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### Smokeless Tobacco dependence and cessation measures in India

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#### **ABSTRACT**

India being the largest smokeless tobacco (SLT) producer and Keywords: consumer in the South East Asia Region (SEAR) entitled with a Smokeless Tobacco, Cessation, range of products. SLT consumption is very common because WHO-FCTC, Healthcare provider. it is associated with socio-economic and cultural perspectives in the India. After the implementation of the first treaty of the World Health Organization Framework Convention on Tobacco \*Correspondence to Author: Control (WHO-FCTC), public health standards were reaffirmed Dr. Ramu Venkatesan and improvised through successful implementation of articles Virtualis Services Pvt. Ltd., 17/B, since 2007 as reported in the global progress factsheet. Many measures have been implemented for achieving the success of Marg, Lower Parel-400013, Mum-WHO-FCTC in India and to control the huge disease burden in- bai, India. duced by tobacco use. The objective of the present study was to understand and explore the factors involved in the SLT demand reduction by revealing the dependence and cessation implemen- How to cite this article: tation in India in the context of strategies and policies. For this study, we searched for SLT dependence and SLT cessation literature survey in PubMed and obtained 102 literatures consisting of studies and reviews, which were further scrutinized by excluding the reviews, studies conducted abroad and studies conducted within the last 5 years (after 2015). No statistical significance of Aging Research, 2020, 3:68 was observed in comparison of National to International SLT dependence and an attempt to quit SLT following the tenure of a year. This is in-line with GATS-2 and international data. We have also discussed a diverse approach in the control of SLT at different levels-such as SLT users, healthcare professional, pol- eSciPub LLC, Houston, TX USA. icy advocates supplier, labeling, legal policies, and educating at Website: https://escipub.com/ various platforms. Effective strategies for the cessation of SLT is mandatory with proper guidance for the manufacturer, users and sellers in controlling SLT products.

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### Highlights:

- 1. COP3 act implemented for tobacco demand reduction in India.
- 2. Behavioral intervention is considered as an effective for SLT cessation.
- 3. Indian and International policies needs additional tool in controlling SLT demand.
- 4. Prevailing gap in adopting WHO-FCTC articles in governance of Indian SLT products.

#### Introduction

According to WHO-FCTC report, India is the third-largest tobacco producer globally, with the tobacco consumer capacity of 32.9% and 18.4% for chewing (SLT), and 24.3% and 2.9% for smoking <sup>1</sup> in males and females, respectively. Though SLT usage is high in India, the controlling measures and policies are not as effectively implemented as the policies for cessation of smoked tobacco (cigarette). SLT available in many forms, some are chewable tobacco: khaini, zarda, kiwam, gundi, betel quid with tobacco; areca nut with tobacco chewable: gutka, manipuri, mawa, dohra, beeda; applying tobacco: gudhaku, gul, creamy snuff, lal dantmanjan, mishri/masher; gaggling/sipping tobacco: tuibur, hidakphu, liquid form tobacco; and inhaling tobacco: snuff. SLT or any form of tobacco is a major leading cause for treatable diseases and death with an estimated 6.3 million victims yearly 2. Similarly, 8 million deaths are estimated due to tobacco consumption by 2030 in low and middleincome countries 3.

In the GATS-2 report on India (2016-2017), SLT users are approximately two-fold higher than the smokers (99.5 million). Also, the SLT users in India have reduced around 20% compared with the 2010 report. To reach the FCTC objective, intensifying measures have been detailed in the tobacco control program, as *gutka* and pan masala banned by Supreme court in 2004 and brought under a legal act-2.3.4 under Food Safety and Standards Act (FSSAI), 2006 <sup>3,4</sup>. Being an active synchronized member of WHO-FCTC, India has enforced rules and regulations

on production, supply, sale of tobacco products, distribution, advertisement, prohibition of sale near to educational centers, etc. through Ministry of Law and Justice (2003), Cigarette and Other Tobacco Products Act (COTPA) <sup>3, 5</sup>. India felt difficulty in the control of tobacco (SLT) because of regional complexity and being the second-largest consuming country (Males: 32.9%, Females: 18.4%) in SEAR <sup>1</sup>. In maintaining the socio-economic and cultural status, the attitude of SLT consumption is unrestrained, hence it is stringently intertwined in Indian practice.

