PREVALENCE OF ORAL MUCOSAL LESIONS AMONG 35-65 YEARS AGE GROUP IN RURAL AREA AROUND LUCKNOW INDIA

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MASTER OF DENTAL SURGERY

In the speciality of

PUBLIC HEALTH DENTISTRY

By

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Under the guidance of

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BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES,

LUCKNOW

(Faculty of Babu Banarasi Das University)

2017-2018

DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled **" PREVALENCE OF ORAL MUCOSAL LESIONS AMONG 35-65 YEARS AGE GROUP IN RURAL AREA AROUND LUCKNOW INDIA. "** is a bonafide and genuine research work carried out by me under the guidance of **Dr. Anuradha P., Professor and Head of the department** of Department Public Health Dentistry, Babu Banarasi Das College of Dental Sciences, Babu Banarasi Das University, Lucknow, Uttar Pradesh.

Date: 30/10/18

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This is to certify that the dissertation titled **"PREVALENCE OF ORAL MUCOSAL LESIONS AMONG 35-65 YEARS AGE GROUP IN RURAL AREA AROUND LUCKNOW INDIA. "** is a bonafide work done by **Dr. Vivek Singh,** under my direct supervision and guidance in partial fulfilment of the requirement for the degree of MDS in Public Health Dentistry.

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Vivek Singh

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LIST OF ABBREVIATIONS

HIV	Human Immunodeficiency Virus
DNA	Deoxyribonucleic Acid
US	United States
NIDR	National Institute For Development and Research
OSMF	Oral Submucous fibrosis
WHO	World Health Organization
FEH	Focal Epithelial Hyperplasia
NHANES	National Health & Nutritional Examination Survey
PMD	Potentially Malignant Disorders
OR	Odds Ratio
ST	Smokeless Tobacco
OML	Oral Mucosal Lesions
I.E.C	Institutional Ethical Committee
CPI	Community Periodontal Index
*	Multiply
%	Percentage
>	Greater than
SPSS	Statistical Package For Social Sciences
±	Plus-minus
n	Number of subjects
≤	Greater than or equal to
NS	Not Significant
SD	Standard Deviation

Abstract

Abstract

Introduction- Oral health is important to the quality of life of all individuals. Oral cavity is called as the "physician's mirror" which reflects the various systemic conditions caused by simple vitamin deficiencies to complex HIV infections. The diagnosis of oral mucosal lesions and normal variants of the oral mucosa is an essential aspect of dental practice, and traditionally, the mucosal membrane of the oral cavity has been looked upon as a mirror of general health.

Objective: The present study was conducted with the objective to assess the Prevalence of oral mucosal lesions in 35- 65 years old in rural areas of Lucknow, India

Material and Methods: A A Cross- sectional study was design to employed with a two stage random cluster sampling technique to conduct the present study. In the first stage, Lucknow city was divided into five zones (North , South ,East ,West, Central). In second stage through simple random technique (lottery method) 12-13 sample areas were selected from rural areas of Lucknow. Data was collected by using a pre-designed proforma. The proforma was prepared with the help of World Health Organization Guide to Epidemiology and Diagnosis of Oral Mucosal Diseases 1980. A single examiner, who was calibrated, conducted the study from April 2018 to August 2018. The data obtained were entered into the spread sheets and analysed using SPSS 17.0 version.

Results: The frequency (%) of Oral Submucous Fibrosis (71.6%), Leukoplakia (9.6%) was higher in non smokers than smokers (bidi and cigarette). It was found that there was an association between smoking and oral mucosal lesions of study population.

Conclusion: The present study brings to light various oral mucosal lesions in 35-65 years of age population, which also highlights the importance of early diagnosis of oral mucosal lesions before it develops into malignancy. There is an urgent need for awareness programes utilizing the community health workers, dentists and allied medical professionals.

Key words: Oral Mucosal Lesions, Leukoplakia, Chewing Tobacco, Smoking , Cross sectional study

Introduction

Oral health is important to the quality of life of all individuals.[1] Oral cavity is called as the "physician's mirror" which reflects the various systemic conditions caused by simple vitamin deficiencies to complex HIV infections.[2] The diagnosis of oral mucosal lesions and normal variants of the oral mucosa is an essential aspect of dental practice, and traditionally, the mucosal membrane of the oral cavity has been looked upon as a mirror of general health.[3]

Oral mucosa is a mucous membrane that covers all structures inside the oral cavity. The mucous membrane is the moist lining of the body cavity that communicates with the exterior.

The oral mucosa separates and protects deeper tissues and organs from the environment of the oral cavity like mechanical forces (biting, chewing etc), surface abrasives and toxic effects of toxins released by the micro-organisms. The oral mucosa performs essential protective functions that significantly affect the general health of the patient. Besides dental caries and periodontal diseases, oral mucosal lesions are another significant problem of public health importance.[4]

The spectrum of causes leading to changes of the oral mucosa is wide and includes:

a) Infections (bacteria, fungi, viruses, parasites and other agents),
b) Physical and thermal causes,
c) Changes of the immune system,
d) Systemic diseases,
e) Neoplasia and
f) Trauma and others; some of these are more characteristic for the aging and the elderly. In particular, chronic habits such as use of tobacco and alcohol may cause precancerous and cancerous lesions. Also the long term wearing of dentures may initiate changes in the oral mucosa, which are generally described as denture stomatitis.

These lesions could develop as a result of reduced immunologic reactivity, impaired DNA repair capacity, impaired carcinogen metabolism and age specific involution and atrophy of oral tissues, particularly of the oral epithelium and the salivary glands. These lesions can be found in any site in the oral cavity.[5]

Oral lesions can cause discomfort or pain that interferes with mastication, swallowing, speech and they can produce symptoms such as halitosis, xerostomia, or oral dysesthesia which interfere with daily social activities.[6,7]

Many oral lesions which are habit related or not are found to have potential to undergo malignant changes. A series of diseases may be unique to the oral cavity and its components; it may also involve other parts of the body. Each year in INDIA, an estimated total of 700000-900000 new cancers are diagnosed. Nearly half of all cancers occur at sites associated with tobacco use. These sites include: mouth (oral cavity), lip & tongue, oropharynx, pharynx, oesophagus, larynx, lung & urinary bladder. Oral cancer is one of the ten most common cancers in the world and shows marked geographic differences in occurrence. It ranks number one among men and number three among women in India.[8,9]

Oral mucosal lesions have various prevalence rates in different populations. Complete oral examination is of great assistance in the differential diagnosis of these lesions. If no local information is available about oral mucosal lesions and they are not diagnosed early, the consequences would harm the patient as well as the society in both emotional and economical terms.[10]

Population between 35 – 65 years are mainly affected by non – transmissible diseases, which are quickly becoming the leading causes of disability and mortality, and many of these diseases share common risk factors with different oral diseases. In addition to dental caries and periodontal disease, oral mucosal disease is another significant problem found in these populations. The oral mucosa performs essential protective functions that significantly affect the general health of an individual. A decline in the protective functions of the oral mucosa could expose the aging individual to a variety of pathogens and chemicals that enter the oral cavity. As human beings age, the oral mucosa becomes more permeable to toxic substances and more vulnerable to external carcinogens. The oral epithelium has been reported to become thinner with age and collagen synthesis by connective tissue decreases. As a result of this, decreased tissue regeneration and disease resistance can be expected.[11]

The prevalence of oral mucosal lesions is an important parameter in evaluating the oral health of any population. Prevalence data of oral mucosal lesions is available

from many countries, but the information is usually restricted to very few lesions in each survey.[5] Hence the need arises for more such prevalence studies. The present study provides important information about the oral mucosal lesions, that will help us to plan of future treatment needs.

Aim and objectives

Aim:

The aim of the study was to assess the prevalence of oral mucosal lesions in 35 – 65 year old in rural areas of Lucknow city, India.

Objectives:

1. To determine the prevalence of oral mucosal lesions in 35 – 65 year old in rural areas of Lucknow.
2. To determine the location of oral mucosal lesions in35 – 65 year old in rural areas of Lucknow.
3. To plan a comprehensive programme for the study population.

Review of Literature

1. **R. Kartik et al[13] in 2018** assessed prevalence of oral mucosal lesions among dental patients with mixed habits in Salem district.

   The practice of betel nut chewing with or without tobacco is still practiced in south India, Salem inspite of its harmful effects. 200 patients visiting the outpatient department,Oral medicine and radiology from Aug 2015 to Aug 2016. In the study, 3 women were exclusively churut smokers. Thirty-eight percent of the dental patients were beedi smoker, 32% were tobacco chewers, 12% were both betel nut and tobacco chewers, 8% were exclusively betel nut chewers, 1% of the dental population were exclusively churut smokers. Mean age group of the study population is 50.2 (14.4). There are 28 females and 172 males in the study group. Chi-square test revealed a statistically significant difference (P = 0.001) between males and females based on soft-tissue findings and no statistically significant difference (P = 0.572) between males and females based on distribution of hard-tissue findings.

2. **Chandak Rakhi et al[14] in 2018** assessed The Prevalence of Oral Mucosal Lesions among Vidharbian Population: A Cross-Sectional Study.

   To evaluate the prevalence of oral mucosal lesions among Vidharbian population. Study group consisting of 1200 patients was selected. Patient categorized in 4 groups as tobacco chewers, tobacco smokers, mixed habits and no habits were diagnosed for presence of oral mucosal lesions. The prevalence of oral mucosal lesion in Vidharbian population was found to be 39.25%. Oral submucous fibrosis was the most prevalent oral mucosal lesion in patients having tobacco chewing and mixed habits while smoker's melanosis and recurrent minor aphthous ulcer was more prevalent in patients with tobacco smokers and patients without habits.

3. **Kamala A Kmbie et al[15] in 2017** assessed the prevalence of oral mucosal lesions in Western Maharashtra: A prospective study.

   The purpose of this study was to determine the number, types, and locations of oral mucosal lesions in patients who attended outpatient department. The patients were divided into four groups based on age: 17–24 years, 25–34

years, 35–44 years and >44 years old. Clinical oral examination was done with diagnostic instruments using the Color Atlas of Common Oral Diseases as a guide for diagnosis. When clinical features were not diagnostic, a biopsy was undertaken. The lesions were divided into 7 major groups – normal variants, tobacco related, tongue lesions, potentially malignant disorders and oral malignancies, reactive lesions, inflammatory and pigmented lesions. Among 1500 outpatients, of the 587 (39.1%) patients diagnosed with oral mucosal lesions, males were 416 (70.8%) and females 171 (29.1%). The age range of the patients was between 17 and 80 years. The overall prevalence of oral mucosal changes or lesions was 39.1%. The most commonly affected age group was >44 years. Overall, tobacco-related lesions (35.9%) were the most frequently detected conditions, followed by tongue lesions (16.1%), premalignant and malignant lesions (13.9%), inflammatory lesions (12.6%), normal variants (9.5%), reactive lesions (7.6%), and pigmented lesions (4.0%).The results of the study provided important information about the prevalence of oral mucosal lesions among patients seeking dental care. The study provides baseline data for future studies about the prevalence of oral lesions in the general population.

4. **Toum el. Somi et al al[16] in 2017** conducted a study on Prevalence and Distribution of Oral Mucosal Lesions by Sex and Age Categories: A Retrospective Study of Patients Attending Lebanese School of Dentistry. Aim of the present study was to determine the prevalence and distribution of oral mucosal lesions of patients attending the School of Dentistry. A descriptive study was carried out by retrospectively examining a total of 231 medical and clinical examination record files of patients, attending the School of Dentistry Lebanese University for multidisciplinary dental treatments. 178 medical records were retained. Each medical and clinical examination record was done by an undergraduate student and then evaluated by a doctor. record file included a civil status, chief complaint, medical history, and extraoral and intraoral clinical examination during the period between October 2014 and May 2015. Exclusion criteria were lack of written information in their medical and clinical examination record and being nonevaluated by a doctor. Data regarding age, gender, socioeconomic status, chief complaint, systemic

diseases, and drugs intake were collected by using a questionnaire while the type of extraoral and oral mucosal lesions by clinical examination.)sample consisted of 102 (57.3%) females and 76 (42.7%) males. age ranged from 10 to 92 years with a mean age of 40.1 years. Among these subjects, 110 (61.8%) presented with one or more lesions. All patients were Lebanese. most common lesion diagnosed was coated/hairy tongue affecting 17.4% of the subjects, followed by melanotic macule (11.2%), gingivitis (9.6), linea alba (6.2%), tongue depapillation (5.1), leukoplakia (5.1), traumatic fibroma (4.5), frictional keratosis (3.9%), fissured tongue (3.9%), hemangiomas (3.9%), Fordyce granules (3.9%), dry mucosa (3.4), angular cheilitis (2.2), gingival hyperplasia (2.2), and crenulated tongue (1.7%). Overall, the prevalence of oral mucosal lesions did not significantly difference between sex and age groups High prevalence of oral mucosal lesions necessitates adequate awareness and management of these lesions in the general population.

5. **Peter.Carneli.Jamema et al al[17] in 2016** conducted Oral mucosal lesions in geriatric population- South Indian hospital based study.

Aimed to document the clinical types of oral mucosal lesions and to study its distribution and possible etiological factors in geriatric population. A total number of 5257 patients above 60 years of age were examined and 130 patients fulfilling the criteria were enrolled for the study. A written consent taken from the patients. A detailed medical history and general physical examination was done to establish the clinical diagnosis. Correlation, if any, with etiological factor was assessed. In relevant cases, necessary investigations to establish the definitive diagnosis were done. The collected data were analyzed by the SPSS 22 version software. In the present study, age group of 60-69 years were commonly involved, with a male preponderance. Buccal mucosa was the most common site involved. The common risk factors observed were smoking, alcohol and betel quid chewing. The most frequent lesions found were malignancy, oral candidiasis and oral lichen planus followed by premalignant etiologies.

