk factors in this region. However, authors do accept certain limitations in the study. As the tobacco use data is self-reported, there is a possibility of under reporting especially among the female study participants and due to certain logistic constraints, those diagnosed with OPML did not undergo confirmatory tests for malignancy.

Though the survey has revealed a low prevalence of OPML in this population, proportion of them using tobacco in any form was considerably high. These habits are expected to cause significant consequences in the future. Hence, it is crucial to strengthen the existing

cost-effective oral cancer screening and awareness initiatives further in this region.

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