The vast varieties of the SLT are scientifically proven with high addiction in the Indian culture similar to smoked tobacco products. The present scenario of the SLT products worsen the health status and addiction, and points to tough challenges in the global implementation of regulations. WHO-FCTC is an authenticated and reliable party to look after the control of all tobacco products (smoked tobacco and SLT) burden. The unresolved SLT issue combined with the lack of data globally leads to a delay in the implementation of the FCTC policy. Guidelines that are aimed at emphasizing the adaptation of FCTC demand reduction measures and cessation policies and requested the convention secretariat to maintain a database of parties, implementation reports and other international sources 6, 7. India has created 429 cessation facilities across the country functioning under the National Tobacco Control Programme (NTCP) and few community cessation clinics. Furthermore, India 8 and Thailand developed national tobacco cessation manuals in different regional languages. Additionally, NTCP launched telephonic helplines in trying to establish tobacco cessation at the national and district levels 8, 9. WHO-SEARO developed the following manuals in tobacco control and cessation at the healthcare provider level:

- a) Helping People Quit Tobacco: A Manual for Doctors and Dentists.
- b) Tobacco Cessation: A Manual for Nurses, Health Workers and Other Health Professionals.

- c) Manual on Tobacco Control in Schools.
- d) Community Cessation Manual.

In order to address the tobacco burden associated with cancer incidence, many workshops were conducted by the Institute of Medicine (IOM) for the National Cancer Policy Forum along with suggested guidance for cancer treatment; tobacco dependence and cessation programs. Furthermore, the federal and state level laws and regulations in controlling tobacco use through the medium of tobacco control education; message and advocacy were implemented. Finally, the financial and legal challenges to tobacco control were overcome by expanding the infrastructure of tobacco control strategies <sup>10</sup>.

Similarly, the U.S. Department of Health and Human Services (USDHHS) conducted tobacco cessation programs and derived outcomes of nicotine replacement therapy (NRT) and provided NRT products (gum, patches or lozenges); interviewed assessment over the phone; customized quit plans; executing counselling service; biweekly follow-up calls for successful implementation of strategies; conducting an online survey every six months for the readiness of quit plan to ensure the success of the program.

The robust consumption of SLT products in India requires effective control and implementation through all types of legislative measures like production, supply, distribution, consumer, pricing, sale and taxation. Moreover, WHO-Global Action Plan has set a goal of 30% relative reduction in current tobacco use frequency by 2025 <sup>11</sup>. India has taken many measures in controlling tobacco consumption (smoking and SLT) through laws (COTPA, 2003), but still need some perfect tools and measures in tobacco cessation. Few are listed below:

#### i) Cessation at User level

India extends the clinic service of tobacco cessation through the Ministry of Health and Family Welfare, Government of India and WHO, which are now anticipated as a central node for National Tobacco Con-

trol Programme (NTCP). Tobacco cessation clinics (TCC) regularly register the tobacco user profile and document it. TCC set 5A's, a list of evidence-based intervention strategies, which have proven to be a successful tool for counselling <sup>12</sup>. Users continue consuming SLT products based on the different perceptions like community acceptance, unawareness of adverse health effects, addiction, work environment, lack of health provider attention, etc. Pratima Murthy et al carried out a survey on 58 Key Informants based on the WHO SEARO emphasized on inadequate knowledge on harm of SLT use between users and health care providers <sup>13</sup>. Many surveys state that users having a misconception about SLT having low health risk, a high intention of shifting between different forms of SLT products and low demand for SLT guit assistance. The results of the survey pointed out that SLT users resist enrolling in the list to encourage society to quit tobacco products. Specific attention cannot be created by targeting users by mailing, phone and advertisements on discussing guitting SLT products. Hence there is a need for some additional parameters like healthcare provider or counselor-based approach in the SLT cessation to users which fails otherwise due to a lack of knowledge at the user level.