6. **Ain. S Tasneem et al al[18] in 2016** assessed the prevalence of oral mucosal lesions and associated habits in Kashmir, India

The final study sample comprised of 7000 patients visiting 2 Government Hospitals in Srinagar and Pulwama district, Kashmir, India. All the selected subjects were examined for any oral mucosal lesions. The diagnosis of the lesion was made based on history, clinical features, according to standard guidelines and color atlas.

Prevalence of oral mucosal lesions was found to be 8%. Smoker's palate was the most frequently found oral lesion comprising of 33.89% followed by oral lichen planus and leukoplakia (13.55% each). Other lesions included chemical burns, erythroplakia, OSMF and lichenoid reactions. Subjects indulged into various habits; the most prevalent being the cigarette smoking (56.46%), followed by hukka and bidi smoking and smokeless tobacco.

7. **Lodha S RAMA et al al[19] in 2015** conducted a study on Prevalence of oral soft tissue lesions and risk behavior in slum inhabitants of Bhopal City.

A Community based cross-sectional study were done at Bhopal slum area among randomly selected people >15 years of age. All of them were interviewed and examination of their oral cavity was done. In this study 476 out of 670 peoples (71%) were addicted. The prevalence of overall oral lesions was 69% (n=462). Tobacco was most common habit in the study population (48.5 %%), followed by both type habits that is 16.8% and 35.7 % non tobacco substance user.

8. **Kumar Sravan Yeturu et al al[20] 2015** conducted a study on Prevalence of oral potentially malignant disorders in workers of Udupi Taluk.

The objective was to assess the prevalence and risk factors of oral potentially malignant disorders (PMD) among industrial workers of Udupi taluk, Karnataka. The sample consisted of industrial workers aged >18 years from randomly selected industries in Udupi Taluk. A self-administered questionnaire was given to the participants to assess sociodemographic factors and abusive habits (Tobacco, Alcohol, and Betel quid) followed by clinical oral examination by single trained and calibrated examiner. A total of 396 completed all steps of the survey and were included for analysis. A total of 14, 11.4, and 14.4% were tobacco, alcohol, and betel quid users, respectively. A

the need for formulation of public health programmes discouraging these practices and public awareness of their ill-effects.

16. **Fariborz Mansour Ghanaei et al**[28] in 2013 conducted a study to assess oral mucosal lesions in adult Iranian population

The study was done to assess the prevalence and types of oral lesions in a general population in Rasht, Northern Province of Iran. 1581 people aged > 30 years old who were inhabitant of Rasht, Iran, enrolled in a cross-sectional study. For each individual a detailed questionnaire based on the world health organization (WHO) guidelines in order to diagnosis of the lesions was filled and it contained all the required data. Participants were divided into two groups with and without oral mucosal lesions and oral mucosal lesions were divided into two groups with and without. Demographic characteristics and clinical information including age, sex, smoking (cigarette and tobacco), opium consumption, medication and oral and dental hygiene were collected and compared between these two groups. The prevalence of mucosal lesions in study was 19.4%. Their data demonstrated higher prevalence of oral mucosal lesions in males and young adults (30-40 years). The most common mucosal lesion among our participants was Fissured tongue(4%), followed by Fordyce granules(2.8%), geographic tongue(2.6%) , Pigmentation(2.5%), Candida(1.8%), Smoker Plate(1.6%), lingual Varices(1.5%), Petechiae(1.4%) and lingual labial(1.4%) . Leukoplakia was observed only in two people (0.1%).No case of malignant lesions was detected. No statistically significant difference was confirmed between the two groups regarding smoking, opium consumption, medication and oral and dental hygiene.

17. **Pratik Prerna et al**[29] **in 2012** assessed The Prevalence of habits and oral mucosal lesions in Jaipur, Rajasthan.

The present study is an attempt to assess and compare the various deleterious habits and its associated oral mucosal lesions among patients visiting outpatient department of Jaipur Dental College, Jaipur, Rajasthan.It was found that the prevalence of habits was 51.4% including both the sexes and prevalence of oral mucosal lesions were 9.9%.The prevalence of habits and

oral mucosal lesions is very high as compared with other studies. The habit of smoking was higher in males as compared to females.

18. **Mohammad Ali et al[30] in 2012** assessed prevalence of oral mucosal lesions in patients of the Kuwait University Dental Center

The purpose of this study was to determine the number, types, and locations of oral mucosal lesions in patients who attended the Admission Clinic at the Kuwait University Dental Center to determine prevalence and risk factors for oral lesions. Intraoral soft tissue examination was performed on new patients seen between January 2009 and February 2011. The lesions were divided into six major groups: white, red, pigmented, ulcerative, exophytic, and miscellaneous. Five hundred thirty patients were screened, out of which 308 (58.1%) had one or more lesions. A total of 570 oral lesions and conditions were identified in this study, of which 272 (47.7%) were white, 25 (4.4%) were red, 114 (20.0%) were pigmented, 21 (3.7%) were ulcerative, 108 (18.9%) were exophytic, and 30 (5.3%) were in the miscellaneous group. Overall, Fordyce granules (n= 116; 20.4%) were the most frequently detected condition. A significantly higher ($p< 0.001$) percentage of older patients (21–40 years and P41 years) had oral mucosal lesions than those in the 620 years age group. A significantly higher ($p< 0.01$) percentage of smokers had oral mucosal lesions than did nonsmokers. Most of the lesions and conditions were found on the buccal mucosa and gingiva. The authors concluded that white, pigmented, and exophytic lesions were the most common types of oral mucosal lesions found in their study.

19. **Gambhir Singh Ramandeep et al[31] in 2011** conducted a study The prevalence of oral mucosal lesions in the patients visiting a dental school in Northern India in relation to sex, site and distribution A retrospective study.

To determine the distribution of oro-mucosal lesions in patients of Maharishi Markendeshwer College of Dental Sciences and Research, (MMCDSR), Mullana. Further to identify sex predilection and different sites which are more susceptible to different oro-mucosal lesions. A hospital based retrospective study was carried out from 1st January 2007 till 31st December

consumption and mucosal lesion occurrence. Besides, no relation was found between systemic diseases and oral mucosal lesion occurrence.

24. **Patel. Priyanka et al[36] in 2008** assessed The Oral mucosal lesions among residence of a town in North Gujrat.

The purpose of this study was to determine the prevalence of oral soft tissue lesions in patients and to assess their clinicopathological attributes. 3030 subjects belonging to a Kalol town in western India were screened. Patients were examined with an overhead examination light and those who were identified with a questionable lesion underwent further investigations. 8.4 percent of the population studied had one or more oral lesions, associated with prosthetic use, trauma and tobacco consumption. With reference to the habit of tobacco use, 635(21%) were smokers, 1272(42%) tobacco chewers, 341(11%) smokers and chewers, while 1464(48%) neither smoked nor chewed. 256 patients were found to have significant mucosal lesions. Of these, 216 cases agreed to undergo scalpel biopsy confirmation. 88 had leukoplakia, 21 had oral submucous fibrosis, 9 showed smoker's melanosis, 6 patients had lichen planus, 17 had dysplasia, 2 patients had squamous cell carcinoma while there was 1 patient each with lichenoid reaction, angina bullosa hemorrhagica, allergic stomatitis and nutritional stomatitis. The findings in this population reveal a high prevalence of oral soft tissue lesions and a rampant misuse of variety of addictive substances in the community. Close follow up and systematic evaluation is required in this population. There is an urgent need for awareness programs involving the community health workers, dentists and allied medical professionals.

25. **M.Meleti et al[37] in 2008 conducted** a study on Pigmented lesions of the oral mucosa and perioral tissues: a flow-chart for the diagnosis and some recommendations for the management.

The term "pigmentation of the oral mucosa" is applied to a wide range of lesions or conditions featuring a change of color of oral tissues. Lesions not associated with an accumulation of pigment (e.g., Fordyce spots) are usually not classified as pigmented lesions. Two groups of pigmented lesions of the

34. **Santos.P.J.B et al**[46] in 2003 conducted a study to know the prevalence of oral mucosal conditions among a central Amazonian Indian community in Brazil.

Clinical examinations of a representative, randomly selected sample of patients during routine dental treatment, following ethical procedures recommended by Brazilian laws were made. Diagnostic criteria were those established by Axell and WHO, complemented by some additional criteria proposed by Flink et al and Witkop and Barros. Out of 922 individuals, 587 were examined among which 52.7% of the children up to 12 years old and 73.44% of patients aged 13 years or older presented at least one oral mucosal condition. The conditions more frequently observed were, in decreasing order of prevalence: fissured tongue, focal epithelial hyperplasia (FEH), lesions of traumatic origin, geographic tongue, Fordyce's spots and candidiasis. Only one case of leukoplakia was identified.

They concluded that the conditions observed among these Indians were essentially the same that have been described in other populations around the world, except for FEH, which, as a characteristic lesion of Indians, had high prevalence (20.95%). The lesions observed were related to the way of life of this specific population.

35. **Jainkittivong A et al**[47] in 2002 conducted a study to obtain baseline information on the incidence of oral mucosal conditions in a population of elderly Thai patients.

The incidence of oral mucosal conditions was determined by the clinical examination of a sample of 500 Thai patients aged 60 years and older who attended the Oral Diagnostic Clinic at Chulalongkorn University Dental School .

women, while lichen planus, denture stomatitis and herpes labialis occurred more frequently in the female population.

37. **Reichart PA et al**[49] in 2000 conducted a study to determine the prevalence of oral mucosal lesions in a cross-sectional study among aging Germans.

Three specially trained dental teams examined adults (35-44 years, Group I) and senior individuals (65-74 years, Group 2) in 90 sample points of which 60 were located in the former West and 30 in the former East part of Germany.

655 individuals in Group I (35 – 44 years) and 1367 individuals in Group 2 (65-74 years) were studied. 33.8% (Group 1) and 33.9% (Group 2) were without any pathology of the oral mucosa. Several lesions were not recorded in both groups like oral hairy leukoplakia and gingival hyperplasia and xerostomia. In group 1 history for labial herpetic lesions (31.7%) , Fordyce granules (26.6%), history for recurrent apthous ulceration (18.3%) and lip and / or cheek biting (10.1%) were recorded. In group 2 Fordyce granules (23.7%), history of labial herpes (20.0%), plicated tongue (19.0%) and denture stomatitis (18.3%) were those lesions most frequently recorded. Leukoplakia was seen in 1.8% (West) and 0.9% (East) respectively; men were more often affected than women. There was association between the prevalence of leukoplakia and educational level. Denture associated lesions were seen in 18.3% of Group 1 subjects compared to 2.5% in Group 2 subjects.

38. **Darwazeh.A.M.G et al**[50] in 1998 conducted a study to determine the prevalence of oral lesions among a group of adult Joradanians attending a dental outpatient clinic.

During this investigation, 2175 consecutive patients attending the Initial Treatment Unit in the Faculty of Dentistry, Jordan University of Science and Technology in the city of Irbid, were examined for the presence of mouth

40. **Kleinman DV et al**[52] in 1994 conducted a study to determine the prevalence of oral mucosal lesions of health significance among US schoolchildren and to describe their distribution among selected socio-demographic categories.

As part of the 1986-87 NIDR National Survey of Oral Health in US school children, 39,206 children aged 5-17 year were examined by 14 dentists trained in standardized clinical diagnostic criteria for dental caries, periodontal conditions and oral mucosal lesions. A three stage probability sampling technique was followed. All children were asked whether or not they ever had "cold sores", "fever blisters", or "canker sores", and adolescents (grades 6-12) were questioned about their history of tobacco use. About 4% of the children had one or more oral mucosal lesions present at the time of examination. 33% reported with history of recurrent herpes labialis and 37% reported with recurrent aphthous ulcers. The most prevalent lesions clinically observed were recurrent aphthous ulcers (1.23%), recurrent herpes labialis (0.78%), smokeless tobacco lesions (0.71%), and geographic tongue (0.60%). Differences in prevalence were analysed by age, sex, race, metropolitan area, and geographic region. They concluded that almost 10% of 12-17 year olds reported current use of some type of tobacco product. In adolescents the current use of tobacco products had a marked effect on the prevalence of oral lesions.

. **Axell TE et al**[53] in 1993 has reviewed about oral mucosal changes related to smokeless tobacco usage: The report of the Research Findings in Scandinavia

Smokeless tobacco is used in all Scandinavian countries. By far the highest consumption is recorded in Sweden, where the highest sales figures in the world can be found. Moist non-fermented snuff with a pH value of 8-9 comprises over 99% of the products. A few tons of chewing tobacco are sold per year. Moist snuff as it is used in Scandinavia today gives rise to oral mucosal changes which are reversible after the cessation of the habit. The use of chewing tobacco seems to be associated with pronounced changes of the oral mucosa .The daily amount of snuff used and hours of daily use seem to have a greater impact on the risk for development of more pronounced changes as recorded clinically and histologically than the number of years with the habit and / or age of the subject. They reported that gingival recessions are most frequently found among users of loose snuff than among users of portion-bag packed snuff and they seem to be irreversible.

Materials and Methods

1. Study design

A cross-sectional study design was employed to assess the prevalence and types of oral mucosal lesions in rural areas of Lucknow city.

2. Source of data

Adults, both males and females aged 35 – 65 yrs from the rural areas where formed the study source.

3. Sample size and technique

The current study was done in rural areas of Lucknow. The list of rural areas was obtained from the Lucknow Municipal Corporation office.

Two stage random cluster sampling technique was employed. In the first stage, Lucknow city was divided into five zones i.e. north, south, east, west and central. In second stage through simple random technique (lottery method) 12-13 sample areas were selected from rural areas of Lucknow.

4. Sample size determination

At 80% power and alpha level set at 0.05% and expecting a prevalence of 40%, based on previous literature, it was estimated by the statistician to conduct the study in a sample of 900. A cluster of 15 sample size was selected from each rural areas thus making the sample size of 900.

5. Ethical consent

Ethical clearance was obtained from institutional ethical committee (I.E.C) of Babu Banarasi Das College Of Dental Sciences Lucknow. Informed consent was obtained from each participant prior to the study. A day before the examination concerning village authority, Gram Panchayat, Pradhan permission was taken for the survey.

