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Evaluating the Effectiveness of a One Point Psycho-Educational Intervention for Smokeless Tobacco Users Delivered in an Outpatient Department in India

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Abstract

Introduction: In a recent review it was reported that 51.3% people in India consume SLT. This usage is highest in males living in rural areas and the most common forms of SLT consumed are Khani, Gutka, Beetle quid with tobacco and powdered tobacco.

Aims and Methods: We aimed at 1) studying the prevalence and understanding the demographic variables associated with SLT consumption in patients presenting to our out patient department(OPD). 2) Evaluating the effectiveness of single psychoeducation session on tobacco cessation. After assessing patients based on our inclusion criteria, we administered a Fagerstorm Nicotine Dependence Test, Smokeless Tobacco (FTND-ST) at baseline. Subsequently they were given a structured session of psycho-education and they were then followed up after a month using the same scale and change in the score was recorded.

Results: Our results indicate the following:

1) Maximum SLT consumption was seen in males coming from rural areas.

2) At baseline 39 % were in the category of mild dependence, 41% in moderate dependence and 20% in severe dependence and following up after the single psychoeducation session, 50% were mildly dependent, 47% were moderately dependent and 3% were severely dependent. ($p<0.001$).

3)Maximum reduction was seen in the time taken to consume SLT after waking up and the number of SLT pouches/cans consumed per day($p<0.001$)

Conclusions: The problem of SLT consumption is multi-factorial with social, economic and health repercussion. Though we did not see complete abstinence with our intervention, it served the purpose of reducing the consumption of SLT among our participants in a significant manner.

There is no gold standard for tobacco cessation including pharmacological interventions. Thus our findings have to be viewed as a part of collective and long-term effort towards de-addiction.

Keywords: Smokeless tobacco (SLT); Fagerstorm nicotine dependence test; Smokeless tobacco (FTND-ST); Psycho-education; Legislation; Dependence

Introduction

The use of smokeless tobacco (SLT) represents a major challenge, both in terms of physical and mental health to the population of any country. Though the prevalence of SLT use is less than that other forms of smoked tobacco, it nonetheless is significant. In a recent review on the use of SLT in South East Asian countries, it was found that the prevalence of SLT use in India is 51.3%, and that in Gujarat is 42.4%. Of which 29.3% of people come from rural areas and 17.7% come from urban areas. 32.9% of them are male users and 18.4 % of them are female users [1]. In another recent study conducted in Chennai on 7510 individuals to estimate the prevalence of use of SLT's, it was found that maximum consumption of SLT' s was in rural parts (9.5%) followed by a very similar proportion of 7% in semi urban and urban parts of the region [2].

The most commonly consumed forms of SLT in India are Khaini (11.6%), Gutka (8.2%), Betel Quid with tobacco (6.2%), powdered tobacco (4.7%) and others 4.4%.

Khaini is prepared from sun-dried tobacco and slaked lime is commonly used in the states of Gujarat and Maharashtra.

Gutka or pan masala with tobacco is a ready-to-eat tobacco product has become extremely popular in all parts of India due to its user-friendly packaging. It contains areca nut, slaked lime, catechu, and tobacco as well as flavoring agents and sweeteners that are added to improve taste.

Betel quid or pan contains four main ingredients, betel leaf (Piper betel), areca nut, catechu, slaked lime, and tobacco. Spices and flavoring agents may also be added [3,4].

Highest tobacco consumption was seen in ages 45 years and above and was significantly associated with illiteracy and below primary level education [1].

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Chronic SLT use has serious health consequences. As SLT has high nicotine content which is a very addictive drug, it has been observed that when a person tries to stop SLT use, he develops withdrawal symptoms and most of the people then restart SLT. This leads to a vicious cycle and the person chronically consumes SLT [5].

Smokeless and other tobacco products are known to cause oral, pancreatic, pharyngeal, esophageal and stomach cancers [6]. In a landmark study on the development of oral cancers due to consumption of SLT's, it was found that in India, 52.5% males and 51.6% females developed oral/pharyngeal cancers. This was most significantly associated with consumption of SLT's. The proposed mechanism of action, is that the carcinogens in the SLT's cause metabolic activation of DNA adducts, whose persistent miscoding leads to the mutations in p53 and RAS oncogenes which in turn leads to cancer [7].