# ii) Cessation at Healthcare provider stage

In U.S. high schools, consumption of SLT products by males is around13% <sup>14, 15</sup> as stated in the survey reported by CDC, 2012. The SLT users state their psychological perception of SLT usage is "a safe alternative for smoking" <sup>10</sup>. The U.S. Public Health Service (USPHS) guide for the users to quit/control/cessation of tobacco has a success rate of 66% by engaging in the 5A's strategy 16. It has instructed the health-care providers to apply manual

based practice on tobacco users by documenting, providing adequate training, resources, directing to counselors and recommending regular visits. The quitting tobacco counseling by health care providers is considered to be a successful intervention in the tobacco controlling program <sup>16</sup>. The doctors practice evaluating the environment and systems of tobacco users in a schematic process of queries (5A's; Ask, Advise, Assess, Assist and Arrange) which are updated in the patient chart. Few clinicians find that 70% of smokers ascribe to the acceptance of quitting and 32% acceptance was drawn using evidence based counseling/ medication <sup>17</sup>. Tobacco users are advised to visit at regular intervals, assistance to quit tobacco is provided, tobacco related illnesses are assessed and regular phone calls are arranged, electronic health records are created and E-visits for medical appointments are pursued <sup>18</sup>.

Tobacco cessation program directed tobacco users to undergo counseling mediated motivational interviews to encourage behavior change by providing them openended question sessions, tobacco cessation declaration and persuade online motivational classes through web based ap-(www.motivationalinterviewproach ing.org) made available <sup>16</sup>. Along with motivational interviews, users are provided a strategic plan of multiple clinicians, quitline specialists, practical counseling and medication for tobacco cessation. US-FDA has given approved medications for smoke cessation which is an alternative for tobacco products like nicotine-based replacements (gum, lozenge, transdermal patch, nasal spray and inhaler), bupropion SR and varenicline 16, <sup>19</sup>. Patients are motivated towards tobacco cessation through electronic referrals, quitline and follow-up, health education, etc. It creates patience to standardize electronic health record systems to coordinate and advise about smoke free environments by tracking clinical conditions <sup>16</sup>.

## iii) Cessation at Laws and Regulation level

In 2001, the European Union (EU) tobacco products directives enforced reduction of cigarette emissions and disclosed ingredients. It was revised for further control of tobacco product addictions in 2016. These include ban on characterized flavors; all promotional and misleading advertisement on tobacco products; notifying authorities before products get placed in the market by manufacturers; new labelling and reporting requirements. EU directives partially adopted the WHO-FCTC Articles 9 and 10 (Regulation of contents and disclosure of tobacco products), but still efforts are being made for better implementation of contents and disclosure of tobacco products. EU standards authorized the US-FDA regulation of the Family Smoking Prevention and Tobacco Control Act, 2009 by including the prohibition of reduced harm tobacco products and banning flavoured tobacco products with the exception of menthol <sup>20</sup>. The revised tobacco products directive (2014/40/EU) insisted manufacturers to produce the peer review report of the tobacco products and costs are to be borne by the industry <sup>21</sup>. According to the UK Tobacco Advertising and Promotion Act-2010, the promotion of tobacco products was prohibited from all images, news, music videos, films or TV advertisements. EU directives on Regulation of the contents of tobacco products (Article 9) instructed to display the general warning on the lateral side, front and back surface of pack/ package about the quote of quitting and/or picture warning of hazards of using tobacco products. At a regular interval of every 5 years the quit text should be replaced and picture warning with proper scientific and market development and displaying the quitline help number in the pack/ package <sup>21, 22</sup>.

Considering the public health and future, the United States signed the Tobacco Control Act (Family Smoking Prevention and Tobacco Control Act) on June 22, 2009 for the regulation of the manufacture, distribution, and marketing of tobacco products <sup>23</sup>. The act dealt with restrictions for marketing tobacco products to children, restriction for access of vending machines for children and modified packaging policy by reducing to 20 cigarettes per packet. Furthermore, tobacco brand sponsorship in the field of sports, entertainment, etc., was banned. A ban was also placed on flavored cigarettes (except for menthol) and promotional offers/ free samples were restricted. U.S. Food and Drug Administration Act (US-FDA) amended the Federal Food, Drug and Cosmetic Act in 2019which increased the minimum age to 21 for sale of tobacco products to adults. SLT products were required to be sold with adequate display area (20-30%) of warning labels in the package and announced warning quotes of tobacco causes mouth cancer, gum disease and tooth loss; harmful alternative for cigarettes; induces addictiveness, etc. FDA optimizes the policy for the alternative tobacco products with modified risk for registration under section 911 of the Federal Food, Drug, and Cosmetic (FD&C) Act provided with scientific data. FDA instructed the manufacturer/ companies to consider section 904(a)(1) by mentioning the ingredient list of the finished tobacco products. FDA requires the tobacco companies to register annually, sets compliance standards for tobacco products subjected to process

visits and inspection at every two years interval <sup>24, 25</sup>.