6. Eligibility criteria

a. Inclusion criteria:

1. Subjects of age 35 to 65 years, both males, females.
2. Subject willing to participate.
3. Subjects residing in rural areas of Lucknow city.

b. Exclusion criteria:

1. Subjects with any systemic or infectious disease.
2. Subjects younger than 35 years.
3. Subjects older than 65 years of age.

7. Training &calibration of examiner:

The data was collected by a single examiner who was calibrated and trained in the Department of Public Health Dentistry for all the codes and criteria of the index.

8. Data collection

a. Schedule

A schedule of the survey was prepared prior to data collection. The survey was conducted with in the working hours of college from 9 to 4 pm. An average of 12- 15 subjects were interviewed and oral examination was done on them per day. Examination was carried out from 10 April 2018 to 30 August 2018.

b. Proforma

Data was collected by using a pre-designed proforma. The proforma was prepared with the help of World Health Organization's Guide to Epidemiology and Diagnosis of Oral Mucosal Diseases 1980.

. Clinical examination

a. **Examination area**: Examination was carried out in the respective household of village.

b. **Type of examination**: The examination was conducted with mouth mirrors, which were used to retract the cheeks and tongue and also to examine for the lesions. Examination was conducted under natural light. A torch light was used when the natural light was not sufficient.

c. **Examination procedures:** The subject was positioned on the chair so as to receive maximum sun light. Clinical examination was carried out by the investigator himself. 2 mouth mirror were needed for the examination. Digital palpation of the mucosa was also done when it was necessary to gain idea of the tissue texture. If any patient wearing denture he was asked to remove before starting the examination.

i. Lips : The lips were examined with the mouth closed and open and noted for colour, texture and any surface abnormalities of the vermillion border.

ii. Lower labial mucosa and sulcus: It was visually examined for observing the colour and any swelling of the vestibular mucosa and gingival region,

iii. Upper labial mucosa and sulcus : Maxillary vestibule and frenum was examined with the mouth partially open.

iv. Commissures, buccal mucosa, buccal sulcus : (upper and lower) using mouth mirrors as retractors and with the mouth wide open, examined the entire buccal mucosa. Change in pigmentation, colour, texture and mobility of the mucosa. The commissures were examined carefully and were not covered by the mouth mirrors during retraction of the cheek.

v. Alveolar ridges: It was checked from all sides (bucally, palatally, lingually).

vi. Tongue : The tongue was at rest position and mouth was partially opened. The dorsum of the tongue was inspected for any swelling,

ulceration, coating or variation in size, colour or texture & also checked the pattern of papillae.

vii. Floor of the mouth : With the tongue still elevated, the floor of the mouth was inspected for swelling or other abnormalities.

viii. Hard and soft palate: With the mouth wide open and the subjects head tilted backwards, the base of the tongue was gently depressed with a mouth mirror. first the hard palate was inspected and then soft palate was inspected.

d. **Recording clerk**: Interns posted in Department of Public Health Dentistry was appointed throughout the survey as a recording clerk, who helped in recording of data. Before beginning the survey, the clerk practiced in recording findings from a few preliminary examinations to avoid any errors in recording the data.

e. **Examination position**: Examination was done on a plastic or wooden chair with high back rest and the instruments were arranged on a wooden table available in the rural areas. The recording clerk was made to sit near the examiner to avoid any disturbance in recording the codes and instructions. Lesions based on the characteristics of age, gender, tobacco use, alcohol use dentition and denture wearing status.

f. **Armamentarium:**

1. Mouth mirror
2. WHO probe / CPI probe
3. Tweezers
4. Kidney trays
5. Disposable mouth masks
6. Disposable examination gloves
7. Soap
8. Towel
9. Savlon
10. Questionnaire

g. **Infection control:**

Infection control was carried out at the site of examination by universally accepted method of precautions. Adequate numbers of instruments were carried out to the site of examinations, so as to avoid disturbance. The instruments were used once and were autoclaved in the department of Public Health Dentistry for reuse. Disposable mouth mask and disposable examination gloves were used for examination at the site of data collection.

10. Referral:

If the subjects required any type of treatment they were referred to Babu Banarasi Das College of Dental Sciences for the needful treatment, Lucknow.

11. Data analysis:

The data from the proforma were entered into the Microsoft excel XP software program. data were analyzed using the statistical package for the social sciences for windows 19.0 (SPSS Inc. Chicago, IL,USA)the normal z test for proportions was used to compare the prevalence of the lesions based on the characteristics of age, gender, tobacco use, alcohol use, dentition &denture wearing status.

Chi-square and Fisher exact test have been used to test the significance of prevalence of lesions in association with the age, sex, religion, region, occupation, diet and habits. The Odds ratio (OR) has been used to find the strength of relationship between prevalence of lesions with the study parameters.

BASIC CONSIDERATION

Examination procedure – Thorough methodical procedure for the oral examination should be carefully learned and not varied

A. The lips- should be examined with the mouth closed and open. Note the color, texture, and any surface abnormalities of the vermilion border.

B. Lower labial mucosa and sulcus – Examined visually the mandibular vestibule with the mouth partially open. Observed the color and any swelling of the vestibular mucosa and gingival.

C. Upper labial mucosa and sulcus – visually examined the maxillary vestibule and frenum with the mouth partially open.

D. Commissures ,buccal mucosa, buccal sulcus – upper and lower using the mouth mirror as retractors and with the mouth wide open, examined the entire buccal mucosa extending from the commissures and back to the anterior tonsilar pillar note any change in pigmentation ,colour,texture and mobility of the mucosa. The commissures are examined carefully and are not covered by the mouth mirror during retraction of the cheek.

E. Alveolar ridges(processes) – check from all sides (buccally, palatally, lingually).

F. Tongue with the tongue at the rest and mouth partially open inspect the dorsum of the tongue for any swelling, ulceration, coating or variation in size, color, or texture. The change in the pattern of the papillae covering the surface of the tongue should also be noted. The patient then asked to protrude the tongue and then examiner should note any abnormality of mobility with the aid of mouth mirrors inspect the margins of the tongue. Then observe the ventral surface.

If adequate precautions can be taken by the examiner, the tongue can be examined more efficiently by grasping the tip with a piece of gauze to assist full protrusion and to aid examination of the margins.

G. Floor of the mouth – The tongue elevated inspect the floor of the mouth for swelling or other abnormalities.

H. Hard and soft palate – The mouth wide open and the subjects head tilted backwards , gently depress the base of the tongue with a mouth mirror. First inspect the hard palate and then the soft palate.

Topographical classification of oral mucosa

The study follows guide to epidemiology and diagnosis of oral mucosal diseases and conditions 1982 which includes:

Description of lesions

Target conditions

The conditions recorded will reflect the range of conditions and diseases found in the survey population as well as the particular interest of those conducting the survey and may also be influenced by the supplementary methods of investigation that are available.

These comprise oral carcinoma together with certain mucosal lesions that are known or believed to be precancerous ,relatively common conditions that enter into the differential diagnosis of these lesions, and certain infection that are capable of being diagnosed with a high degree of confidence under field survey conditions.

1. Carcinoma

The most important oral mucosal lesion is the carcinoma, in most cases a squamous cell carcinoma, because it may cause death if not treated at an early stage . The location of an oral carcinoma is often associated with various smoking and/or chewing habits involving tobacco and /or areca (betal) nut. Depending upon where the quid is kept, the carcinoma may be located in a buccal or labial sulcus.reverse smoking is associated with carcinoma of the palate and posterior part of the dorsum of the tongue.

The carcinoma may develop in a white patch (an area of leukoplakia) or in a red area (an erythroplakia) but many carcinomas arise in an area of mucosa that previously

appeared normal. Despite the serious nature of the lesions, there may be little or no pain.

2. Leukoplakia

Leukoplakia is defined as a white patch, or plaque, that cannot be characterized clinically or pathologically as any other disease.

These lesions are characterized by the presence of a white patch anywhere on the oral mucosa,they may vary from a quite small and circumscribed area to an extensive lesion involving a large area of mucosa. The appearance is variable,the surface may be smooth or wrinkled and sometimes smooth- surfaced lesions may be transversed by small cracks or fissures giving an appearance aptly likened to cracked mud.lesions may be white, whitish- yellow or grey and some appear homogenous, while others are nodular, showing white areas intermingled (speckled) leukoplakia.

3. Erythroplakia

Erythroplakia is used analogously to leukoplakia to designate lesions of the oral mucosa that present as bright red velvety plaques which cannot be characterized clinically or pathologically as due to any other condition.

The lesions of erythroplakia are usually irregular in outline though well defined and have a bright red velvety surface.ocaasionally the surface is granular.if red areas are intermingled with white. The lesion should be classified under leukoplakia.

4. Leukokeratosis nicotina palati –

In addition to the leukoplakia patches that may develop anywhere in the oral mucosa in tobacco users, a specific lesion may occur in the plate of heavy pipe and cigar smokers, particularly the former. These changes do not occur in those areas of the palate that are shielded from the tobacco smoke.

5. Lichen planus –

This disease commonly affects the oral mucosa and lesions may occur in the mouth in the absence of skin lesions. Oral mucosal lesions are usually multiple and often have a symmetrical distribution. They commonly take the form of minute white papules that

gradually enlarge and coalesce to form a reticular, annular or plaque pattern. a characteristic feature is the presence of slender white lines (Wickham striae) radiating from the papules.

6.Oral submucous fibrosis –

This condition which is found almost exclusively among Indians and Pakistanis,is slowly progressive disease of unknown etiology the disease is characterized by the presence of palpable fibrous bands in the oral mucosa ultimately leading to severe restriction of the movements of the mouth, including that of the tongue.on clinical examination, limitation of opening of the mouth may be obvious. In the earlier stages of t he disease it will usually be possible to detect vertical fibrous bands in the cheek,which can be felt by running the blunt edge of the mouth mirror backwards and forwards along the cheek mucosa.

7. Acute herpetic gingivostomatitis –

This condition is caused by the herpes simplex virus and it more common in children than in adults. Especially in children, acute herpetic gingivo stomatitis may cause a marked constitutional disturbance(malaise, high fever),together with regional lymphadenopathy, flushing and profuse salivation. The initial oral lesions are small vesicles,which occur on any part of the oral mucosa,particularly on the labial mucosa, but also including the tongue and the palate, and the vesicles may be very numerous.

8. Acute necrotizing gingivitis (stomatitis)

Acute necrotizing gingivitis is known under many other names,the foremost being Vincent's gingivitis, but terms like "ulceromembranous gingivitis" and "fusopirochaetal gingivitis" are frequently used.the oral lesions are characterized by a necrosis at the tips of the interdental papillae and along the marginal gingivae, or the edge of the mucosa flap over an erupting molar.the ulcers are covered by a grayish-yellow pseudomembrane.the lesions are tender and bleed when touched lightly. There is a characteristic oral fetor.

9. Cancrum oris –

Under the names "noma" and "gangrenous stomatitis", cancrum oris has been known for hundreads of years in various parts of the world. Cancrum oris, which is

commonly preceded by an acute necrotizing gingivitis, begins as an ulceration of the oral mucous membrane which extends outwards and causes a well demarcated necrosis of the overlying skin. The necrotic area may become large, the gangrenous tissue separates and may expose necrotic bone. Later the dead bone and the associated teeth may sequestrate.

10. Candidiasis –

In several populations it has been dound that about 50% of normal individuals are carriers of candida. A variety of oral lesions are caused by the fungus candida albicans.The term "candidiasis" is used when lesions are present. The disease is also known as "moniliasis" and "candidiasis". Acute candidiasis may be pseudomembranous or atrophic.the former ,also as thrush,consist of creamy,pearl-white or bluish – white patches which can be removed by gentle scrapping.

Thrush may occur in all areas of the oral mucosa, although the sites of predelication are the buccal mucosa, palate and tongue.the atropic variety , a red and painful lesion,may occur during treatment with antibiotics. Chronic candidiasis may manifest itself in several forms. As persistent angular cheilitis, as denture stomatitis , as a median rhomboid glossitis- like lesion and as a retrocommissural hyperplastic lesion. The latter may often resemble a leukoplakia.

