

The Importance of Over-the-counter Nicotine Replacement Therapy in Smoking Cessation

a report by

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Position and Organisation

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Introduction

According to official data of the World Health Organization, tobacco use, particularly smoking, ranks among the most important reasons of premature deaths worldwide¹ and each year approximately five million people die in consequence of tobacco-induced diseases, representing about one-tenth of all adult deaths across the world. It is estimated, according to current trends that until 2020 the number of tobacco-induced deaths will be as high as 10 million people yearly. It means that about one-half of current smokers, i.e. 650 millions people, will die from tobacco-induced diseases.

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. However, this task is not easy one, taking into consideration many factors, but primarily the strong addictive potential of nicotine. Beside cognitive-behavioral approaches, pharmacotherapy has been found to be effective in the cessation process, alleviating it and significantly increasing quit rate. Within this, several forms of nicotine replacement therapy (NRT), mainly thanks to their wide availability and relative low price, have become an integral part of smoking cessation interventions, showing their positive effect particularly among heavy smokers.

Nicotine Replacement Therapy – Forms and Usage

NRT used in smoking cessation was firstly introduced in 1984.² NRT products aid nicotine addicts to overcome withdrawal symptoms caused by a nicotine deficit quitting. Their effect is based on a release of nicotine into the quitter's bloodstream and thus alleviating unpleasant withdrawal effects, particularly irresistible craving and reduce of the possibility of relapse (i.e. to increase probability of long-term abstinence). These drugs occur in the following application forms: patches for transdermal application (acting through skin), chewing gums, microtablets, and lozenges (acting through bucal mucosa), nasal spray

(acting through nasal mucosa) and inhalator (acting through pharyngeal and bronchial mucosa).

The positive effects of NRT on cessation rate in smokers dependent on nicotine have been well documented,^{3,4} as well as cost-effectiveness of its use,⁵⁻⁹ leading also to a reduction in cigarette sales.² So, NRT became an integral part of smoking cessation evidence-based guidelines.¹⁰ According to existing data, NRT can achieve a quit rate of 5–30%, when the extent of the reached quit rate is influenced also by other factors, particularly other underlying interventions and intensity of cognitive-behavioral therapy. However, comparison with placebo with same underlying conditions, after one year of therapy, gives a relatively uniform increase of quit rate by a factor 1.5–2.0.^{4,11}

From the currently existing forms of NRT the most commonly used ones are patches and chewing gums.¹⁰

Nicotine patches are currently designed for 24-hour wear (usually containing 7, 14, or 21mg of nicotine) or for 16-hour wear (5, 10 and 15mg of nicotine). Client applies one patch a day just after getting up and nicotine is continuously released through the skin for either 16 or 24 hours. The whole therapy should last about three months. Within the therapy period, dosages are gradually decreased. The main advantage of patches is very easy application and regular release of nicotine. Allergic skin reaction can occur rarely.

Nicotine chewing gums are designed in 2mg and 4mg dosage. Clients use 8–12 gums daily and gradually reduce the number of used gums per day. A dosage of 4mg is appropriate for heavy smokers during first weeks of therapy while in moderate smokers (15–20 cigarettes per day) both dosages have shown approximately the same effect.¹² The therapy course also should last about three months. The main advantages of gums are a possibility to individually tailor the usage according to current needs, for example craving, etc., as well as relatively rapid release of nicotine into bloodstream. The main disadvantage of nicotine gums is a need for appropriate technique of chewing to avoid gastrointestinal irritation and nausea.

As for as other forms, their characteristics are similar to the above-mentioned NRT forms. Advantages are a simple application and rapid release of nicotine. Other adverse effects are very rare.

Spread of Use and Effect of Over-the-counter NRT

Considering the benefits and relative safety of NRT, in 1996, the US Food and Drug Administration (FDA) approved over-the-counter (OTC) sales of these drugs. After this, OTC sale of NRT was approved also in many other countries, facilitating its availability and widespread use.