In India, according to the COTPA-2003 (Control of Tobacco Products Act) and National Guidelines for Tobacco Cessation, survey data obtained from NFHS2 & 3 revealed that the estimated prevalence rate of chewing tobacco consumption rose to 35.4% (men) and 18.2% (females) from 28.3% (men) and 12.4% (females). COTPA act deals with the prohibition of advertisement, provides guidelines and regulations of trade and commerce in production, supply and distribution of Tobacco products. After resolution of 39th WHO assembly, member states were urged to consider tobacco control strategies, plans and measures for protecting citizens with special attention to pregnant women and children by rejecting direct and indirect advertisement, promotion and sponsorship towards tobacco products 12, 5.

The act declares that the practice of control over the tobacco industry given directives to the state government. The policy encourages the creation of awareness for tobacco products by means of caution advertisement of tobacco use in any form like notice, circular, label, document or by oral announcement or musical, sound, smoke/gas display. Similarly, any kind of advertisement of tobacco products for the production, supply/ distribution in any mode (pamphlet, announcement, sound, display) is banned. The COTPA act strictly by prohibiting free sample supply, exporting tobacco products with grammatical variations and cognate expression for export outside India. Instructions are given for neat representation by writing, marking, stamp, printing, graphical matter on a package in any Indian regional language of the corresponding region or the English language in the tobacco product is only accepted to be

placed in the market. The access (sale, consuming) of tobacco products in any kind of public place (auditorium, hospital, railway waiting room, restaurants, amusement, public offices, court building, education building, libraries, public transport) is strictly prohibited and punishable. Tobacco product consumption in any public place should be physically separated by a closed partition; this provision is allowed by prescribing to the rules made under this act. Any kind of advertisement agent should be barred to sign the contract for promotion/advertisement of any kind of tobacco products. Using the trademark, the brand name of tobacco products should not be used to facilitate or sponsor any event. The sale of tobacco products to the students or the person under eighteen years of age should be rigorously forbidden.

In the case of supply/ distribution of any tobacco products, it should display all the details of products with specified warning including pictorial depiction of skull and crossbones in the packet/ package panel. All the warning write-ups in the package/ packs should be legible with major known

languages (English and/or Indian regional dialect or multiple language(s) along with English), prominent and noticeable with colored font size and bold. Import of tobacco products is a legal offense, any tobacco products required to show the nicotine and tar contents of their product and if suspicious, the inspection shall be carried out by rank officers (Sub-inspector of police or any Food or Drug safety officers). When there is any noncompliance with COPTA, 2003, the rank officer has the authority to question or seize the product and submit it to District jurisdiction court or the authority can place a fine in lieu of the confiscated items. In this junction, the affected person shall have the right to incline under the provisions of this act. In the same way, the law has given the facility to the owner to surrender a reason for confiscating within 90 days or can appeal to the court for judgement of confiscation. No further appeal can be made against the court order <sup>5</sup>. Few proceedings/ offence and the punishment in India against the action as mentioned in Table 1.

Table 1. Proceedings/ offence and the punishment in India

SI. No.	Offense	Punishment
1.	Failure to produce/ specify warning and nicotine and tar contents – First conviction	Rs.5000/- or imprisonment for 5 years or both
2.	Failure to produce/ specify warning of nicotine and tar contents  – Second conviction	Rs.10000/- or imprisonment for 5 years or both.
3.	Person sells or distributes tobacco products with no proper labelling/ specified warning and nicotine and tar contents – First conviction	Rs.1000/- or 1year imprisonment or both
4.	Person sells or distributes tobacco products with no proper labelling/ specified warning and nicotine and tar contents – Second conviction	Rs.3000/- or 2 years imprisonment or both
5.	Smoking in restricted places	Rs.200/-
6.	Advertisement of Cigarettes and tobacco products – First conviction	Rs.1000/- or 2 years imprisonment
7.	Advertisement of Cigarettes and tobacco products – Second conviction	Rs.5000/- or 5 years imprisonment
8.	Sale of cigarettes and tobacco products to below eighteen years age	Rs.2000/-