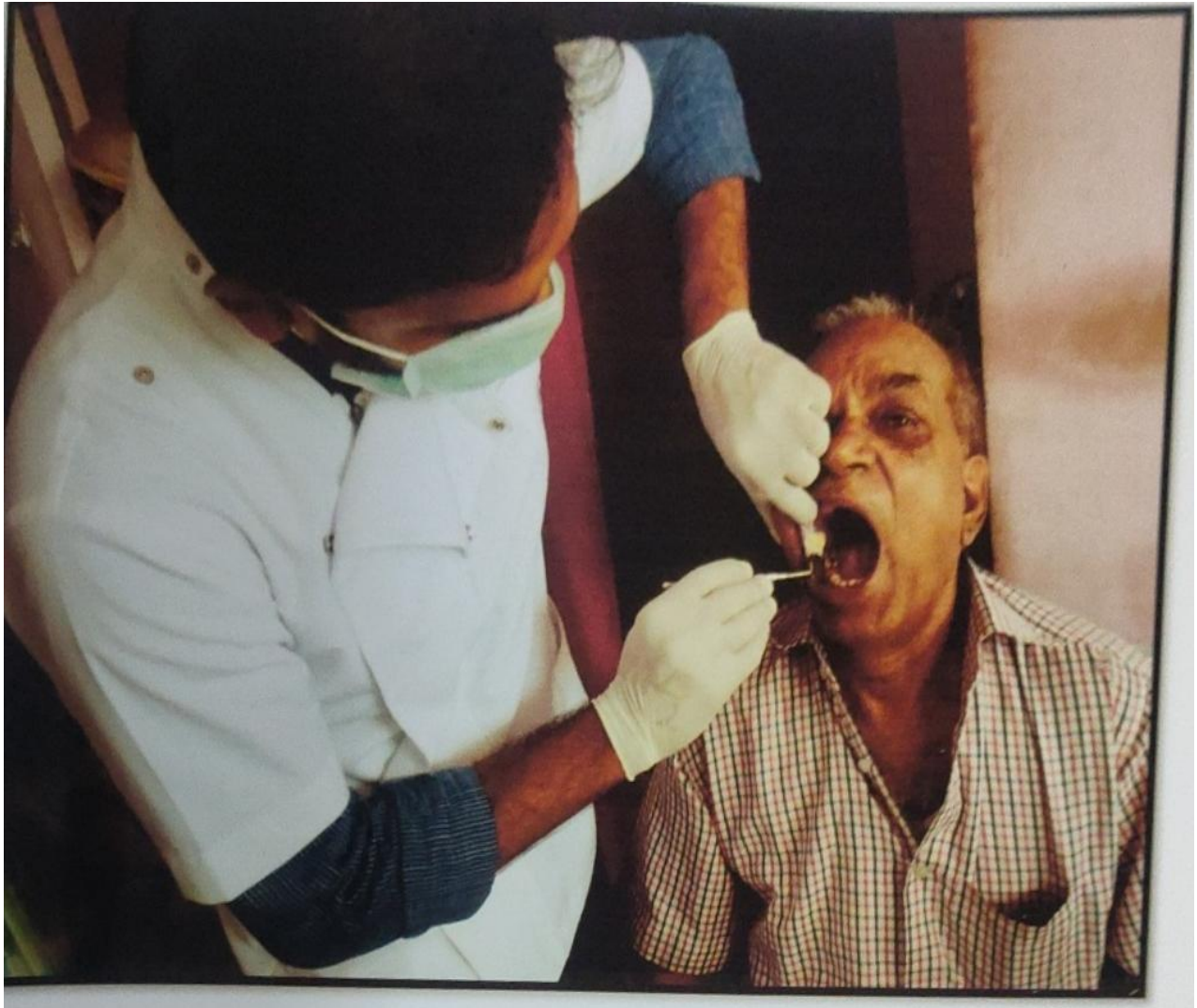
11. Recurrent oral aphthae –

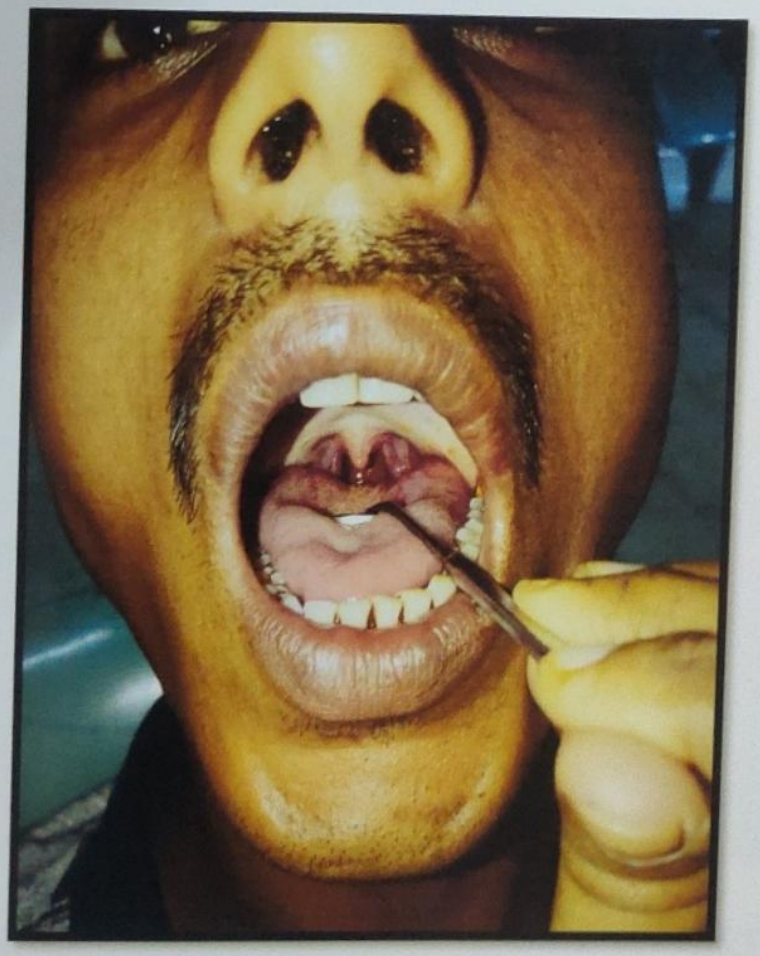
Apart from gingivitis the most prevalent oral mucosal lesions are ulcerations of the types known as "canker sore" and "aphthous ulcerations", with a prevalence ranging from 10% to 60% in various population samples. Three main clinical patterns may be recognized. in the most common (minor apthae, Mikulicz aphthae) there are typically 1-4 ulcers in each attack. these are usually confined to the non- keratinized parts of the mucosa and therefore do not involve the hard palate or the gingival. Each ulcer reaches a diameter of 1-2 cm over a period of about a week and is usually healed by the end of the second week from onset. the ulcers are shallow, but painful , and they do not cause scarring.

Statistical analysis

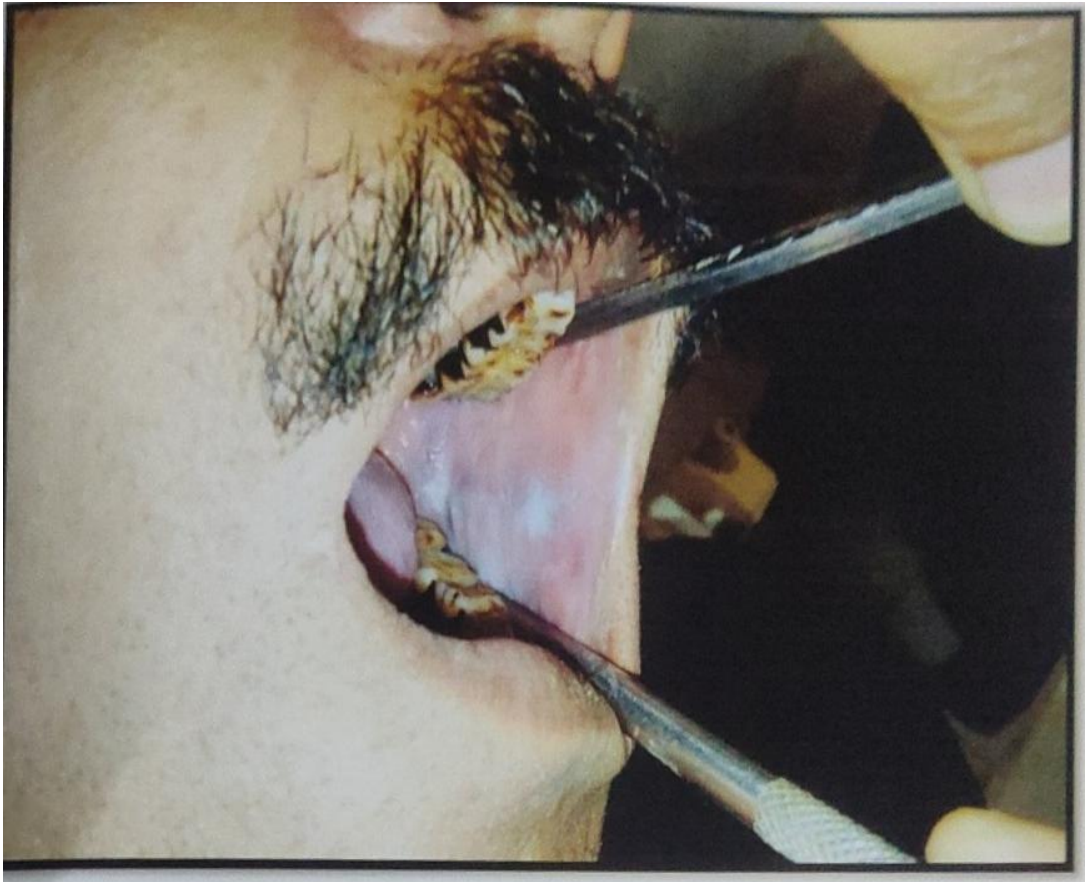
Continuous data were summarised in Mean ± SD (standard deviation) whereas categorical (discrete) data were summarised in number (n) and percentage (%). Categorical groups were compared by chi-square (χ^2) test. A two-tailed (α=2) $p<0.05$ was considered statistically significant. Analyses were performed on SPSS software (Windows version 17.0).

Dermafilm





EXAMINER CONDUCTED DIAGNOSIS OF THE PATIENT



EXAMINER CONDUCTED DIAGNOSIS OF THE PATIENT

Results and Observations

The present study evaluates prevalence of oral mucosal lesions among 35-65 years age group in rural area around Lucknow city, India. Total 900 subjects, age between 35-65 yrs either gender were recruited and evaluated. The primary objective of the study was (i) to determine the occurrence of oral mucosal lesions in rural areas of Lucknow, (ii) to determine the location of oral mucosal lesions in rural areas of Lucknow, and (iii) To plan a comprehensive programme for the study population. The secondary objective of the study was to correlate oral mucosal lesions with gender, smoking, tobacco chewing and both smoking and tobacco chewing.

Total population

Demographic characteristics

The demographic characteristics (age, gender and diet) of all recruited subjects (total population, *n=900*) is summarised in Table 1. The age of all subjects ranged from 35 to 65 yrs with mean (± SD) 47.59 ± 9.46 yrs and median 47 yrs. According to median, 50.0% of subjects were <47 yrs and 50.0% were ≥ 50 yrs age.

Further, among subjects, 559 (62.1%) were males and 341 (37.9%) were females (Table 1 and Fig. 1). The study total population was thus male predominance with 1.6 to 1.0 male to female ratio.

Furthermore, among subjects, mostly were vegetarian (59.7%) followed by mixed (vegetarian and non vegetarian) (36.7%) and non vegetarian (3.7%) (Table 2 and Fig. 2). The diet of study total population was thus predominance to vegetarian.

Table 1: Demographic characteristics of total population

Demographic characteristics	No. of subjects (n=900) (%)
Age (yrs): Mean ± SD, Range, Median	47.59 ± 9.46, 35 to 65, 47
Gender:	Total (%)
Male	559 (62.1)
Female	341 (37.9)
Diet:	(%)
Veg	537 (59.7)
Mixed	363 (40.4)

Age were summarised in Mean ± SD, range (min to max) and median whereas gender were summarised in number (n) and percentage (%).

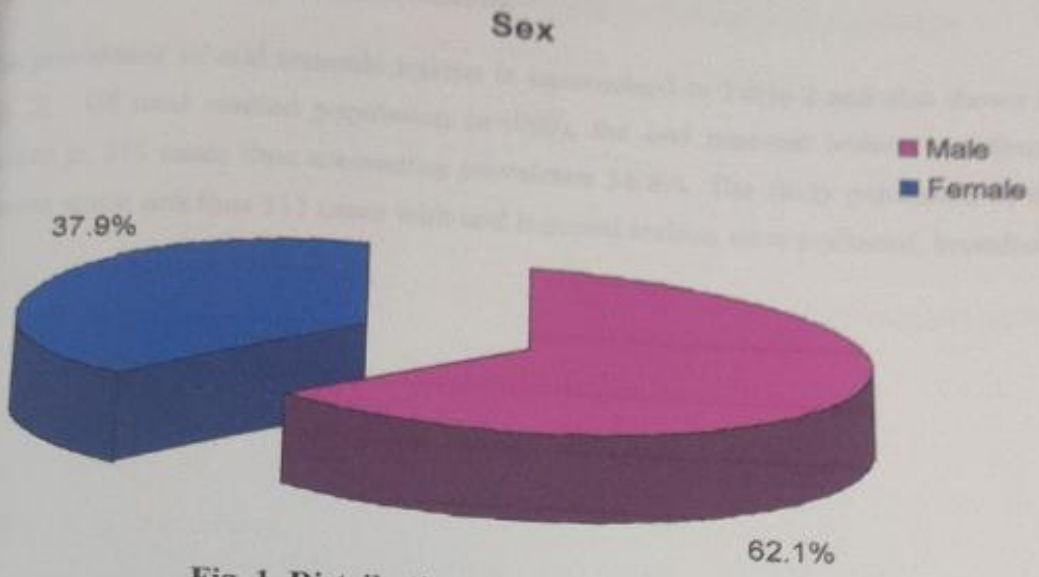


Fig. 1. Distribution of sex of total population.

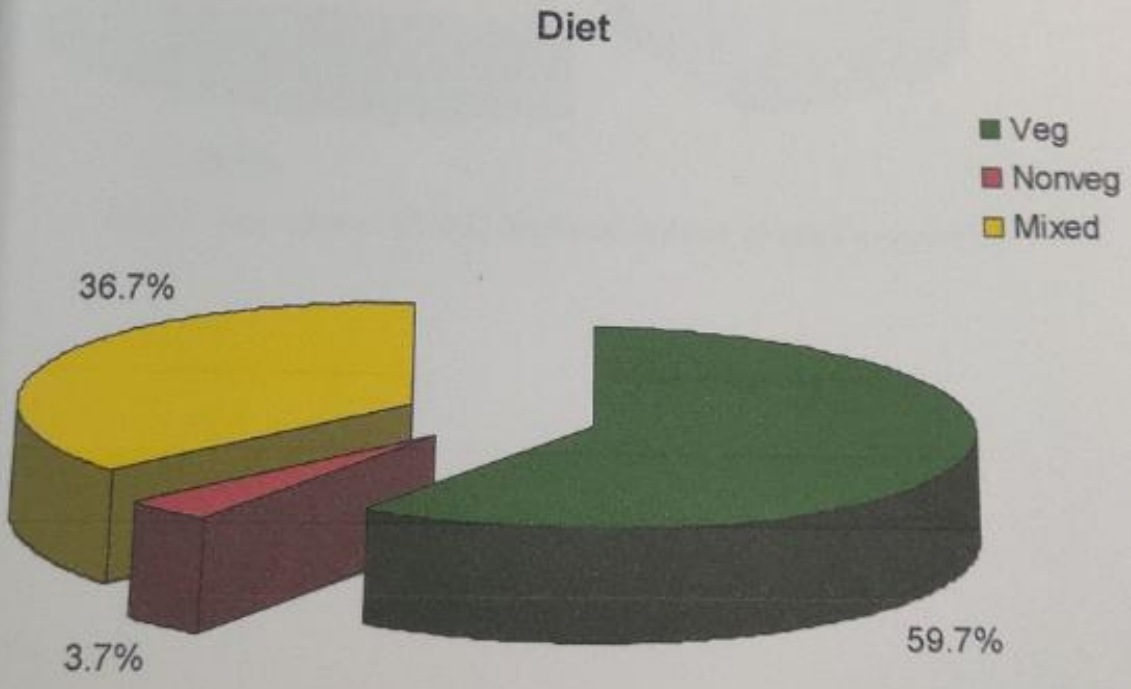


Fig. 2. Distribution of diet of total population.