SLT not only is a serious carcinogen, it also has potential cardio vascular toxicity. As per the recent American Heart Association guidelines, they have recommended to not use SLT as an alternative to smoking. They agree upon the low incidence of cardiovascular (CV) risk with SLT, but based on multiple case control studies they have concluded that:

1) Long term use of SLT is associated with greater risk of fatal myocardial ischemia and stroke.

2) Long term use of SLT may complicate or reduce the chances of survival after stroke.

3) It can cause increased CV mortality by causing a dual smoking pattern in patients already smoking tobacco [5,8].

The age adjusted relative risk in females, for all cause mortality over 10 years due to tobacco chewing was 1.3, which was statistically significant. When combined with beetle quid, defined as mixed habit, the RR was 1.4 for males ($p<0.05$) [9].

The implications of use of SLT products are grave as noted above. The issues of SLT associated morbidities have been in discussion since the early 1990's. A paper in the British Medical Bulletin in 1996 talks about the possibilities of development of oral cancer due to the carcinogenic elements in SLT and also its probable relationship with development of cardiovascular disorders [6].

As pointed out by a recent study from Chennai the problems with SLT consumption are: 1) either people are not aware of the implications of the use of these products. 2) Or they are aware of the implications but find the process of quitting tough due to the side effects [2].

Substantial work has been done in finding optimal ways to help people quit addictive substances. Though most work has been focused on alcohol and smoking cessation, similar principles can be used for smokeless tobacco cessation. A number of strategies have been used for cessation including the use of text messages, emails or hypnotherapy with a variable degree of effectiveness [10-13].

Single intervention strategies have also been used to achieve abstinence from smoking. In a landmark study being conducted in India, by Sarkar et al. the relative efficacy of a combination of brief advice with yoga training v/s very brief advice is being studied in tobacco cessation [14].

We hypothesize that a single point intervention strategy will be helpful in reducing the dependence of patients on smokeless tobacco.

One of the main factors for having this approach is to make vital information more accessible to the patient to help them take an informed decision and to cater to the needs of the many at the same time. The massive task of delivering health care to this vast nation makes it relatively very difficult to provide personalized health care.

Methods

Study population

A prospective intervention study on 130 participants consuming SLT products, randomly selected from Dhiraj Hospital, a tertiary care hospital, Out Patient Department (OPD) was conducted. The majority patients in our setup are from the rural parts of the country having a low to middle socio-economic status. The setup has days dedicated to specialty clinics with the de-addiction clinic running on Friday. Majority of the patients coming to our consultation on this day have a substance abuse disorder, most commonly nicotine addiction, followed by alcohol and then opioid and benzodiazepine addiction.

Patients with nicotine addiction presented mostly without any comorbid psychiatric illness e.g. depression. In order to eliminate as many confounds as possible we decided to include only those patients who did not have any comorbid mental or physical illness. Those patients considered for the study were first sent for a physician reference where basic blood investigations were done free of charge to rule out any underlying conditions. Then they were evaluated for any underlying metal conditions using clinical indicators and structured scales such as Hamilton rating scale for depression/anxiety. Frankly psychotic patients were excluded from the beginning.

The Sumandeep Vidyapeeth Institutional Ethics Committee approved the protocol before the study was initiated. Participants were randomly selected and were enrolled into the study after taking a prior written informed consent.

Inclusion Criteria:

1) Those who identified SLT as their primary tobacco product

2) Patients who fulfilled the criteria of nicotine dependence based on DSM IV TR

3) At least 18 years of age and of either gender

Exclusion Criteria:

1) History of comorbid psychiatric disorders or physical disorders.

2) Under treatment for tobacco de-addiction in the past 30 days.

3) Patients with a history of smoking cigarettes or bidis or who currently engage in the same.

4) No other co- substance abuse e.g. alcohol or opioids.

Data Collection and measures

A total of 130 participants were selected and screened. Of them 110 participants were included as they matched our inclusion criteria. These participants were given a Fagerstorm Nicotine Dependence Test, Smokeless Tobacco (FTND-ST) at baseline and their respective scores were recorded [15]. 20 participants were excluded because they had underlying medical co-morbidities. Most common amongst them were respiratory problems, e.g. upper respiratory infection, tuberculosis under investigation or patients with severe anemia (Hemoglobin under 9 mg/dl).