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# iv) Cessation at Self help guide – Application

In America, currently 22% of the SLT users are residing in towns and rural areas. According to the 2006 online SLT cessation program, 2523 SLT users were recruited through media, google advertisement, links through web sites, paid advertisement, direct mailing and targeted mails to healthcare professionals. Users showed interest and smoothly paved ways to help them to quit, hence online based self help guide through links and guidance through applications can increase the success rate of quitting SLT products <sup>26</sup>.

National Cancer Institute (NCI) funded a research program which tested intervention programs (RTIPs) and provided information for the self-help cessation manual for SLT users (both male and female) of all age ranges. The intervention supports SLT users very effectively for quitting in a short span of time. The program assisted SLT users with the booklet of cessation manual, education on health hazards by SLT products, 20 minutes of self-help guide videos and two supportive phone calls from tobacco cessation counselors <sup>27</sup>. Similar to RTIPs, many web-based self-help intervention programs appeared on the internet for international and national SLT users. This program collects data from users at sign-in level. 'Chew-Free.com' is an internet-based program which helps SLT users by giving different levels of education, self-help manuals and videos with links for counselling and phone call options.

In India, under the Ministry of Health and Family Welfare (MHFW), The National Tobacco Control Programs (NTCP) handle multifaceted approaches towards the tobacco cessation programs. Through this platform, multiple notifications to implement the WHO-FCTC guideline are

proposed, along with a cessation management program and a helpline for the tobacco users by directing them to Quitline, M-cessation (SMS) and counselling facilities at a district level. Along with the NTCP, few non-governmental organizations are also arranging tobacco control programs <sup>8</sup>. QuitX is a user-friendly webbased tobacco cessation application that utilizes a panel of counsellors, educating manuals and guidelines for the SLT users and also collects national and international data about the SLT users for featured surveys <sup>28</sup>.

## v) Future perspective of Monitoring & Cessation

SLT consumption associated with a lot of major health threats needs advance scrutinizing policies at various levels of approach in the production, composition, distribution, marketing, sales, user consumption, healthcare provider and policies. Vast burden of health risk associated with SLT products cannot be defended with negligible measures against the SLT. Interventions are poorly implemented or merely neglected and execution of cessation programs is remarkably less effective in comparison with smoking tobacco. The license criteria for the manufacturing, marketing, selling of SLT products should be tailored which in turn support the control of SLT and tobacco products <sup>29</sup>. Prioritizing the systematic approach of SLT dependence and cessation through health-care providers, counselors, pharmacotherapy and national quitlines, establishing the platform with less effort, cost-effective tobacco control policy and tobacco dependence treatment system can help the SLT users to guit at the earliest from the burden <sup>6</sup>. Enhanced SLT cessation intervention with a randomized controlled trial and cohort studies observed through multifaceted/ combination approach by sequential applying

of above intervention programs show a success rate of more than 50% <sup>30</sup>.

The strategy for selection of literature from Pub-Med is described in Figure 1:

### Methodology

The data for the review on the SLT dependence and cessation in India was collected from Pub-Med irrespective of the period of date or observations collected from national or state-level surveys. The data was scrutinized and screened for various parameters and the articles for reviewing were searched and selected for the period of 2015 to 2020 (last 5 years). The special consideration was given to screen the nicotine dependence and quit attempt in SLT users and discussed.

### Statistical analysis

Data were analyzed in GraphPad Prism Software version 5.01 for statistical variation in simple proportions. Statistical significance between two groups was analysed by Student's t-test using GraphPad Prism software. The difference and pattern of SLT quit attempt/ willingness and dependence use are reported in percentage. A P value <0.05 was considered as statistically significant.