Prevalence of oral mucosal lesions

The prevalence of oral mucosal lesions is summarised in Table 2 and also shown in Fig. 2. Of total studied population (*n=900*), the oral mucosal lesions was found present in 511 cases thus accounting prevalence 56.8%. The study population of the present study was thus 511 cases with oral mucosal lesions were evaluated, hereafter.

Table 2: Prevalence of oral mucosal lesions among total population

Prevalence of Oral Mucosal Lesions	No. of subjects (n=900) (%)
No	389 (43.2)
Yes	511 (56.8)

Distribution of oral mucosal lesions were summarised in number (n) and percentage (%).

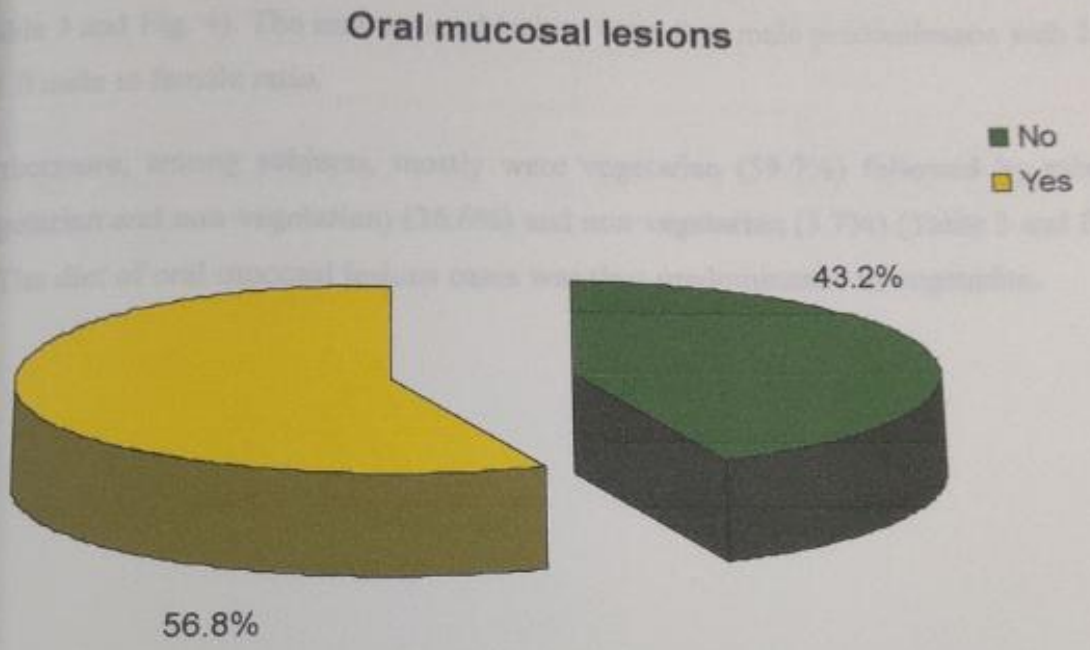


Fig. 3. Prevalence of oral mucosal lesions in total population.

Oral mucosal lesion population

Demographic characteristics

The demographic characteristics (age, gender and diet) of 511 cases with oral mucosal lesions (i.e. study population) were further summarised in Table 3. The age of study subjects ranged from 35 to 65 yrs with mean (± SD) 47.80 ± 9.71 yrs and median 47 yrs. According to median, 50.0% of subjects were <47 yrs and 50.0% were ≥ 50 yrs age.

Further, among subjects, 338 (66.1%) were males and 173 (33.8%) were females (Table 3 and Fig. 4). The oral mucosal lesions were thus male predominance with 2.0 to 1.0 male to female ratio.

Furthermore, among subjects, mostly were vegetarian (59.7%) followed by mixed (vegetarian and non vegetarian) (36.6%) and non vegetarian (3.7%) (Table 3 and Fig. 5). The diet of oral mucosal lesions cases was thus predominance to vegetarian.

Table 3: Demographic characteristics of study population

Demographic characteristics	No. of subjects (n=511) (%)
Age (yrs): Mean ± SD, Range, Median	47.80 ± 9.71, 35 to 65, 47
Gender :	
Male	338 (66.1)
Female	173 (33.8)
Diet:	
Veg	305 (59.7)
Nonveg	19 (3.7)
Mixed	187 (36.6)

Age were summarised in Mean ± SD, range (min to max) and median whereas sex and diet were summarised in number (n) and percentage (%).

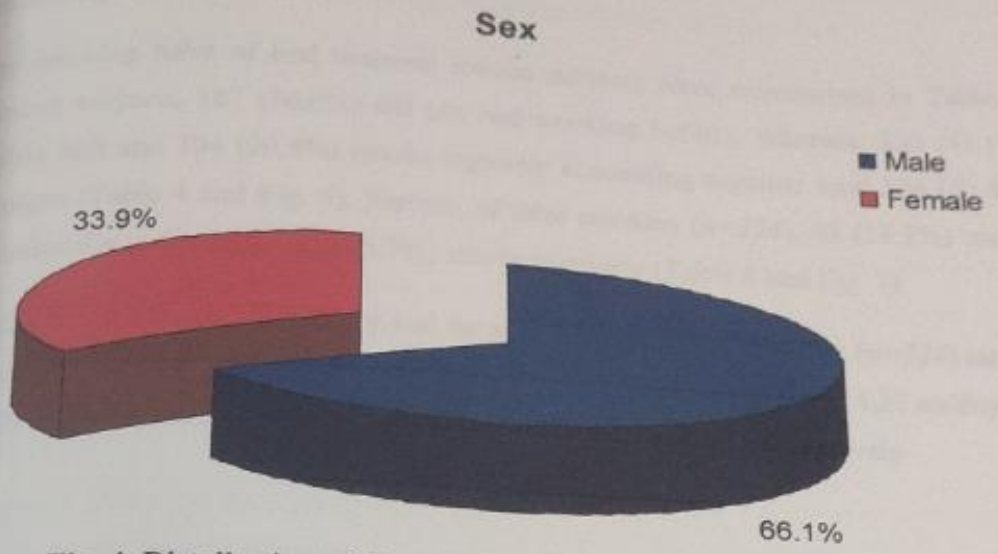


Fig. 4. Distribution of Gender of Oral Mucosal Lesion population.

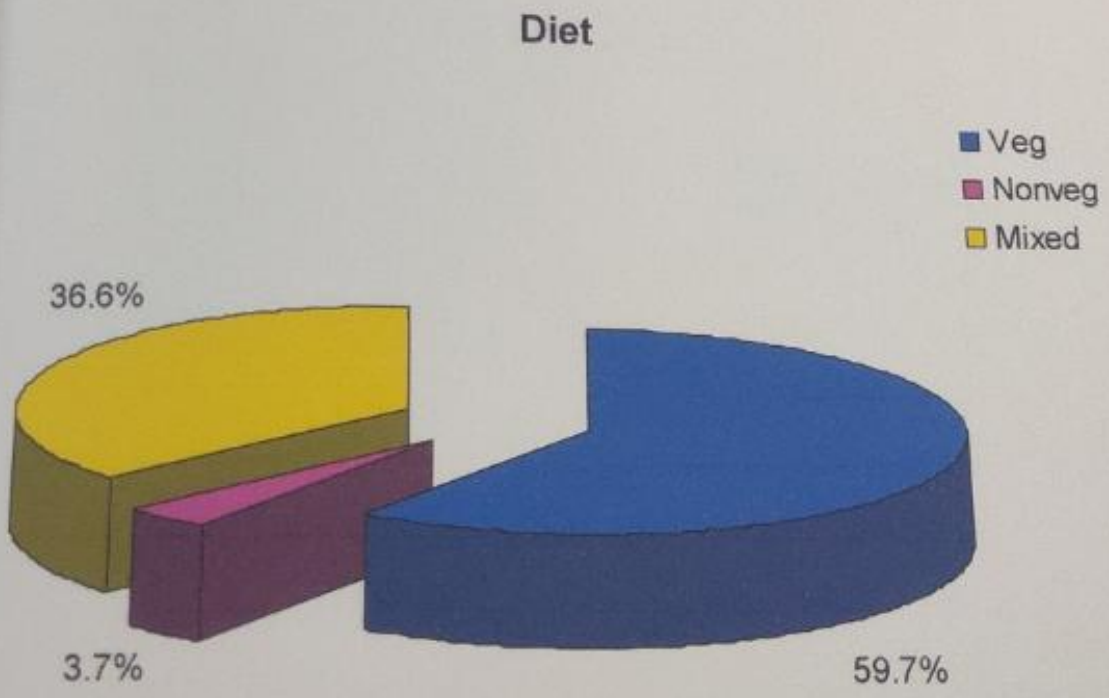


Fig. 5. Distribution of diet of Oral Mucosal Lesion population.

Smoking habit

The smoking habit of oral mucosal lesions subjects were summarised in Table 4. Among subjects, 187 (36.6%) did not had smoking habit; whereas, 220 (43.1%) smoke bidi and 104 (20.4%) smoke cigarette accounting together total 324 (63.4%) smokers (Table 4 and Fig. 6). Further, of total smokers (*n=324*), 43 (13.3%) smoke occasionally and mostly 281 (86.7%) smoke regularly (Table 4 and Fig. 7).

Furthermore, smoking frequency and duration of smoking in smokers (*n=324*) ranged from 1-18 no/day and 1-50 yrs respectively with mean (± SD) 4.90 ± 4.22 no/day and 13.29 ± 15.96 yrs respectively and median 4 no/day and 7 yrs respectively.

Table 4: Smoking habits of study population

Smoking habit	No. of subjects (n=511) (%)
Smoking type:	
No	187 (36.6)
Bidi	220 (43.1)
Cigarette	104 (20.4)
Smoking habit (*n=324*):	
Occasionally	43 (13.3)
Regular	281 (86.7)
Smoking frequency (no/day):	
Mean ± SD, Range, Median	$4.90 \pm 4.22_{(n=324)}$, 1 to 18, 4
Smoking duration (yrs):	
Mean ± SD, Range, Median	$13.29 \pm 15.96_{(n=324)}$, 1 to 50, 7

Smoking frequency and duration were summarised in Mean ± SD, range (min to max) and median whereas smoking type and habits were summarised in number (n) and percentage (%).

Tobacco chewing habit

The tobacco chewing habit of oral mucosal lesions subjects were summarised in Table 5. Among subjects, 311 (60.9%) had tobacco chewing habit; whereas 200 (39.1%) did not intake it (Table 5 and Fig. 8). Further, of total chewers (*n=311*), 39 (12.5%) intake it occasionally and mostly 272 (87.5%) take it regularly (Table 5 and Fig. 9).

Moreover, tobacco chewing frequency and duration in chewers (*n=311*) ranged from 1-20 no/day and 1-20 yrs respectively with mean (± SD) 4.81 ± 4.79 no/day and 7.30 ± 6.23 yrs respectively and median 4 no/day and 4 yrs respectively.

Table 5: Tobacco chewing habits of study population

Tobacco chewing	No. of subjects (n=511) (%)
Tobacco chewing:	
No	200 (39.1)
Yes	311 (60.9)
Tobacco chewing habit (*n=311*):	
Occasionally	39 (12.5)
Regular	272 (87.5)
Tobacco chewing frequency (no/day):	
Mean ± SD, Range, Median	$4.81 \pm 4.79_{(n=311)}$,1 to 20, 4
Tobacco chewing duration (yrs):	
Mean ± SD, Range, Median	$7.30 \pm 6.23_{(n=311)}$,1 to 20, 4

Tobacco chewing frequency and duration were summarised in Mean ± SD, range (min to max) and median whereas tobacco chewing and habits were summarised in number (n) and percentage (%).

Both habits

The both (smoking and tobacco chewing) habit of oral mucosal lesions subjects were summarised in Table 6. Among subjects, 127 (24.9%) had both smoking and tobacco chewing habits habit; whereas 384 (75.1%) did not had both the habits (Table 6 and Fig. 10).

Table 6: Both smoking and tobacco chewing habits of study population

Smoking and tobacco chewing	No. of subjects (n=511) (%)
Both habits:	
No	384 (75.1)
Yes	127 (24.9)

Both smoking and tobacco chewing habits were summarised in number (n) and percentage (%).

