STUDY PROTOCOL

An epidemiological study of oral tobacco use amongst urban slum inhabitants in a town from central urban India [version 1; peer review: awaiting peer review]

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First published: 19 Jul 2023, 12:847
https://doi.org/10.12688/f1000research.136353.1
Latest published: 19 Jul 2023, 12:847
https://doi.org/10.12688/f1000research.136353.1

Abstract

Background: Smokeless tobacco users receive levels of nicotine known to be addictive, and clinical symptoms of dependency and withdrawal for smokeless tobacco are identical to those for cigarettes. Smokeless tobacco usage patterns share significant parallels with patterns of use of other addictive drugs. Because everyone spits after using oral tobacco, there are more persons who spit in public due to its use. Use of smokeless tobacco during pregnancy increases the chance of low-birth-weight babies by two to three times and is linked to stillbirths. Other negative health implications of smokeless tobacco use include dental decay, gum recession, high blood pressure, oral sub-mucous fibrosis (OSF), a crippling disorder, and mouth and food pipe malignancies. This warrants the study of patterns of oral tobacco use and its determinants in urban slum areas.

Objective: To estimate the prevalence and patterns of oral tobacco use and assess the motivating and demotivating factors associated with it amongst urban slum inhabitants.

Methods: A community-based cross-sectional study will be conducted in the urban field practice area of a tertiary care hospital. A semi-structured questionnaire assessing the socio-demographic profile, prevalence and pattern associated factors for oral tobacco use among the study participants will be implemented.

Study implications: This study will help to determine the prevalence and pattern of oral tobacco use, as well as the motivating and demotivating factors that contribute to oral tobacco use. Insights gained shall be useful to implement focussed prevention strategies.

Keywords
Tobacco use, Oral tobacco, Urban slum, Epidemiological study.
This article is included in the Datta Meghe Institute of Higher Education and Research collection.

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**Author roles:** Kuruwanshi S: Conceptualization, Visualization, Writing – Original Draft Preparation, Writing – Review & Editing; Joshi A: Supervision, Validation, Writing – Review & Editing

**Competing interests:** No competing interests were disclosed.

**Grant information:** The author(s) declared that no grants were involved in supporting this work.

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**How to cite this article:** Kuruwanshi S and Joshi A. An epidemiological study of oral tobacco use amongst urban slum inhabitants in a town from central urban India [version 1; peer review: awaiting peer review] F1000Research 2023, 12:847 https://doi.org/10.12688/f1000research.136353.1

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Introduction

The United Nations’ World Health Organization (WHO) oversees global public health. The primary goal of the WHO, according to its constitution, is to ensure that everyone has the best possible level of health. Smokeless tobacco users receive levels of nicotine known to be addictive, and clinical symptoms of dependency and withdrawal for smokeless tobacco are identical to those for cigarettes. Smokeless tobacco usage patterns share significant parallels with patterns of use of other addictive drugs. The mandate of the WHO calls for global collaboration to enhance health, uphold world peace and harmony, and assist the vulnerable. It encourages a billion more people to participate in monitoring public health risks, coordinating emergency medical response efforts, promoting health and wellness, and implementing universal health care.

Smokeless tobacco is made from tobacco leaves that are harvested when they turn yellow and brownish stains begin to develop. The leaves are then uniformly dried in the field, tied into bundles with water or molasses to keep them moist, and then stored for a few weeks to ferment. There are several issues with South Asia's smokeless tobacco use in urban slum dwellers. To prepare tobacco for these uses, tobacco leaves are harvested when they turn yellow and brownish stains begin to develop. The leaves are then uniformly dried in the field, tied into bundles with water or molasses to keep them moist, and then stored for a few weeks to ferment. There are several issues with South Asians using smokeless tobacco. It is widely used and becoming more so, especially with the introduction of new smokeless tobacco varieties in recent years that have attracted more consumers.2

