Use of Nicotine Gums, Tablets and Lozenges: A Review

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Difficulty quitting is best predicted by how much one smoke on a daily basis and smoking within 30 min of waking up each day, both of which are measures of nicotine dependence. It has now been established that tobacco smoking often involves dependence to nicotine. This is usually seen as a problem, but often as an opportunity. The cigarette is the most contaminated drug-delivery device. If nicotine is largely what the smoker needs, the use of nicotine from alternative sources to sustain smoking reduction could be exploited for long-term harm reduction to the smoker unable to quit.

Keywords: Lozenges, Nicotine, Tablets

INTRODUCTION

Tobacco is used in smoking as well as in smokeless form. Tobacco was introduced to India by the Portuguese 400 years ago. Since then tobacco consumption has seen a continuous rise in India. Tobacco causes many deaths almost entirely due to the inhalation of tobacco smoke or its oral use, a process driven in today’s world, substantially by tobacco product marketing, and sustained by nicotine addiction. Beside primary prevention of smoking (i.e., avoidance of smoking initiation in non-smokers, namely, children and adolescents), one of the important priorities of tobacco control is smoking cessation. There are various methods of tobacco cessation - one of which is nicotine replacement therapy (NRT). Discussed in this article are nicotine gum, lozenges and sublingual tablets as NRT devices.

NICOTINE GUM

Nicotine based chewing gums were the first type of NRT to become popular in which a nicotine resin complex is present in a buffered chewing gum base which facilitates the buccal mucosa to absorb nicotine directly, leading to approximately half the plasma concentrations that is produced by smoking a cigarette.¹

Nicotine gums act as a substitute and as a source of nicotine that controls the withdrawal symptoms experienced by the subject on cessation of tobacco use. Different flavors and strengths of these chewing gums are available and can be used at regular intervals or as needed basis. Tapering of the dose can be considered after 8-12 weeks.

How it is used:
• Should be used orally as a chewing gum and not swallowed
• Treatment is usually started using 2 mg gum
• Heavy smokers/tobacco users may start the treatment by using 4 mg gum
• Patient should be instructed to chew one piece of nicotine gum every 1-2 h at first, or chewing one piece of gum whenever there is an urge to use tobacco
• The gum should be chewed slowly until the taste of nicotine or slight tingling is felt in the mouth
• After chewing the gum should be placed (parked) between cheek and gum
• Parking the nicotine gum is essential for the absorption of nicotine through the buccal mucosa, not doing so will lead to more nicotine being swallowed which might result in side effects such as nausea and vomiting
• Once the tingling is gone (almost 1 min), start chewing again
• Repeat this procedure for about 30 min.
Precautions:
- Don’t chew nicotine gum too fast
- Don’t chew more than one piece of gum at a time
- Don’t chew one piece too soon after another
- Don’t chew more than 30 pieces of 2 mg gum in a day if under supervision
- Don’t chew more than 24 pieces of 2 mg gum in a day if not under supervision
- Eating and drinking (especially acidic beverages such as coffee or soft drinks) should be avoided for 15 min before and after nicotine gum chewing for proper absorption of nicotine
- Gradually reduce the amount of nicotine gum use after 2-3 months, which prevents nicotine withdrawal symptoms.

**WEANING OF NICOTINE GUM (NRT)**
- Start decreasing the total number of nicotine gum pieces being used per day by about one piece in every 4-7 days
- Chewing time should be reduced with each piece from 30 min to 10-15 min for 4-7 days. Then, gradually total number of pieces used per day should be decreased
- Increase the duration between the use of nicotine gum pieces
- Increase intake of drinking water
- Start substituting one or more pieces of nicotine gum with sugarless gums and gradually increase it over a period of time
- If using 4 mg gum, replace it with 2 mg gum and apply any of the aforesaid steps
- Consider stopping the use of nicotine gum when the craving for nicotine is satisfied by chewing just one or two pieces of gum per day
- Avoid using nicotine gum for durations longer than 3 months.

**AVAILABILITY OF NICOTINE GUM IN INDIA**

Composition: Nicotine polacrilex

Dosages: 2 mg and 4 mg

Nicotine pastilles have also been introduced in India. Here, the procedure to use is to roll the pastille in the mouth rather than chew.

Nicotine patches, inhalers, and sprays are not presently available in India.

NRT products available in India:
- GOOD Kha Chewettes
- Nicotine Polacrilex Gum USP
- Eucomint.

**STUDIES ON NICOTINE GUMS**

Kelemen and Fulton assessed the effects of cigarette abstinence and nicotine gum (0 mg vs. 2 mg nicotine) on sustainance of attention, free recall, and metacognition using a within-subjects design. Moderate smokers (10 women and 22 men) received one training session followed by 4 test sessions on consecutive days. He found that nicotine gums helped in improving sustainance of attention in both abstinent and non-abstinent states, however, predicted or actual recall levels showed no significant difference. Free recall ability and magnitude of participants’ predictions of their own performance were significantly impaired by cigarette abstinence also, overconfidence about participants future memory was noticed when abstinent. Thus, performance in basic aspects of cognition (e.g., sustained attention) can be improved in smokers using nicotine gums. However, the detrimental effects of cigarette abstinence on higher-level processes such as memory and metacognition may not be alleviated.

