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IM-POINT OF VIEW

The emerging role of oral nicotine pouches in tobacco harm reduction

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Abstract
Global smoking prevalence remains high, underscoring the need for strategies that complement conventional cessation. Tobacco harm reduction (THR) offers a pragmatic strategy by promoting substitution of combustible cigarettes with substantially less harmful alternatives. Oral nicotine pouches (ONPs) have emerged as a promising option. Modeled on the Scandinavian success of snus, ONPs deliver pharmaceutical-grade nicotine without tobacco leaf or combustion, eliminating thousands of toxicants and lowering exposure to carcinogens such as tobacco-specific nitrosamines to near-undetectable levels. Epidemiological evidence from snus users provides a strong precedent for ONPs' potential impact on population health. Preclinical, toxicological, and biomarker studies consistently demonstrate a favorable safety profile for ONPs, with minimal cytotoxic or inflammatory effects. Their discreet, odorless, and spit-free design may further promote adherence compared with traditional nicotine replacement therapies. Despite this promise, skepticism persists within public health, particularly concerning youth uptake and the potential renormalization of nicotine use. Yet current evidence indicates that ONPs are primarily adopted by adult smokers and smokeless users seeking lower-risk options. Regulatory responses are uneven: while the U.S. Food and Drug Administration has authorized their marketing, other jurisdictions have enacted prohibitions that risk perpetuating cigarette consumption. Incorporating ONPs into tobacco control frameworks, especially in low- and middle-income countries where cessation support is scarce, represents both an urgent and ethical opportunity to accelerate progress toward ending combustible tobacco use.

Keywords smoking · oral nicotine pouches · oral nicotine pouches

Introduction: redefining tobacco control for the twenty-first century

The global public health community remains steadfast in its pursuit of a world free of tobacco-related disease and death. Yet, as we progress further into the twenty-first century, it has become increasingly clear that reliance on traditional cessation strategies alone is insufficient to achieve this goal [1]. Despite significant investments in tobacco control, millions of people continue to smoke, and smoking prevalence remains stubbornly high in most regions of the world [2, 3].

Against this backdrop, the concept of tobacco harm reduction (THR) has gained traction as a pragmatic complement to conventional abstinence-based approaches [4, 5]. THR acknowledges that abstinence is not always possible and instead emphasizes risk minimization for individuals unable or unwilling to quit, encouraging substitution of combustible products with less harmful nicotine delivery systems [6]. The rationale for THR as an evidence-based public health strategy is growing [7]. One of the most promising

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new tools in this arena is the oral nicotine pouch (ONP), a smokeless, tobacco-free product designed to deliver nicotine with minimal exposure to harmful constituents (Fig. 1).

Lessons from snus: epidemiological evidence and risk reduction

Sweden has long served as a natural experiment in THR. For decades, male smoking rates there have been the lowest in the European Union, largely due to the widespread use of snus, a low-nitrosamine oral tobacco product [8, 9]. Whereas overall nicotine/tobacco consumption has remained relatively stable due to snus at about 22%, daily smoking rates have decreased dramatically to as low as 5% [10]. Epidemiological studies consistently show that snus use is associated with substantially lower risks of lung cancer, cardiopulmonary disease, and oral cancer compared with smoking [11–13]. Importantly, the substitution of smoking with snus has contributed to reduced overall tobacco-related mortality among Swedish men [14]. Reflecting this evidence, the U.S. Food and Drug Administration granted Swedish snus the first license as a "modified-risk" (i.e., less harmful) tobacco product [15, 16], authorizing the claim: *"Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis."*

Drawing on the Scandinavian experience with snus [9, 17] and supported by a growing body of scientific literature [7, 18], ONPs have the potential to accelerate reductions in smoking-related harm, particularly where conventional cessation tools are inaccessible or ineffective. However, nicotine is not risk-free and its use in all forms should be avoided.

Nicotine may provoke decompensation in people with unstable angina or recent myocardial infarction [19], but epidemiological studies of users, who are exposed to nicotine but not smoke, show no generalized increase in cardiovascular events or mortality [20–22]. A causal role for nicotine in cancer initiation or progression is not supported by human data [23, 24], and observational studies of long-term users of nicotine replacement therapies and smokeless tobacco do not show increased cancer incidence [25, 26]. Respiratory effects attributed to nicotine are largely absent in the absence of smoke [27–29]. While smoking is an established cause of chronic obstructive pulmonary disease (COPD) and lung cancer, these conditions are not driven by nicotine itself [30]. Pregnancy and developmental considerations warrant careful attention. A large, randomized trial of nicotine patch and e-cigarette use in pregnancy found no evidence of harm [31, 32]. Still, a total abstinence from nicotine consumption should be advised to pregnant women to avoid possible adverse impact on the developing child [33].

Building on the success of snus, ONPs have emerged as a modern alternative, offering comparable benefits with even lower exposures to unwanted contaminants. Unlike snus, ONPs do not contain tobacco leaf, but instead use pharmaceutical-grade nicotine embedded in cellulose-based pouches. This design eliminates harmful constituents associated with tobacco combustion and further reduces exposures to known carcinogens, including tobacco-specific nitrosamines (TSNAs), to non-detectable levels (< 0.01 µg/g) [34]. While some ONPs users report localized gingival irritation [13], novel pouch technologies incorporating an impermeable barrier have been developed to minimize direct contact and gum irritation [35].