All participants were given one similar session of structured psycho

education (details attached in the supplement), aimed at creating awareness about the long-term potentials of consuming SLT products. The members of the department, keeping in mind the socio economic class and the literacy level of the patient, collectively develop this psycho education protocol. The protocol has not been validated and has been developed to suit the needs of the patients coming to our OPD. This protocol is also currently being used to psycho educate the patients.

The intervention was common to all and conveyed the exact same information. Thus there was homogeneity in the amount and quality of information imparted to all the participants.

Of these 110 participants, 10 participants could not be followed up after one month due to logistical reasons and hence were excluded from the study. The remaining 100 were assessed again after 1 month using the FTND-ST.

Along with administering the scale, a case sheet was also recorded which contained demographic information and other variables; we thought could influence the intake of SLT.

Statistical analysis

The score of the scales were tabulated in MS EXCEL spreadsheet and were assessed using suitable statistical parameters such as Chi square, correlation matrix and ANOVA. SPSS was used to calculate the p value.

Results

Of our sample size of 100 patients, 82 % were males and 18 % were females with an average age of 36.5 years (SD 10.77). Of these participants 91% were married and 47% had received secondary education. 31% of them were farmers and 33% had an income of > Rs. 19,575, annually. 63 % of them lived in rural areas and 59% of them had a nuclear family, and 55 % of the participants were the heads of the family (Table 1).

At baseline the performance of the participants on FTND-ST was the following:

39 % were in the category of mild dependence, 41% in moderate dependence and 20% in severe dependence. After one session of psycho education, when we followed them up after one month, the rates of dependence were as follows. 50% were mildly dependent, 47% were moderately dependent and 3% were severely dependent ($p<0.001$) (Table 2).

Of the 6 parameters that were tested upon the FTND-ST, the most significant differences ($p<0.001$) were on the following parameters.

A) time of consumption after waking: Before the intervention 24% consumed tobacco within 5 minutes of waking up. This number reduced significantly after the intervention, with just 2% of the original population consuming tobacco within the first 5 minutes (Table 3).

B) Intentional swallowing of tobacco juice: Before the intervention 11% swallowed tobacco juice intentionally. This number reduced after the intervention, to 8% of the original population.

C) Chew you would hate to give up: Majority 78% would hate to give up the first chew in the morning. This number reduced by a marginally 1% after the intervention.

D) Numbers Of Cans And Pouches: Before the intervention, 32% consumed >3 pouches per day and this number reduced to just 10% on follow up [16] (Table 4).

E) More frequent chewing in the first hours of the morning: 78% of our study sample consumed tobacco more frequently in the first hours of the morning. This number reduced to 72% after the intervention.

Demographic details		Percentage
Gender	Male	82
	Female	18
Age	21-30	31
	31-40	34
	41-50	23
Marital status	Single	8
	Married	91
	Widowed	1
Literacy	Illiterate	15
	Primary	26
	Secondary	47
	Higher secondary	12
Occupation	Unemployed	2
	Unskilled work	17
	Farmer	31
Religion	Hindu	87
	Muslim	6
	Others	7
Family type	Nuclear	59
	Joint	41
Locality	Urban	63
	Rural	35
Head of the family	Yes	55
	No	45

Table 1: Demographic variables of respondents.

FTND-ST Score	At Baseline	After Intervention
Mild Dependence	39%	50%
Moderate Dependence	41%	47%
Severe Dependence	20%	3%

Table 2: Effect of one session of psychoeducation on Fagerstorm Nicotine Dependence Test (FTND-ST) Score.

Time of consumption of first dip after waking up	At baseline	After Intervention
Within 5 mins	24%	12%
6-30 mins	49%	18%
31-60 mins	13%	68%
>60 mins	14%	2%

Table 3: Effect of one session of psychoeducation on time of consumption of first dip after walking up.

Cans/Pouches	At Baseline	After Intervention
1	19%	20%
2-3	49%	70%
More than 3	32%	10%

Table 4: Effect of one session of psychoeducation on consumption of number of cans/pouches of tobacco.

F) Chewing if you are ill and bed-ridden: 21% population would chew tobacco even when ill and in bed. This number changed to 22% after the intervention.

Discussion

The study was designed to serve two purposes. 1) We aimed at understanding the demographic diversity among people consuming SLT and 2) To assess the impact of one single session of psycho education on the reduction in the use of SLT.