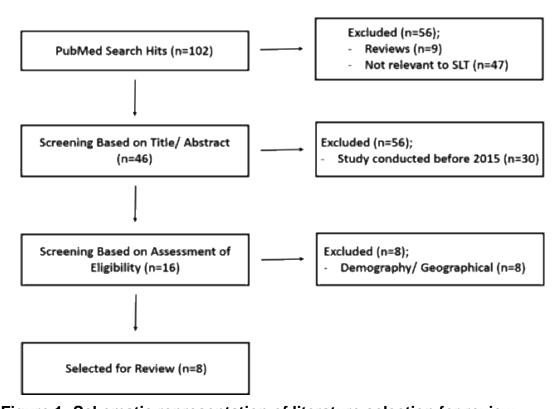


Figure 1: Schematic representation of literature selection for review.

#### Result

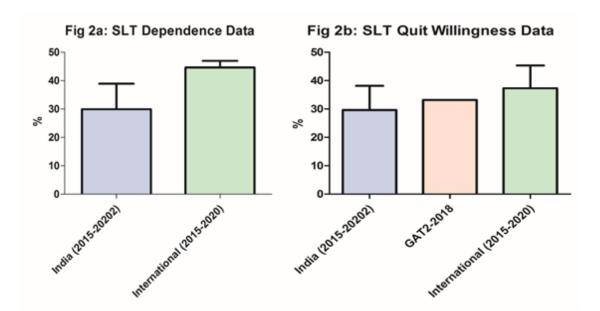
Majority of the SLT dependence and cessation survey in India concludes with higher dependence in SLT, especially from 258 respondents' report of Tertiary care hospital, Bhavnagar, Western India identified using Fagerstrom Test Nicotine Dependence (FTND). The result clearly indicates that the SLT users have consumed varieties of chewable tobacco forms such as mawa, vimal pan masala, zarda, khaini and

mishri, with most consumed being higher in men than women. Their higher dependency of chewable tobacco concerned to duration is 18.92±9.7 years, with the average age of tobacco chewing started in 23.31±6.45 years and the number of packets of chewable tobacco consumed is 3.77±1.99 per day. Also reported in the survey about the higher willingness/attempt to quit SLT products are 38.8% of respondents with at least one attempt in their life <sup>31</sup>. On the basis of the

questionnaire conducted with 759 participates in an industrial part of the Western region of India, the prevalence of SLT users of 28% (SLT alone) and 9.7% (smoking & smokeless tobacco) all fall in the age range of 18-54 years. Users with tobacco dependence score of 24% showed highest dependence rate with both the smoking & smokeless products whereas 17% of nicotine dependence observed in smokeless products predicted through FTND test (Figure 2a). The highest percentage (19-34%) of SLT users fall in the age of 21 to 45 years and 52.9% of users attempted to quit tobacco products at least once <sup>32</sup> which is identical to the SLT quit attempt in 12 months of GAT2, 2018 report <sup>1</sup> (Figure 2b).

Mohammed et al conducted the study by using 120 participants (60 cases leukoplakia and oral submucous fibrosis group and 60 control group) selected through dental hospitals around Chennai city. The participants consumed SLT products such as mawa, pan masala, gutkha, khaini and betel quid with FTND dependency score for SLT products being 7.83±2.17 with usage frequency per day of 5.97±1.90 number of times of

consumption 33. Key informant's (KI) (SLT users and health care providers) survey found 62% of KI-SLT users, majority SLT users (68%) started SLT consumption between 16-39 years and 35.1% of SLT users made quitting attempts at least once in the past. The health care provider KI's 52.3% reported awareness of tobacco cessation. The major SLT products consumed by the SLT users were guthka, kaddipudi or hogesoppu. The main cause for the SLT use stated by KI's are enjoyment, time-pass, habit, stress relief, easily availability and very feasible marketing strategies (available in pouches), and few states continue consuming to maintain social community. The awareness about the health adverse effect by SLT products was less in SLT users (<43%). In the focused group discussion, they expressed no intention for cessation and lack of knowledge on SLT product adverse effect <sup>13</sup>. Consumption of SLT products by pulmonary tuberculosis (TB) patients is associated with worsening the condition of TB patients and leads to an increase in the death rate 34.