Transport employees who are under stress are more likely to abuse alcohol and other drugs, with cigarettes being the most popular. There has been research on a connection between smoking and job stress. It is often believed that a substantial percentage of bus drivers and other employees smoke cigarettes. The second leading cause of death worldwide and the leading contributor to morbidity and mortality that may be prevented is tobacco smoking. Oral malignancies and possibly malignant lesions, the degree and depth of periodontal disease, and poor wound healing are the most harmful impacts of tobacco use on the oral cavity.3 Although its use varies around the world, betel quid (pan), the most popular type of smokeless tobacco, quickly adopted tobacco as a new ingredient after its introduction. However, the legal gaps are being effectively used. For instance, replacements like “supari mix” packets are offered for sale with a free packet of Zarda or Khaini chewing tobacco. Except for a few limited geographic locations, both men and women regularly chew betel nut, but smoking tobacco is far more prevalent among men in Bangladesh, India, Pakistan, and Sri Lanka than among women.4 To enable the creation and implementation of efficient intervention plans, this knowledge is necessary. The goal of the current report is to analyse in depth the smoking habits of a community in northern India and how they relate to the three different living strata, namely urban, urban-slum, and rural. However, the amount of substance being consumed, and the age of commencement are frequently not mentioned in these questionnaires. Studies on the epidemiology of coronary heart disease and its risk factors have either concentrated on urban or rural settings. studied the incidence of tobacco usage in northern Indian villages, towns, and cities.5 But it is crucial to emphasize a few points that are crucial for comprehending how addicted smokeless tobacco is. The use of smokeless tobacco rapidly increased, the products were found to be carcinogenic, and the demographics of users abruptly changed, all of which led to the development of smokeless tobacco addiction as a public health issue in the United States in the middle of the 1980s. Older folks were the main consumers of its products, and when they died off there were no new consumers to take their place. The smokeless tobacco business turned this trend around by creating new products, notably moist snuff products, and employing strong marketing techniques.6

Rationale

India is a diverse nation that is home to numerous cultures, faiths, and languages in addition to various socioeconomic classes. Community health is a concern for all swaths of society, including the poor, the wealthy, children, adults, the elderly, men, and women. The Tobacco Control Team for the India Region works to reduce the burden of illness, mortality, and the financial costs associated with tobacco use and passive smoking. Tobacco use is currently the leading cause of death that may be prevented worldwide. Depending on the metastasis’s location and features, other structures including the internal jugular vein, sternocleidomastoid muscle, or spinal auxiliary nerve may need to be sacrificed.7

A significant portion of the nation’s gross domestic product (GDP) and export earnings come from the production of tobacco, which is exported in 98 percent of cases. Typically, the crop accounts for roughly 10% of GDP, 30% of overall exports, and more than 50% of agricultural exports. The Tobacco Control team works to reduce the burden of illness,
mortality, and the financial costs associated with tobacco use and exposure to passive smoking. Currently, smoking is the leading preventable cause of mortality in the world. For smokeless tobacco control, various strategies are required, including media campaigns and related programmes. Variable tobacco industry marketing tactics, lax enforcement of tobacco control laws, persistent affordability, and incomplete knowledge of the health hazards of tobacco use are all contributing reasons that are raising the use of smokeless tobacco.8

Objectives

Primary objective
To study the prevalence of oral tobacco usage amongst residents from an urban slum in central urban India

Secondary objectives
1. To study the pattern of oral tobacco usage amongst residents from an urban slum in central urban India.
2. To assess the motivating and demotivating factors associated with usage of oral tobacco in our study settings.

Protocol

Study design and duration
A cross-sectional study will be conducted in Wardha district from June 2023 to Nov 2023.

Setting
The present study will be conducted in the urban slums of Wardha District.

Participants
Both male and female adult inhabitants of urban slums from the field practice area of the urban health training center of institute will be approached by door-to-door household surveying using the systematic random sampling method.

Eligibility criteria
Inclusion criteria: Study participants (>18 years) who are willing to participate.

Exclusion criteria: Study participants (>18 years) who do not consent to take part in the research study.

Sampling method: The personal interview method will be used to visit the households to reach the sample size.

Variables
1) Oral tobacco use
2) Types of oral tobacco used
3) Motivating & demotivating factors

Data sources
Information on the participants’ knowledge, attitudes, and perceptions of tobacco use gathered used a questionnaire that modified from the Global Youth Tobacco Survey and the Global Adults Tobacco Survey (Table 1). This questionnaire is designed to obtain data on tobacco usage, including the type of tobacco used, how long used, when people first started chewing tobacco etc.

Data analysis plan
The data collected will be entered into a Microsoft Excel spreadsheet.

Descriptive statistics like mean, frequency and percentages of various parameters will calculated, the Open Epi version 3.01 Epi Info software (https://www.openepi.com/Menu/OE_Menu.htm) and data will be presented using tables and graphs.
Table 1. The study variables and questionnaire.