The first experiences of OTC sales of NRT in the US evidenced a dramatic increase of its use by 152%, representing 114,000–304,000 ex-smokers annually.¹³ Other studies also showed substantial increase of NRT after the introduction of OTC sales, and their analysis documented an increase of nicotine patches and nicotine gum use by 78–92% and 180%, respectively.¹⁴ According to results of California Tobacco Surveys, between 1992 and 1999, NRT use among quitters increased from 9.3% to 14.0%.¹⁵ A prospective study carried out as a part of the Community Intervention Trial for Smoking Cessation (COMMIT) showed an increase of NRT patches and gums of about 60% following OTC reclassification.¹⁶ On the other hand, one study reported no significant change in NRT use after switching to OTC status, when the proportion of smokers using NRT at a quit attempt within one year increased only from 20.1% to 21.4%; among non-Whites, use of NRT even decreased (from 20.6% to 3.2%).¹⁷ The decrease of use among minors shows that also other factors play role, most probably economic reasons.

A meta-analysis of studies that focused on the effect of OTC NRT showed a quit rate similar to that seen in prescribed NRT.¹⁸ This was evidenced two years later,¹⁶ when the quit rate in patch users did not changed after OTC reclassification, and in gum users even increased (9.7% vs 14.6%). Several studies also documented a significant effect of OTC NRT in placebo-controlled and prospective studies.^{19–21}

Possible Complications and Inappropriate Use

According to several studies, serious adverse effects and complications of NRT use are very rare.^{19,22,23–28} Moreover, any noxious effect of NRT has not been proven for the fetus in pregnant women during a cessation course²⁹ and NRT used during pregnancy by smokers led to a significantly larger birth weight compared with placebo.³⁰ Also, NRT used in cardiac

patients and minors appears to be relatively safe and can be recommended them in some circumstances.^{31,32}

Concerns about the dangerous addictiveness of NRT have never been confirmed^{33,34} and only very small fraction of NRT users persistently purchased these drugs (1% of gums and 0.05% of patches 24 months and more).³⁵

Underuse (i.e. insufficient dosage or too early withdrawal) ranks among the most frequent flaws regarding OTC NRT use.¹⁵ Among NRT users, as many as 61% of them took the drug less than two weeks and more than 40% of them reported receiving no instructions from a doctor or pharmacist.³⁶ Such low levels of adherence on current guidelines lowers the cessation rate and can lead to smokers being discouraged from NRT. These findings indicate a need for a better involvement of physicians and pharmacist in counseling and giving qualified advices regarding NRT.^{36–40}

Conclusions

The introduction of NRT represents a landmark in the treatment of tobacco dependence. It can effectively increase quit rate in cigarette smokers and at the same time its use is exceptionally safe and any adverse effects are infrequent and benign.

The largest benefit of OTC sale of NRT lies in its wide availability. Its use is also acceptable for many people who do not want to visit a physician, a smoking cessation clinic or a counseling centre. Although the effect of OTC NRT could not be dramatically high, the main benefit is given by a very high number of smokers using NRT. An intervention impact on population depends principally on a number of intervened people.⁴¹ It means that very sophisticated and expensive methods (e.g. specialized cessation clinics), although giving a relatively high quit rate, provide help for only a tiny fraction of smokers. On the other hand, a simple method, even providing just small cessation rate, thanks to its inexpensiveness and availability, can address considerable higher numbers of smokers and its real-world efficacy and intervention impact in the population can definitely be much higher. Thus, well-promoted OTC NRT has a potential to improve population health, i.e. fewer smoking-attributable deaths, increased life expectancy, and quality of life for current smokers.⁴²

However, there are still problems using NRT, particularly among minorities, for which purchase of these preparations is not affordable. A similar situation can be seen in the transforming countries of Central and Eastern Europe, where the price of NRT is too high for a

considerable proportion of the population. In such cases, involvement of health insurance companies to pay at least a part of the price would probably help the situation.⁴³

Another concern is improper use of NRT in a large part of smokers, particularly underdose, caused by

knowledge deficit about optimal length of course and appropriate dosage. There is, therefore, still plenty of room for improving compliance with the current guidelines. Pharmacists and physicians can play an important role to counsel adequately smokers how to use NRT and quit. ■

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