**Figure 2:** Comparison of SLT dependence & willingness to quit with international and GATS-2 report. (a) No statistical significance in the SLT dependence in patients between 5-year data of national and international survey/ publication. (b) No statistical significance was observed in willingness to quit SLT within a 12-month period captured from last 5-year data of national and international published data and in comparison with GATS-2 fact sheet report. The data presented here is in percent mean and standard deviation.

In India, the nicotine content in the SLT products marketed have a much varied range from 1.0 to 50.0 mg/gm. There is no compliance in the policy and regulation for bringing resolution of nicotine content. Nicotine content in the tobacco products plays a major role in the addiction which persistently regulates access to any form of tobacco products, effectiveness of the tobacco controlling interventions and policies face hardships in taking the measure of cessation <sup>35</sup>. Factors connected to SLT consumption in day to day lives are literacy rate, work related practice and acceptance of the SLT product/ users among society/ work environment. However, the majority of the SLT users (90%) preferred to quit and were recognized with a higher score of quit attempts in the daily activity but found no obstruction in the usage of SLT products from society, company policies or law enforcement <sup>36</sup>. The tobacco dependence study assessing and evaluating for the accuracy of the self-reports given by SLT users by using double-blind placebo-controlled clinical trials revealed 34.1% of SLT users under-reported the tobacco use in nicotine dependence medication by varenicline 37, 38

#### **Discussion**

According to the statistics provided by the Food and Agriculture Organization of the United Nation, India is the third-largest producer of tobacco globally <sup>2, 39</sup>. WHO-FCTC global reports on tobacco dependence and cessation programs implemented by 69% parties of FCTC membersby excelling in health, tobacco control and educational plans and programs. FCTC revealed that the lack of relevant recent data on smokeless tobacco products causes a hindrance in the execution of tobacco product cessation 40. According to a household survey conducted by the National Cancer Institute and Centers for Disease Control and Prevention, around 80% of 290 million people (232 million) were SLT users <sup>2</sup>. SEAR regions have a high prevalence of SLT use with a wide variety of SLT product options for SLT users to switch to, the most popular products considered are *gutkha*, pan-masala, *mawa*, *mishri*, *snus* and *khaini* <sup>3</sup>.

Healthcare based cross-sectional study conducted in the Western part of India reveals 258 SLT users have a higher dependence rate (20%) with a 61% of willingness to guit SLT products. The healthcare professionals illustrate that occupation related stress and travelling is counterbalanced by using SLT products especially in illiterates 31. As per *Divinakumar et al*, 41% of tobacco product users and 750 SLT users have a history of lower literacy rate, occupation associated with travelling, family history of tobacco uses and alcohol consumption. Tobacco product users (20%) have a higher prevalence of nicotine dependency (72%) and a large percentage of them (52.9%) attempted to guit tobacco more than once in life 32.

Nicotine, a reversible agonist of neuronal nicotinic acetylcholine receptors (nAChRs) causes stimulation similar to various neurotransmitters such as noradrenaline, acetylcholine (Ach), gamma-aminobutyric acid, dopamine and glutamate. The activation of nAChR receptors enhance number of physiological and metabolic processes such as anxiety, nociception, learning, memory, attentiveness and locomotion leads to the alleviation of stress in the brain and causes addiction. Nicotine addiction, a chronic condition of tobacco product use, encourages users to make an attempt of tobacco use over time and prevents them from quitting tobacco products. Nicotine, being the main constituent of tobacco products, is directly linked to addiction. Many studies have been conducted to prove the addiction toward nicotine by FTND score through self-report of the survey and/or health professional counselling, but chances of underreporting tobacco dependence, guit and cessation is common. Hence the self-report and survey program should support evidence and validation-based reports from the SLT users in the cessation program <sup>37</sup>.

According to Article 14, the first importance is given to the guidance for the development of basic infrastructure on treatment and stress.