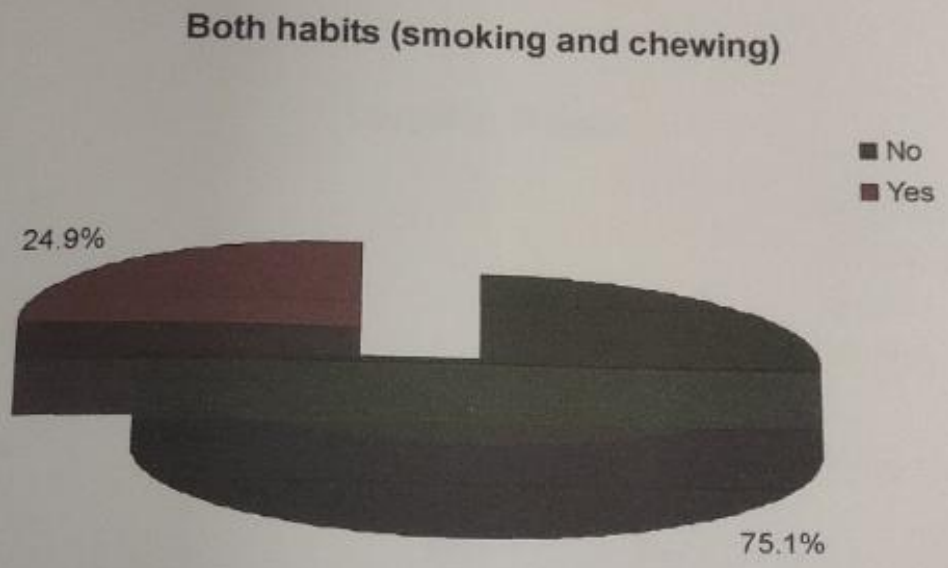


Fig. 10. Distribution of both tobacco smoking and chewing habits of oral mucosal lesion population.

Location of quid

The location of quid of oral mucosal lesions subjects were summarised in Table 7. Among tobacco chewers (*n=311*), 50 (16.1%) subjects take/keep it at left side, 40 (12.9%) at right side, 63 (20.3%) both sides (left and right) and mostly 158 (50.8%) at other side (Table 7 and Fig. 11).

Oral mucosal lesion

The distribution of oral mucosal lesions of study population were summarised in Table 8. Of total (*n=511*), mostly had oral sub-mucous fibrosis (OSMF) (71.6%) followed by leukoplakia (9.6%), lichen planus (6.8%), recurrent apthous stomatitis (6.3%), herpetic gingivo stomatitis (4.1%), stomatitis palatinus (1.0%) and carcinoma (0.6%) (Table 8 and Fig. 12).

Further, site of oral mucosal lesions of most the subjects was 19/20 (48.7%) following by 19 (19.0%) and 20 (11.2%) accounting together 78.9% of the total sites (Table 8 and Fig. 13).

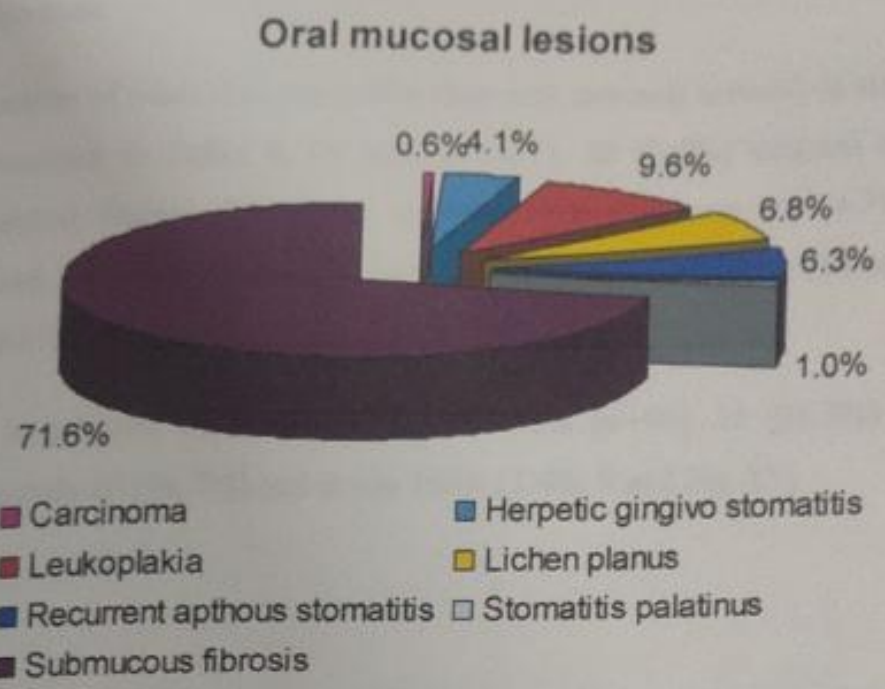


Fig. 12. Distribution of oral mucosal lesions of studied population.

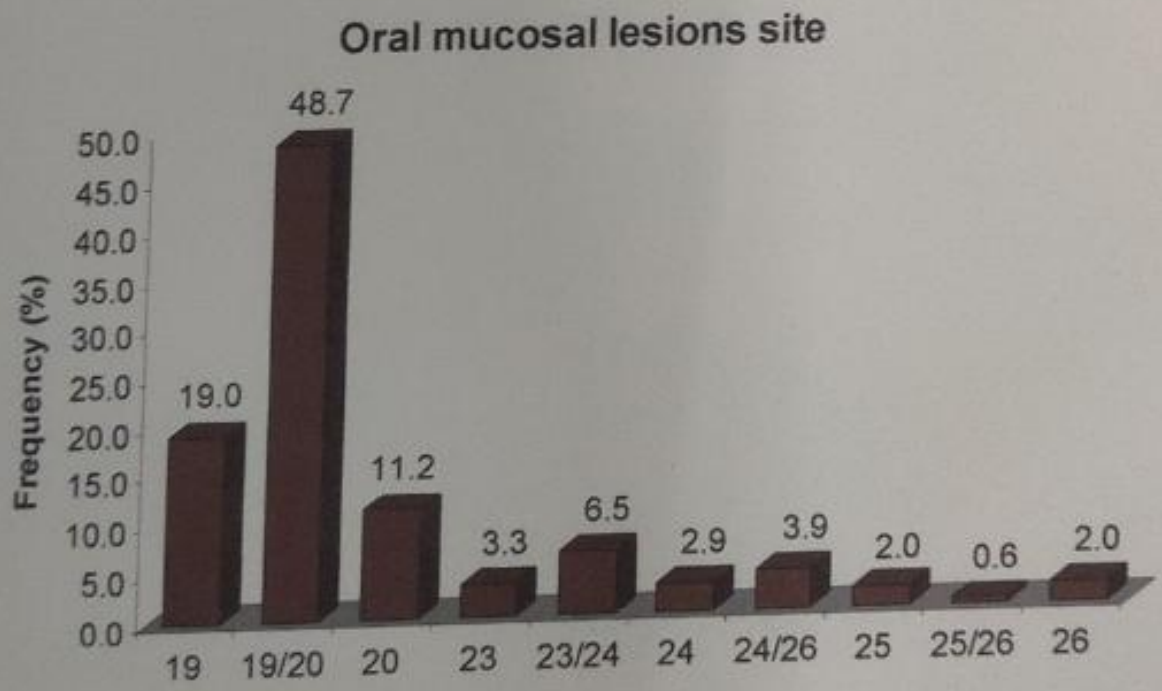


Fig. 13. Distribution of site of oral mucosal lesions of studied population.

Other diseases

The distribution of other diseases (other than oral mucosal lesions) of study subjects were summarised in Table 9. Of total (*n=511*), 20 (3.9%) subjects had tobacco chewing related disease, 21 (4.1%) smoking related disease, 24 (4.7%) fordyces granulosa and 25 (4.9%) hematoma; whereas mostly 421 (82.4%) did not had other disease (Table 9 and Fig. 14).

Moreover, in subjects with other diseases present (*n=90*), 21 (23.3%) had at site 51/52 and mostly 69 (76.7%) had at site 19/20 (Table 9 and Fig. 15).

Table 9: Other disease of study population

Other disease	No. of subjects (n=511) (%)
Other disease type:	
No	421 (82.4)
Chewing related	20 (3.9)
Fordyces granulosa	24 (4.7)
Hematoma	25 (4.9)
Smoking related	21 (4.1)
Other disease site (n=90):	
19/20	69 (76.7)
51/52	21 (23.3)

Other disease type and site were summarised in number (n) and percentage (%).

Previous treatment

The distribution of previous treatment of study population were summarised in Table 10. Of total (*n=511*), no one had done any type of previous oral treatment (Table 10 and Fig. 16).

Table 10: Previous treatment of study population

Previous treatment	No. of subjects (n=511) (%)
Yes	0 (0.0)
No	511 (100.0)

Previous treatment were summarised in number (n) and percentage (%).

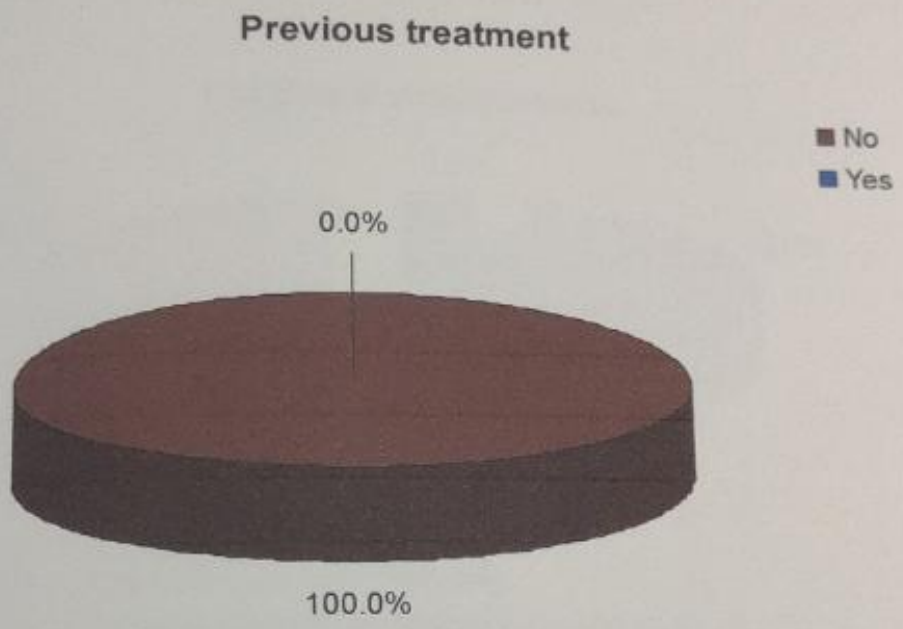


Fig. 16. Distribution of previous treatment of oral mucosal lesions population.

Treatment requirement

The distribution of treatment requirements of study population were summarised in Table 11. Of total (*n=511*), 150 (29.4%) had oral hygiene instructions only, 176 (34.4%) recommended changes of habit and follow up and 165 (32.3%) needed urgent treatment.

Table 11: Treatment requirement of study population

Treatment requirement	No. of subjects (n=511) (%)
No	20 (3.9)
Oral hygiene instruction only	150 (29.4)
Recommended changes of habit and follow up	176 (34.4)
Treatment needed	165 (32.3)

Treatment requirement were summarised in number (n) and percentage (%).

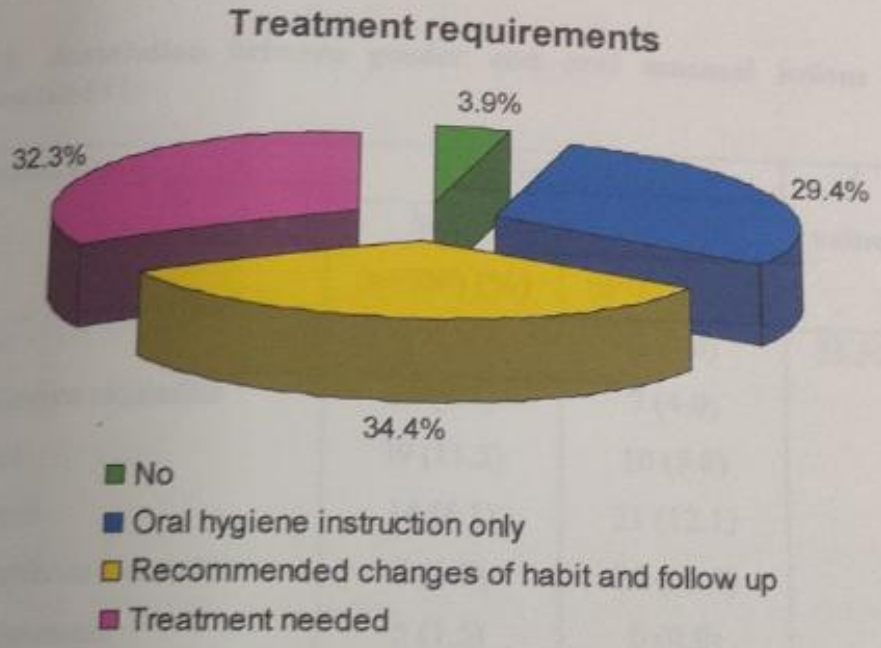


Fig. 17. Distribution of treatment requirements among oral mucosal lesions population.

Association

Gender

The association between gender and oral mucosal lesions of study population were summarised in Table 12. The frequency (%) of both leukoplakia (5.7%) and submucous fibrosis (13.0%) was higher in males than female. In contrast, frequency of both lichen planus (8.0%) and recurrent apthous stomatitis (13.2%) were higher in females than males. Comparing the oral mucosal lesions between two genders, χ^2 test showed significant difference in oral mucosal lesions between the two genders (χ^2=53.55, p<0.001). In other words, oral mucosal lesions may be associated to genders.

Table 12: Association between gender and oral mucosal lesions of study population (n=511)

Oral mucosal lesion	Gender		χ^2 value	p value
	Male (n=338) (%)	Female (n=173) (%)		
Carcinoma	3 (0.9)	0 (0.0)	53.55	<0.001
Herpetic gingivo stomatitis	14 (4.1)	7 (4.0)		
Leukoplakia	39 (11.5)	10 (5.8)		
Lichen planus	14 (4.1)	21 (12.1)		
Recurrent apthous stomatitis	6 (1.8)	26 (15.0)		
Stomatitis palatinus	5 (1.5)	0 (0.0)		
Submucous fibrosis	257 (76.0)	109 (63.0)		

Oral mucosal lesion between two gender groups were summarised in number (n) and percentage (%) and compared by χ^2 test.