Kralikova et al. evaluated the efficacy and safety of nicotine 4 mg gum or nicotine 10 mg inhaler in helping smokers to quit smoking. Smokers willing to control their smoking were included, and individual goals could be set by the participants, to reduce or quit. It was a placebo-controlled study, randomization in a ratio of 2:1 (Active: Placebo) was done, and choice of inhaler or gum was given to the subjects after randomization. Short-term (from week 6 to month 4) and long-term (from month 6 to month 12) outcome was recorded on abstinence or reduction. When not a single cigarette was smoked, and expired CO readings were <10 ppm. It was defined as abstinence. A 50% or more reduction in number of cigarettes per day, verified by a lower-than-baseline CO reading at each visit during the same periods was defined as smoking reduction. In the active group, more smokers managed to quit than in the placebo group, and the difference was significant. Sustained abstinence rates at 4 months were 20.1% subjects in the Active group and 8.6% subjects in the placebo group. Sustained abstinence rates at 12 months were 18.7% and 8.6%, respectively. Reduction in smoking was not different between the groups, (short-term or long-term). 17.2% versus 18.1% reduction was noticed at the end of 12 months, respectively. Any serious adverse events were not reported. He concluded that 10 mg nicotine inhaler treatment or 4 mg nicotine chewing gum caused significantly higher abstinence rate than placebo. Furthermore, a large number of smokers managed to reduce their cigarette consumption by more than 50% compared to baseline.

Usefulness of nicotine chewing gum in some smokers was affected by several factors, such as oral and gastrointestinal side effects, reduced absorption when coupled with coffee.
or acidic beverages, improper dosing, and a risk that some smokers may transfer their dependence from cigarettes to the gum.\(^5\)

- Nicorette - Pharmacia and Upjohn
- Gum 2 mg
- Approximate cost: 15 pieces Rs. 150.00.

**NICOTINE LOZENGES**

The chances of successful cessation of smoking are doubled by the use of NRT. However, a considerable number of cessation attempts are still made without any treatment. This newer oral formulation, (lozenge containing nicotine bitartrate dihydrate) was developed to increase the success rate of efficient smoking cessation drug therapies, with the view in mind that increasing the treatment options will encourage more number of smokers to seek the support they need to stop smoking. Three pharmacokinetic (PK), (one safety and two efficacy) studies were carried out with Nicotine lozenges. Previously conducted PK trials were (1) a single dose, three-way crossover study involving comparison of 1 and 2 mg lozenges with 2 mg nicotine gum; (2) a multiple-dose, two-way crossover study involving comparison of 1 mg lozenge with 2 mg gum; (3) a multiple-dose, three-way crossover study involving comparison of 1 and 2 mg lozenges with 4 mg gum and also a safety trial: (4) Which was a single dose study to assess the safety of swallowing up to 12 lozenges containing 1 mg nicotine. Efficacy trials: Two efficacy studies in France\(^6\) and the USA,\(^9\) including more than 900 smokers followed-up for up to 1 year, conducted with the 1 mg lozenge. The results of the individual PK trials showed that the 2 mg polacrilex gum is bioequivalent to 1 mg nicotinell lozenge, same was proved by similar blood PK parameters (t\(_{\text{max}}\), C\(_{\text{max}}\), AUC). The nicotine delivered by a 2 mg lozenge was found to be within the range of those delivered by 2 and 4 mg polacrilex gum. The short-term efficacy of the 1 mg lozenge when compared to that of placebo also showed significantly more subjects with continuous abstinence from smoking with active lozenges after 6 weeks in two different populations wiz. Moderate to heavy smokers and heavy to very heavy smokers. With Nicotinell lozenges, only mild and reversible adverse events were founded are regarded to be safe. Even when misused the safety of the 1 mg lozenge formulation, was also demonstrated.

It was ascertained that the data in this review demonstrated excellent safety profile, high nicotine bioavailability, and proven short-term efficacy of nicotinell lozenges. A nominal doses 1 and 2 mg nicotinell lozenges delivered larger amounts of bioavailable nicotine than the nicotine polacrilex gum. According to the data recorded here, the ranking of efficacy could be as follows: 4 mg polacrilex gum > 2 mg nicotinell lozenge > 1 mg nicotinell lozenge = 2 mg polacrilex gum.\(^5\)

**SUBLINGUAL NICOTINE TABLETS**

The sublingual tablet is further addition to the range of products available. Dose and duration of the treatment is controlled by the patient and varies according to cigarette consumption. At least 3 months use is recommended by the manufacturers.\(^7\) These tablets may have the advantage of being a discreet method of using NRT, although there are no long-term trials to establish the effectiveness of this product.\(^8\)

Tablets and lozenges were created for people who cannot or prefer not to use chewing-gum. Sublingual tablets exist in 2 and 4 mg doses. The tablet is held under the tongue until it dissolves, delivering nicotine similarly to chewing-gum. Food and acidic drinks should be avoided 15 min before and during use.\(^9\)

Smokers of 20 cigarettes or fewer per day should start using 2 mg sublingual tablets. People who continue to have withdrawal symptoms or craving and heavier smokers can use the 4 mg dose. One nicotine sublingual tablet can be used hourly, as needed. The maximum recommended daily dose is 80 mg for 3 months, followed by a gradual reduction in use over the next 3 months for a treatment period of 6-month.\(^9\)

**DISCUSSION**

Smoking cessation and prevention strategies hold tremendous potential to improve public health. Although evidence-based recommendations indicate that smoking cessation programs are useful in helping smokers to quit, breaking smoking addiction can be difficult. Relapse within the first month of abstinence has been seen in approximately 80% of the smoker who attempt to quit on their own and after 6 months only about 3-5%.

**CONCLUSION**

Any regular cigarette smoker prepared to make a quit attempt should generally be offered NRT in conjunction with behavioral support. Smokers, who are not motivated to quit, are unlikely to gain from NRT as they do not experience or expect to experience nicotine withdrawal symptoms.

**REFERENCES**