Firstly, from the demographic point of view it is clear to us that in our sample, middle aged males living in rural areas, having a basic education and with an income of > Rs 19000 are the highest consumers of the SLT. We align ourselves with the previous authors on the prevalence being more in rural areas than in urban areas [2].

None of the covariates had a significant interaction with the points on the scale, both at baseline and after intervention. We think of this as a finding due to the limitation of the sample size and believe that each one of these can serve independently as a risk and/or a protective factor.

Secondly, the intervention, we gave one session of psycho education, which was not tailored for individual needs. The session was designed to cover the most important aspects of tobacco consumption. It was directed towards those lacking this information and was aimed at creating awareness and not fear. The important thing about this session was that it was designed to objectively convey facts and allow the participants to take an informed decision. Thus it was not about creating a scare but it was more about understanding and assessing the future impact of their choices.

Having said this we at the same time understand and acknowledge the limitation of not tailoring the solution as per the participants needs. The "one size fits all" principal helped us in part by demonstrating a significant reduction in tobacco consumption, but none of our participants became abstinent. Had we been more accommodating in our approach towards individual participants we could have seen higher abstinence rates.

But achieving higher abstinence rates was not the purpose of the study. We already know of intervention studies that have been effective when custom solutions have been offered to patients. But as we discussed earlier, given the burden of disease in the county and the population we were keen to test the "one size fits all" hypothesis. Based on our results we would state that single psycho-education technique does have the advantage of catering to a huge mass at one go, while simultaneously having a modest effect on reduction of tobacco consumption. It has a little or no effect on SLT cessation. (Based on our study results)

Though at the same time, this was a prospective study with one month follow up which could be too short a time to see abstinence. It is probable that patients who reduced their consumption could, with time also become abstinent.

A sustainable solution would be focused on developing a more personalized delivery solution to the patients. We propose that the first point of contact should always be such psycho-education sessions, which can be conducted by health givers in their primary facility. We would encourage them to have multiple such one-point sessions, in order to reinforce their message and deliver information to a large number of people. We hope to see abstinence when multiple such sessions are given and when the message is reinforced. Also in those patients that do not benefit from these sessions, they could be refereed to an advanced center for de-addiction. Thus the individual needs of the patient could be catered to and the patient can find sustainable solutions in terms of psychotherapy and psychotherapeutics. Recently some studies have looked at the effectiveness of the use of varenicline in the reduction/cessation of SLT use among chronic users. Both the studies point to the effectiveness of varenicline at reducing consumption at 6 months, as compared to placebo, bupropion or psychotherapy [17-19].

Another indicator of the effectiveness of this approach is the use of specific branding standards on SLT products. Based on some research findings it has been found that the graphic and text warnings on SLT products are robustly associated with the perception of health risk and appeal of the product [20,21]. This goes on to prove our point that repeated awareness about the ill effects of tobacco consumption in any form, be it psycho-education; psychotherapeutics, branding or legislation has a positive co-relation with reducing tobacco intake.

Limitations of the Study: The most important limitation of the study was the sample size and the follow up period. Earlier studies have shown that longer periods of follow-ups are required to ascertain the degree of cessation better. Also the fact that a more customized solution set was not delivered to the patient is a shortcoming of our project. We conducted this project in a high turn over setting, so loosing patients due to financial and logistical reasons is a common thing, which also could have impacted the results. Further as patients were from low socio-economic class, it wasn't always possible to get in touch with them via a cell phone. Multiple small limitations also exist including the homogeneity of the sample size and the fact that any regulatory authority did not approve the intervention. We would like to propose a longer study with takes into account these limitations.

Conclusion

To conclude, we would like to say that there is a higher prevalence of SLT consumption in the rural areas of the country and in our study we particularly found higher prevalence in men.

State of the art de-addiction centers along with tough legislative reforms seem to be the most sustainable solutions to this growing problem.

The problem of SLT consumption is multi-factorial with social, economic and health repercussion. As per a recent paper the SLT industry in India is worth Rs 10,000 crores and the cost of health expenditure caused due to its consumption is worth more. Given the wide spectrum of its repercussions, even legislative and economic sanctions are tough measures to come by. But given the recent stands of the government and its firmness to ban nicotine-containing products in many states, it definitely seems like a positive start [22].

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