Smoking

The association between smoking and oral mucosal lesions of study population were summarised in Table 13. The frequency (%) of both recurrent apthous stomatitis and submucous fibrosis was higher in non smokers than smokers (bidi and cigarette). In contrast, frequency of leukoplakia was higher in smokers (bidi and cigarette) than non smokers. Comparing the oral mucosal lesions between three groups, χ^2 test showed

significant difference in oral mucosal lesions among the groups (χ^2=31.90, p=0.001). In other words, oral mucosal lesions may be associated to smoking.

Table 13: Association between smoking and oral mucosal lesions of study population (n=511)

Oral mucosal lesion	Smoking			χ^2 value	p value
	No (n=187) (%)	Bidi (n=220) (%)	Cigarette (n=104) (%)		
Carcinoma	1 (0.5)	2 (0.9)	0 (0.0)	31.90	0.001
Herpetic gingivo stomatitis	8 (4.3)	9 (4.1)	4 (3.8)		
Leukoplakia	4 (2.1)	25 (11.4)	20 (19.2)		
Lichen planus	10 (5.3)	21 (9.5)	4 (3.8)		
Recurrent apthous stomatitis	15 (8.0)	14 (6.4)	3 (2.9)		
Stomatitis palatinus	2 (1.1)	2 (0.9)	1 (1.0)		
Submucous fibrosis	147 (78.6)	147 (66.8)	72 (69.2)		

Oral mucosal lesion between three smoking groups were summarised in number (n) and percentage (%) and compared by χ^2 test.

Tobacco chewing

The association between tobacco chewing and oral mucosal lesions of study population were summarised in Table 14. The frequency (%) of leukoplakia was slightly higher in non chewers than chewers. In contrast, frequency of submucous fibrosis was slightly higher in chewers than non chewers. Comparing the oral mucosal lesions between two groups, χ^2 test showed similar frequency of oral mucosal lesions between the groups (χ^2=3.71, p=0.715). In other words, oral mucosal lesions may not be associated to tobacco chewing.

Table 14: Association between tobacco chewing and oral mucosal lesions of study population (n=511)

Oral mucosal lesion	Tobacco chewing		χ^2 value	p value
	No (n=200) (%)	Yes (n=311) (%)		
Carcinoma	1 (0.5)	2 (0.6)	3.71	0.715
Herpetic gingivo stomatitis	9 (4.5)	12 (3.9)		
Leukoplakia	24 (12.0)	25 (8.0)		
Lichen planus	14 (7.0)	21 (6.8)		
Recurrent apthous stomatitis	13 (6.5)	19 (6.1)		
Stomatitis palatinus	3 (1.5)	2 (0.6)		
Submucous fibrosis	136 (68.0)	230 (74.0)		

Oral mucosal lesion between two tobacco chewing groups were summarised in number (n) and percentage (%) and compared by χ^2 test.

Both habits

The association between both habits (smoking and tobacco chewing) and oral mucosal lesions of study population were summarised in Table 15. The frequency (%) of sub mucous fibrosis (9.4%) was higher in non habits as compared to have both habits. In contrast, frequency of leukoplakia was higher in those who had both habits than those who had no habits. Comparing the oral mucosal lesions between two groups, χ^2 test showed significant difference in oral mucosal lesions between the two groups (χ^2=12.64, p=0.049). In other words, oral mucosal lesions may be associated to both habits (smoking and tobacco chewing).

Table 15: Association between smoking and tobacco chewing both and oral mucosal lesions of study population (n=511)

Oral mucosal lesion	Both (smoking and tobacco chewing)		χ^2 value	p value
	No (n=384) (%)	Yes (n=127) (%)		
Oral mucosal lesion type:				
Carcinoma	2 (0.5)	1 (0.8)	12.64	0.049
Herpetic gingivo stomatitis	17 (4.4)	4 (3.1)		
Leukoplakia	28 (7.3)	21 (16.5)		
Lichen planus	24 (6.3)	11 (8.7)		
Recurrent apthous stomatitis	24 (6.3)	8 (6.3)		
Stomatitis palatinus	5 (1.3)	0 (0.0)		
Submucous fibrosis	284 (74.0)	82 (64.6)		

Oral mucosal lesion between two smoking and tobacco chewing groups were summarised in number (n) and percentage (%) and compared by χ^2 test.

Discussion

The cause for occurrence of oral mucosal lesions is thought to be varied. Oral mucosal lesion may occur due to certain infections (bacterial, viral, fungal), local trauma and or irritation (traumatic keratosis, chemical burns), systemic disease (metabolic or immunological), or related to lifestyle factors such as the usage of tobacco, areca nut, betel quid, or alcohol. Assessment of oral mucosal condition is necessary for detection of premalignancy or an early cancer.[43]

Oral lesions can lead to interference of daily activities due to discomfort or pain that interferes with mastication, swallowing, and speech, producing additional symptoms such as halitosis, xerostomia, or oral dysesthesia, which hampers an individual's daily social activities. A state of tobacco epidemic with a larger population of tobacco users emerging day by day is seen in today's universe. In India, there are 240 million tobacco users , accounting for one –fifth of the world tobacco consuming population.[43] .

Many parts of Asia , mostly in India pan masala and guthka are easily available. Many brands of these products contain areca nut and tobacco, both of which have been implicated in occurrence of oral mucosal lesions & oral cancer.[43] India is 2nd largest producer & consumer of tobacco next to China.[44,45] In comparison to western country populations, in which oral cancer represents about 3% of malignancies, it accounts for over 30% of all cancers in India; this difference can be attributed to regional variation in the prevalence and pattern of habits.[46] Tobacco was introduced in India by Portuguese traders about 400 years ago.

According to the World Health Organization (WHO) estimates, in India, 194 million men and 45 million women use tobacco in smoked or smokeless forms.[47]

The WHO also predicts that India will have the fastest death rate attributable to tobacco in the future years. India also has one of the highest rates of oral cancers in the world, partly attributed to high prevalence of tobacco chewing.[48]

Tobacco use is basically of two forms – smoking and smokeless tobacco. In general, cigarettes account for only 20% of all tobacco consumed, while gutkha and chewing tobacco each account for about 40% of tobacco consumption.[49]

In India, the prevalence of cigarette smoking is very less. On the other hand, over half of all tobacco consumed in India is smoked as bidis and about one-fourth of tobacco consumption is in smokeless form. Bidi smoking and smokeless tobacco use continues to be practiced by a large percentage of the population in India. Smokeless tobacco use is twice as high as bidi smoking among adolescents. Initiation of use of these products among youth leads to lifelong adult tobacco use continues to be practiced by a large percentage of the population in India. Smokeless tobacco use is twice as high as bidi smoking among adolescents. Initiation of use of these products among youth leads to lifelong adult use.[50]

Although tobacco was initially smoked, it later became popular in a smokeless form. Of the 400 million individuals aged 15 years and above in India, 47% use tobacco in smoke form, while 16% use it in a smokeless form. About 250 million kilograms of tobacco is consumed each year, of which 86% is used for smoking, 13% in smokeless forms, and 1% as snuff.[50] Smokeless tobacco is used in diverse forms in different regions of India — for chewing, holding in the mouth, or applying over teeth and gums. Smokeless tobacco is chewed, more often as betel quid (*paan*), consisting of betel leaves (*Piper betle*), areca nut (*Areca catechu*), slaked lime and catechu (e.g., *Manipuritobacco*, *mawa*, *paan masala*). A mixture of tobacco and slaked lime (*khaini*) is kept in the mouth and sucked. Other products like roasted and powdered tobacco (*mishri*), dry snuff (*bajja*), or tobacco paste with molasses (*gudhaku*) are applied over the teeth and gums.[51]

The association of tobacco and oral cancer was noticed in India as early as 1902 by Niblock.[53]

Oral mucosal lesion (OML) is known as any abnormal alteration in color, surface, swelling, or loss of integrity of the oral mucosal surface. Although a proportion of Oral Mucosal Lesions are benign and require no active treatment, some may present with significant pathology. Of particular importance are oral potentially malignant disorders which may progress into malignancy. Besides, Oral Mucosal Lesions can interfere with daily quality of life in affected patients through impacts on mastication, swallowing, and speech with symptoms of burning, irritation, and pain.[53]

Early diagnosis is the most important single factor in combating oral cancer and improving survival rate. The purpose of this study is to investigate the prevalence of oral mucosal changes in individuals with smoking, chewing, and mixed habits.[54]

The prevalence of Oral Mucosal lesions and their malignant transformation rates varies globally. The prevalence of oral submucous fibrosis (OSMF) ranged from 0.4% to 1.2%.[56] and the frequency of malignant transformation has been reported to vary from 7.6% to 40%).[57,58]

The prevalence of leukoplakia varied from 0.2% to 4.9%[57,58]. The malignant transformation of leukoplakia range from 3.6% to 17.5%.[59,60] Erythroplakia is not as common as leukoplakia and has an incidence of 0.02–0.83%.[61,62,63] reported the global mean prevalence of oral erythroplakia to be 0.11% (0.01–0.21%). All erythroplakia cases show some degree of epithelial dysplasia in which 51% were invasive squamous cell carcinoma,[64]

A cross – sectional study design was employed to assess the prevalence and types of oral mucosal lesions in rural areas of Lucknow. Adults, both males and females aged 35 to 65 years from the rural areas of Lucknow. Disease prevalence is usually determined by cross sectional studies. To the best of our knowledge, this is the first study to provide data on the prevalence and characteristics of Oral Mucosal Lesions in 35 to 65 years rural population around Lucknow.

Data collected in small surveys in Uttar Pradesh show high tobacco use. In the sentinel survey of individuals 10 years and above in rural Uttar Pradesh, 51% of males were tobacco users(28.2% smokers and 24.5 % smokless users, while 9.2 % of females used tobacco mainly in smokeless forms. In the Urban areas of the some districts,45% males were tobacco users(24% smoked, 22.5 % used smokeless tobacco) and 8.2 % of females were users again mainly in smokeless forms.[65]

Examination comprised of few questions regarding the tobacco habit and clinical assessment of the oral mucosal lesions was done according to the criteria's given in the " **Guide to epidemiology and diagnosis of oral mucosal disease and conditions**"[12] the guide had provided a standard system for the examination, identification and recording of a wider range of oral mucosal conditions : in particular, those that had significant implications in relation to urgent needs for

treatment or for prevention. Hence the Guide was chosen for the study. Enormous literature stands evidence to this. Few studies are Taiyeb Ali T.B et al[66], Zain Rosnah Binti et al[67] JD Shulman[68], Dunder Nesrin and Illhar Kal Betul[69], Mehrotara Ravi et al[33], Patel Priyanka et al.[36] No histopathological examination were conducted to stand the complement the oral mucosal lesions with contraindication, Ramandeep Singh Gambhir et al[31] proformed incisional biopsies in his studies to compare oral mucosal lesions.

In this study, Mean age of the study population 47.59 $^{+}$_ 9.46years. This age group was chosen by us. it would exhibit accumulation of the risk factor in causing the disease. Ramandeep Singh Gambhir et al[31] in study also supported the higher prevalence of Oral Mucosal Lesions in the age group of 31- 40 years. This was attributed to their long standing oral habits. Age was significantly related with the development of Oral Mucosal Lesions.

In present study reported a higher prevalence of male participants 66.1% and 33.9% were females. this could probably be due to the higher presence of risk factor in the males group. this result is in comparison with the study conducted by M.Krishna .Priya et al[32] who also found the number of females participants was 4% which was very lower. when compared to males 96%.This difference could be related to the difference in habit frequency between male and female individuals, diet, or other factors.

In our study, the prevalence of Oral Mucosal Lesions was 56.7%, which is higher than reported by Rakhi chandak et al[14] also found 39.25%. which is lower than our study. Mathew et al[42] also found similar rate of prevalence of oral mucosal lesion which was 41.2 % It is important to mention that it is difficult to compare results with those of other studies because of the methodological variability and sociocultural and demographic differences present in the studied populations. Tobacco contains N-nitroso compounds, well known carcinogens, which play a key role in the malignant transformation in the oral cavity.

In our study prevalence of oral sub mucous fibrosis is 71.6%, the a study done by Jameema et al[17] the occurrence of Oral sub mucous fibrosis was 36%, 36%.Yet a study done by Shalini Gupta et al[25] also found 71% of oral sub mucous fibrosis

which was similar with our study. It could be noted that oral sub mucous fibrosis was the predominant lesions in our study.

In our study prevalence of Leukoplakia was 9.6% results noted. Another study done by Jeemma et al[47] who found Leukoplakia to be 54% present. Kumar et al[20] also noted 10.5% prevalence study, while Petti et al[59] found 4.9% which is similar with our study findings.

In the present study, only 3 individuals had carcinoma (0.6%) which is similar to the findings of Rakhi Chandak et al[14] who found 4 individuals with carcinoma who were tobacco chewers, while 3 individuals belong to mixed habit group .Yet another study done by Kumar et al found 51% carcinoma, which was higher when compare to our study

In our study prevalence of Lichen Planus was reported to be 6.8% while another study done by Rakhi Chandak et al[14] who found 6% Lichen Planus ,which is similar with our study. Yet another study done by Saraswathi T R et al[60] found 0.15% Lichen Planus in their study population.

In the present study the prevalence of recurrent apthous stomatitis was 6.3% which was higher then study done by Saraswathi T R[60] et al who found 0.89%. in another study done by Ravi M[73] et al, the authors' found 0.1% prevalence which was contrast with our study.

The prevalence of Herpetic gingivo stomatitis in our study was 4.1%, which was high then the study done by Ravi M et al[73] who reported 0.67%. Yet another study done by G.Murucu et al[72] who reported 4% which is similar with our study.

The prevalence of Stomatitis Palatinus in our study was 1.0% which was similar with study done by G.Murucu et al[72] who reported 0.5% in a Turkish population.