Secondly, evidence-based approach for the treatment of tobacco cessation through clinical trial and observation must be given prominence. The practice for tobacco dependence and cessation by taking the effective step through scientific evidence (survey) of users, and consequently suggesting counselling and regular follow-up by mobile or any other mode <sup>6, 7, 16</sup>. Price and taxation measures on tobacco products contribute to better outcomes with more stimulus in the program of quitting tobacco and its dependence 41. High endurance and well-structured FCTC articles on tobacco dependence reduction and cessation measures are not fully implemented for SLT cessation like those for smoking tobacco. Tobacco cessation interventions for youths are established by using a small number of studies that are difficult in concluding the exact behavioral interventions and pharmacotherapy in developed and developing countries 42. Twenty case-controlled clinical trials (16-USA; 3-India & Sweden) were conducted with more than 28000 SLT users during the period of 1992-2017 given behavioral intervention. It was efficiently promoted through self-help guide, videos, motivational interviews, counselling (telephonic), athletic trainer referral, nicotine replacement therapy (NRT), pharmacotherapy, non-nicotine therapy, etc. It was finalized with proper followup of about 3-6 months for counselling and oral examination considered for efficient success of the advanced intervention <sup>6, 16, 30</sup>.

Tobacco cessation intervention and strategies are available and applied specifically to control smoking tobacco. The setback of SLT cessation and intervention is specifically due to cultural/societal acceptance, limited knowledge on SLT harmfulness and potential habituation/addiction. The results of current review matches to the GATS-2 report on quit attempts (33.2%) by SLT users in a 12-month period. From this fact, it is clear that SLT users have the high intention of addictiveness towards SLT products <sup>1</sup>. The high nicotine content in the SLT products with no enforcement barriers accounts for much of the addiction.

Further, the pharmacotherapy intervention in the SLT cessation program seems to be less effective. An evaluation of varenicline efficacy on SLT users in a double-blind placebo-controlled trial showed no significance between control and varenicline treated users 38. In the case of nicotine replacement therapy and bupropion, the tobacco quitting attempts are high in comparison with placebo. But the pharmacotherapy interventions are more successful in smoking tobacco than chewing tobacco 41,43. By reducing targeted demand and disturbing the SLT use by improving the education, motivating the SLT users to quit and legalizing the SLT cessation programs in the workstation and in communities might help promote SLT cessation. In India around 429 tobacco cessation facilities are available in 31 states/ provinces 8, which has to increase to get better management of the cessation program. The number of the programs conducted in the past 5 years are quite limited and not covered in different parts of the country. However, the study came with multiple issues for tobacco dependence and cessation and it may give robust information on the outline of the concerns.

#### Conclusion

The looming threat of SLT products across the world needs to encourage evidence-based research with scientific proof in low-income and middle-income countries of SEAR. The policies and regulations of WHO-FCTC need to be implemented by each of the ruling parties of the member countries. SLT products cessation program and policies in India are efficiently discussed only at the proposal level. Concluding with the pathetic condition of the execution of the aforementioned policies, it has to be implemented as effectively as policies to curb use of smoking tobacco. There are lots of lacunae in the SLT dependence and cessation interventions in Indian practice. Being a major consumer of SLT products globally, the odd challenges are yet to be identified in addressing the WHO-FCTC Article 14 policies in India for controlling SLT dependence and cessation. New approaches have to be integrated with behavioral

interventions for the feasible advancement in SLT cessation starting from self-help guidance, at the healthcare provider level, counselling, follow-up, training, pharmacotherapy, school campaigning, etc. The key approach has to be of recommendation from the international, national and sub-regional manufacturer, seller, etc., all the interventions have to take part in controlling SLT products. Strong regulation needs to be employed for the standardized formulation of SLT products with the content disclosure specifically for nicotine (total alkaloids) and TSNA contents. The availability, low cost and accessibility of SLT products have led to a high rate of abuse, and this should be immediately controlled by increasing the taxation and pricing. This shall reduce the dependence and improve cessation among SLT users by reducing the affordability as per Article 6 in demand for reduction measures of tobacco. According to FCTC Article 11 packing and labelling of the SLT need to follow with the weight of evidence by targeting regional/ national resident based necessity. Healthcare providers should approach SLT users with appropriate knowledge to guide the users to guit tobacco products, by providing behavioral interventions with the proper suggestion of follow-up and counselling sessions. The government policies with proactive initiatives for smoking tobacco control implementation also have to reciprocate the same attention for SLT products.

#### **Conflicts of Interest**

The authors declare no conflict of interest.

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#### **Ethical Approval**

This study does not include any medical research performed on human participants or laboratory animals by any of the authors.

### **Authorship Contribution Statement**

All authors contributed equally.

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