<table>
<thead>
<tr>
<th>SN</th>
<th>Key study parameters</th>
<th>Variables</th>
<th>Data Sources</th>
<th>Data collection method</th>
</tr>
</thead>
</table>
| 1. | Socio-demographic profile | • Age  
• Education  
• Occupation  
• Economic status | Households from field practice area from Urban Health Training Centre, Wardha | Interview method using a Questionnaire |
| 2. | Assess the pattern of oral tobacco use | • Early initiation  
• Oral tobacco duration  
• First time chewing tobacco | Households from field practice area from Urban Health Training Centre, Wardha | Interview method using a questionnaire |
| 3. | Assess the motivating and demotivating determinants | Ever thought of quitting tobacco  
Have you ever stopped in the past  
What were the motivating factors for stopping the habit | Participants who consume tobacco | Interview method using a questionnaire |

Bias: There may be information bias and selection bias and social desirability bias in this study.

Selection bias will be addressed using systemic random sampling, and information and social disability bias will be minimized as much as possible by building good rapport with study participants and making the beneficiaries understand the importance and objective of the study.

Study size: The average population is around 28,000. Using formula \( n = \frac{pq}{L^2} \) and precision 10% sample size comes to be around 384 using prevalence 51% as per previous studies.

**Quantitative variables**

1. Data analysis on the quantitative variables

Descriptive Statistics like mean, frequency and percentages of various parameters will calculated, via the Open EPI Software and data will be presented using tables and graphs. Inferential statistics like chi square tests will be used.

2. Different types of households in urban city areas use these tobacco products in different ways, so such households in field practice areas will be selected using systematic random sampling

Statistical method: Data will be entered using Microsoft Excel. All the responses will be tabulated, and graphical representation will be made wherever necessary. Data will be analysed by using the Open Epi Info software which is freely available in the public domain.

**Expected outcomes/results**

Through our study we expect to assess the prevalence and pattern of oral tobacco use and its determinants in urban slum area and plan preventive strategies accordingly.

**Ethical consideration**

Ethical approval for this study (DMIHER (DU) IEC/2023/643) was provided by the Ethical committee of Data Meghe Institute of Higher Education and Research (Deemed to be University) on 11/02/2023.

**Discussion**

Squamous cell carcinomas of the oral cavity (OSCC) make up a large percentage of cancer cases in India. The two most dangerous forms of oral cancer, with a higher incidence in India, are buccal mucosa and tongue OSCC. Patients with oral cancer are always expected to require an intubation or a difficult airway. The safest way to perform nasotracheal intubation in these circumstances is with FOB assistance. By autocrine and paracrine production of different growth factors, cytokines, and multiple proteolytic enzymes, the cancer-associated fibroblast would have the capacity to create an
aggressive tumour phenotype. Invasive behaviour, local recurrence, and survival of carcinoma are all predicted by the expression of -SMA. The main imaging modalities for loco-regional staging of head and neck squamous cell carcinoma continue to be CT and MRI. Both techniques aid in the evaluation of the primary tumour and the identification of non-palpable lymph nodes. Nevertheless, to distinguish between benign and malignant lymph nodes, both techniques rely on size-related and morphological parameters. This choice justifies a trustworthy and economical strategy in patients with early-stage oral cancer. For minor to severe oral cavity deformities, inferiorly based islanded nasolabial flaps offer a one-stage procedure that is safer, quicker, and more dependable.

**Key results**

The study will provide knowledge and awareness regarding the initiation of oral tobacco use amongst urban slum inhabitants in both male and female.

The information gathered in the study can further help decide what lifestyles and setting is responsible for oral tobacco problems in male and female. Moreover, the need to promote healthy lifestyle and proper assigning of lifestyles to avoid oral tobacco problems. Women with conditions where oral tobacco is contraindicated i.e. untreated active oral Cancer.

**Limitations**

As the study is a cross sectional study being conducted at urban slums in catchment area of urban health training centre of a tertiary care hospital only so external validity of study shall be limited as prevalence and pattern and determinants of oral tobacco use may vary between geographical locations and prevailing socio-economic-cultural context.

As the study relies on participant’s response to oral tobacco use and perceptions, determinants there is chance of social desirability bias being introduced in the study.

**Interpretation**

In this study, the early initiation of oral tobacco use amongst urban slum inhabitants, exclusive tobacco consumption, determine the knowledge, attitude, and practice of oral tobacco use amongst urban slum inhabitants. Study explains the importance of early initiation of tobacco cessation as a public health priority and it is an important intervention strategy in reducing the oral disease, Avoidance of tobacco consumption and ensuring early initiation of tobacco cessation.

**Data availability**

No data is associated with this article.

**Acknowledgement**

I would like to thank Statisticians and Members of the Research Guidance Unit, Research & Development Cell, DMIHER for their contribution in a part of sample size calculation to the completion of research manuscript.

**References**


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