In our study, the prevalence of smoking tobacco on regular basis was 86.7% and chewing tobacco 87.5% which was higher with the study done by Newfield et al[74] who found the prevalence of smoking tobacco is 16.2% and chewing tobacco is 14% in their study population. one more study done by Saraswathi TR et al[60] who found the overall prevalence of smoking 15.02% and chewing tobacco is 6.99% ,Vellappally et al[75] found that in a survey of 805 subjects ,the highest prevalence of oral mucosal

lesions were present in tobacco chewers 22.7%,followed by regular smokers 12.9%,occasional smokers 8.6%. the difference of higher habit frequency in the present study could be because of the age group chosen (35-65yrs). People in rural areas believe that tobacco has many medicinal properties in getting rid of foul smell, curing toothache, controlling morning sickness and maintaining the oral hygiene. An increasing number of individuals are indulging in various deleterious habits due to easy availability of products, peer pressure, various advertisement etc. Indicating that the trend of usage is deep rooted and not a recent one and this is also supported by a study done by Pednekar and Gupta in 2004[70].

In our study we found that the prevalence of both smoking and chewing habits of 24.9% which is dissimilar another study done by Ambekar DM et al[24] who found the 14% the overall prevalence of both smoking and chewing habits (mixed users). Singh Gambhir et al[31] done a study who found 4.5% of the subjects were in the habits of both smoking and chewing tobacco which is highly contra- indicatory.

In our study we found that prevalence of smoking habit was 63.5%, tobacco chewing habit 60.9%, both smokers and chewers were 24.9% and another study done by Patel Priyanka et al[36] who found that habit of tobacco use in 3030 subjects were 635 (21%) smokers,1272 (42%) tobacco chewers,341 (11%) smokers and chewers both. which is lower than our study.

A strong association was obtained with habits (smoking and chewing tobacco) to the incidence of Oral Mucosal Lesions in the present study. In People who were smokers, oral mucosal lesions was present statistically significant level with p value of 0.001 (χ^2=31.90).this was similar to the study finding of Shalini gupta et al[25] & Ravi mehrotra et al[33].

In the present study the right and left buccal mucosa were found to be the most common sites of occurrence which is 48.7%.The another study also supported, done by Mehrotra Ravi et al[33] also found that buccal mucosa was most common site 53%.Garcia-Pola et al[72] and Mathew et al[42] also found the buccal mucosa was the common sites for the oral mucosal lesions.

The prevalence of oral lesions in population has been documented in otherparts of the world like Colombia, Mexico, Brazil , Chile , Spain , Argentina , USA, Israel

Cambodia[50], mainly based on clinical evaluation of the lesions. Conducted prevalence studies based on the clinicopathological correlation, evaluating the biopsies of the observed lesions to further confirmed the study diagnosis.

The findings from this study can be used to design case control or cohort studies to further understand the relation between habits and oral lesions. Studies of this nature could potentially help clinicians in identifying high- risk population and which would be most beneficial for providing better oral hygiene programs. Programmes to improve oral health should be conducted regularly to promote oral health care in the population.

Limitations

1. Since the information on habits was garnered by the study population using a questionnaire, the possibility of an information bias should be considered while interpreting the results.

2. Another limitation of the study was that due to the rather small sample size survey, there can be lack of generalizability and limited statistical significance.

3. Detection bias is a possibility, knowing the exposure status of subjects looking harder for lesions in those subjects. As the self-reported tobacco usage status was not verified using other means like urinary cotinine test and EtG (Ethyl Glucuronide) test, there is a possibility of reporting bias, although self-reports are reliable and commonly used in epidemiological research.

Recommendations

1. Dentist should spend quality time in counseling and helping the habituated people to quit tobacco.

2. Health education regarding adverse effects of tobacco should be imparted to the rural society with prime focus to outreach programmes and community health programmes.

3. Anti tobacco programmes and tobacco control campaigns should be a part of school dental health programmes in rural areas such that the habit should be stopped from being taken by the young generations.

4. Inspite of the recent curbs on the manufacture and sale of tobacco products, the government has to take strict action to pass stringent rules and laws to cut down the sale of tobacco.

5. Oral health promotion of these individuals has to be brought under the regular provision of dental services. As a Public health dentist it becomes our duty of imparting education regarding the harmful effects of tobacco and conduction of tobacco cessation programmes, in every outreach programmes.

6. The need for continuing educational campaigns at various levels to educate the public about the risk factors and early signs/symptoms was also highlighted. Health care workers must be encouraged to perform oral cancer examinations as part of their patient care regime, and to be knowledgeable about early signs of oral cancer and premalignant disorders.

7. Workplace screening programs for detection of oral malignant and premalignant disorders in these groups is suitable and cost effective alternative measure and emphasis

should be given to the management of the industries for organizing regular screening of oral and general health.

8. Effective utilization of existing infrastructure and manpower through involvement of medical and dental colleges in the areas can also help in screening and early diagnosis.

9. Industries should be promoted to ban sale and use of tobacco related products in around the workplace which would decrease the usage of the product and overall might reduce the disease prevalence and severity of the oral premalignant and malignant lesions.

Conclusion

Following conclusions can be drawn from the study done :

1. The result of the present study provides information about the prevalence of oral mucosal lesions was found 511 cases thus accounting prevalence of 56.8%.
2. Tobacco consumptions was found among 338 male subjects (66.1%), whereas females were 173 subjects (33.8%).
3. The oral mucosal lesions had thus male predominance with 2.0 : 1.0 (male : female) ratio.
4. The prevalence of smoking bidi was in 220 subjects (43.1%), whereas smoking cigarette was in 104 subjects (20.4%).
5. The prevalence of tobacco chewing habit was in 311 subjects (60.9%), whereas 39 subjects (12.5%) occasionally and 272 subjects (87.5%) were take it regularly.
6. The prevalence of both habits (smoking and chewing tobacco) of oral mucosal lesions was found in 127 (24.9%) subjects
7. The distribution of oral mucosal lesions of study population were mostly had Oral sub mucous fibrosis (71.6%), Leukoplakia (9.6%),Lichen planus (6.8%), Recurrent apthous stomatitis (6.3 %), Herpetic gingivo stomatitis (4.1%), Stomatitis palatines (1.0%) Carcinoma (0.6 %).
8. A positive association was noted between smoking habit and prevalence of oral mucosal lesions with a p value of 0.001.
9. A positive association was noted between the usage of habits (both smoking and chewing tobacco) to Oral Mucosal Lesions prevalence at p value of 0.049.

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Annexures

ANNEXURE-1

BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES
(FACULTY OF BBD UNIVERSITY), LUCKNOW

INSTITUTIONAL RESEARCH COMMITTEE APPROVAL

The project titled **Prevalence of Oral Mucosal lesions among 35-65 years age group in rural area around Lucknow. India** submitted by **Dr. Vivek Singh** Post graduate student from the Department of **Public Health Dentistry** as part of MDS Curriculum for the academic year 2016-19 with the Accompanying proforma was reviewed by the institutional research committee present on **7th April 2017** at BBDCODS. The Committee has granted approval on the scientific content of the project. The proposal may now be reviewed by the institutional ethics committee for granting ethical approval.

Prof. (Dr).Vivek Govila

Principal

PRINCIPAL
Babu Banarasi Das College of Dental Sciences
(Babu Banarasi Das University)
Faizabad Road, Lucknow-226028
BBD Univ.

Chairperson, Institutional Research Committee

Babu Banarasi Das University
Babu Banarasi Das College of Dental Sciences,
BBD City, Faizabad Road, Lucknow – 226028 (INDIA)

Dr. Lakshmi Bala
Professor and Head Biochemistry and
Member-Secretary, Institutional Ethics Committee

Communication of the Decision of the V[th] Institutional Ethics Sub-Committee

IEC Code: 38 **BBDCODS/03/2017**

Title of the Project: Prevalence of [illegible]al Mucosal lesions among 35-65 years age group in rural area around Lucknow.

Principal Investigator: Dr. Vivek Singh

Department: Public Health Dentistry

Name and Address of the Institution: BBD College of Dental Sciences Lucknow.

Type of Submission: New, MDS Project Protocol

Dear Dr. Vivek Singh

The Institutional Ethics Sub-Committee meeting comprising following four members was held on 02[nd] March, 2017.

1.	Dr. Lakshmi Bala Member Secretary	Prof. and Head, Department of Biochemistry, BBDCODS, Lucknow
2.	Dr. Neerja Singh Member	Prof. & Head, Department of Pedodontics, BBDCODS, Lucknow
3.	Dr. Rana Pratap Maurya Member	Reader, Department of Orthodontics, BBDCODS, Lucknow
4.	Dr. Manu Narayan Member	Reader, Department of Public Health Dentistry, BBDCODS, Lucknow

The committee reviewed and discussed your submitted documents of the current MDS Project Protocol in the meeting.
The proposal was reviewed, comments were communicated to PI thereafter it was revised.

Decisions: The committee approved the above protocol from ethics point of view.

Lakshmi Bala 20/4/17
(Dr. Lakshmi Bala)
Member-Secretary
IEC

Member-Secretary
Institutional Ethics Committee
Babu Banarasi Das College of Dental Sciences
BBD University
Faizabad Road, Lucknow-226028

Forwarded by:

(Dr. Vivek Govila)
PRINCIPAL
Principal
Babu Banarasi Das College of Dental Sciences
(Babu Banarasi Das University)
BBDCODS
BBD City, Faizabad Road, Lucknow-226028

Department of Public health Dentistry

Prevalence of Oral Mucosal Lesions among 35-65 years of age group in rural area around Lucknow, India.

W.H.O Assessment form for oral mucosal lesions 1980

ANNEXURE:-II

(1) T 1 (5) Date.....19 (6)(7) Registration No. (8)(12)

PERSONAL AND DEMOGRAPHIC INFORMATION

Sex M=1, F=2 (13)

Age in years (14) 4 1 (15)

Ethnic group (16)

Religion (17)

Occupation Supervisor (18)

Diet Mixed (19)

Name Ram Baran Yadav
Family Other

Address

Geographic location (20)(21)

Examiner (22)

SMOKING HABITS

1 = Occasionally
2 = Regularly

If no habit present - leave box blank

		Number per day	Duration years
Cigarettes	(23)	(24)	(26)
Cigars	(28)	(29)	(31)
Others (specify)	(33)	(34)	(36)
		Grams per week	
European pipe	(38)	(39)	(41)
Water pipe	(43)	(44)	(66)
Others (specify)	(48)	(49)	(51)

CHEWING AND OTHER HABITS

1 = Occasionally
2 = Regularly

Location of quid
1 = Left side
2 = Right side
3 = Both sides
4 = Others (specify)

		Number per day	Duration years	
Areca nut, lime and leaf	(53)	(54)	(56)	(58)
	(59)	(60)	(62)	(64)
Tobacco chewing	(65) 2	(66) 2 0	(68) 2 0	(70) 3
Other habits (specify)		Grams per week		
Areca nut, lime and leaf	(71)	(72)	(74)	(76)
Areca nut, lime and leaf	(77)	(78)		

1

WHO ASSESSMENT FORM FOR ORAL MUCOSAL DISEASES

(1) T 1 (5) Date ..... 19 (6) (7) Registration No. (8) (12)

If no disease or condition present - leave box blank.

CODES

Carcinoma
Leukoplakia: 1 = Present; 1 = Smooth & fissured, 2 = Ulcerated, 3 = Nodolo-speckled
Erythroplakia
Lichen planus: 1 = Present; 1 = Atrophic or ulcerative, 2 = Other types
Submucous fibrosis: 1 = Present
Candidiasis: 1 = Acute pseudo-membraneous, 2 = Other types

Location code		Carcinoma	Leukoplakia	Erythroplakia	Lichen Planus	Submucous Fibrosis	Candidiasis	
						1		(20)
						19/20		(28)
								(36)
								(44)
								(52)
								(60)
								(68)

(13) (21) (29) (37) (45) (53) (61)

Leukokeratosis nicotina palatin (69)

Herpetic gingivostomatitis (70)

Acute necrotizing gingivitis (71)

Cancrumoris (72)

Recurrent aphthae (73)

Other specify..... (74)

..... (75)

PREVIOUS TREATMENT

0 = unknown 1 = yes (76) 0

Biopsy 1 = punch, 2 = incisional (77)

Photograph 1 = yes (78)

TREATMENT REQUIREMENTS

0 = none
1 = Oral hygiene instruction only
2 = Recommended change of habit and follow-up
3 = Treatment needed
4 = Urgent treatment needed with referral

(79) 3

ANNEXURE-3

Formula used for the analysis

Arithmetic Mean

The most widely used measure of central tendency is arithmetic mean, usually referred to simply as the mean, calculated as

$$\bar{X} = \frac{\sum_{i=1}^{n} X_i}{n}$$

Standard deviation and standard error

The standard deviation (SD) is the positive square root of the variance, and calculated as

$$SD = \sqrt{\frac{\sum X_i^2 - \frac{(\sum X_i)^2}{n}}{n-1}}$$

and SE (standard error of the mean) is calculated as

$$SE = \frac{SD}{\sqrt{n}}$$

Where, n= no. of observations

Minimum and Maximum

Minimum and maximum are the minimum and maximum values respectively in the measure data and range may be dented as below

Range = Min to Max

and also evaluated by subtracting minimum value from maximum value as below

Range = Maximum value-Minimum value

Median

The median is generally defined as the middle measurement in an ordered set of data. That is, there are just as many observations larger than the median as there are smaller. The median (M) of a sample of data may be found by third arranging the measurements in order of magnitude (preferably ascending). For even and odd number of measurements, the median is evaluated as

$$M = [(n+1)/2]^{th} \text{ observation- odd number}$$

$$M = [n(n+1)/2]^{th} \text{ observation – even number}$$

Chi-square test

The chi-square (χ^2) test is used to compare the categorical data as

$$\chi^2 = \Sigma\Sigma \frac{(Fij - fij)^2}{fij}$$

where, F_{ij} is the observed frequency while f_{ij} the expected frequency. The degrees of freedom (DF) is calculated as

$$DF = (r-1)(c-1)$$

Statistical significance

Level of significance "p" is the probability signifies level of significance. The mentioned p in the text indicates the following:

$p > 0.05$	Not significant (ns)
$p < 0.05$	Just significant (*)
$p < 0.01$	Moderate significant (**)
$p < 0.001$	Highly significant (***)