Recently, the FDA also authorized the legal marketing of ONPs in the United States [36]. When the ONP Zyn was cleared by the U.S. Food and Drug Administration (FDA),

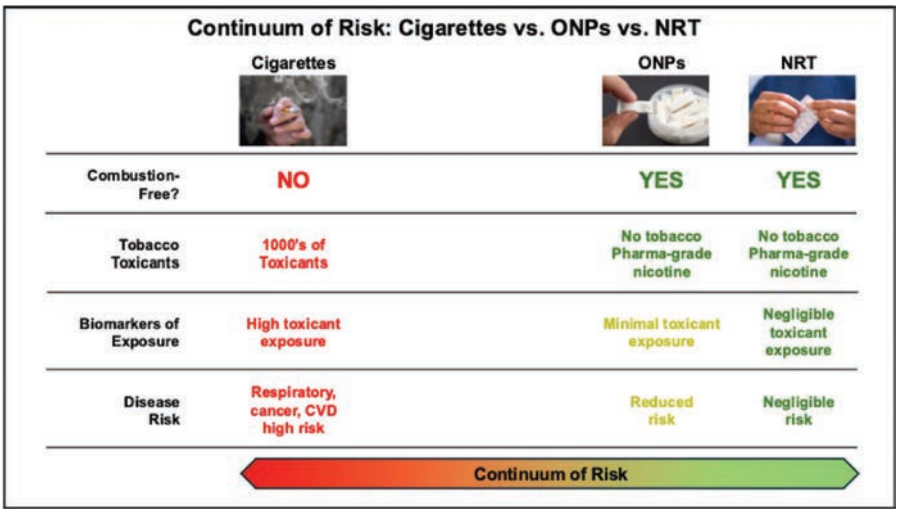

Fig. 1 Continuum of risk for nicotine products. Cigarettes represent the highest health risk due to combustion and toxicant exposure. Although not risk-free, oral nicotine pouches (ONPs) instead deliver nicotine without combustion or tobacco leaf, resulting in minimal toxicant exposure and substantially lower health risk. Nicotine replacement therapy (NRT) (i.e., nicotine gums) provides pharmaceutical-grade nicotine with negligible toxicant exposure, representing the lowest risk profile

the agency emphasized the crucial distinction between nicotine dependence and the harms of combustion: "Nicotine is what keeps people using tobacco products. However, it's the thousands of chemicals contained in tobacco and tobacco smoke that make tobacco use so deadly" [37]. The decision was based on toxicology, usage patterns, and population-level impact data.

Scientific rationale and exposure profile of ONPs

Toxicological assessments of ONPs have consistently demonstrated a favorable exposure profile (Fig. 1). Compared to cigarettes, ONPs emit negligible levels of harmful and potentially harmful constituents (HPHCs). In vitro studies have shown that ONP extracts are not cytotoxic, mutagenic, or genotoxic, and do not trigger pro-inflammatory responses in respiratory or oral epithelial cells [38]. While all tobacco harm reduction products are characterized by the absence of combustion, ONPs do not rely on combustion or any thermal process, thus eliminating potentially toxic thermal degradation emissions. This represents an important advantage of ONPs compared to other nicotine products. Biomarker studies confirm that ONP users have significantly lower levels of exposure to toxicants compared to smokers. The ingredients in the major ONP brands are very close and often the same as in pharmaceutical nicotine products with the exception of somewhat higher nicotine content and more flavorings.

In the context of smoking cessation and relapse prevention, ONPs offer several practical advantages. They are discreet, spit-free, odorless, and easy to use, making them acceptable in any social setting. These features may enhance sampling, adherence, and long-term switching among individuals seeking alternatives to cigarettes. Moreover, ONPs deliver nicotine in a controlled and consistent manner, which can help manage cravings and withdrawal symptoms more effectively than unassisted quitting [39].

Although current ONP use is concentrated among people who smoke or formerly smoked, this distribution will likely evolve as smoking continues to decline. Evidence from Scandinavia shows that, as snus diffused and smoking fell, the share of never-smoker users increased [40]. The relevant comparison, therefore, is not user vs non-user, but ONP use vs the counterfactual of continued or potential cigarette use. This framing remains valid even if ONP uptake grows among never-smokers, because the key policy question is whether ONPs displace smoking initiation or persistence.

Addressing misconceptions and regulatory challenges

Despite their potential benefits, ONPs have been met with skepticism and resistance from some quarters of the tobacco control community. Critics argue that the promotion of alternative nicotine products may undermine tobacco control efforts, renormalize nicotine use, or act as a gateway to smoking among youth. While these concerns warrant careful consideration, the current body of evidence does not support them.

Recent data from countries where ONPs have been introduced show no evidence of increased youth smoking or progression from ONPs to cigarettes [41, 42]. On the contrary, ONPs are used predominantly by adult smokers, former smokers, and traditional smokeless tobacco users seeking less harmful alternatives. Regulatory frameworks should therefore aim to preserve this harm reduction potential by enforcing robust age restrictions and marketing controls to minimize youth appeal and initiation, while also implementing stringent product standards to ensure product quality, purity, and stability.

Unfortunately, policy responses to ONPs have often been shaped more by prohibition ideology than evidence. In some jurisdictions, such as Belgium, France, and Germany, ONPs have been banned outright or subjected to stringent regulations that do not reflect their substantially lower risk profile. Such measures follow the EU prohibition on the sale of snus, the most extensively studied harm reduction product, and may inadvertently discourage smokers from switching to safer alternatives, thereby undermining public health goals. A more balanced and evidence-based approach is needed—one that recognizes the continuum of risk across tobacco/nicotine products and incentivizes transitions away from combustible tobacco. The restrictions on less harmful products give a monopoly to cigarettes when instead the cigarettes should be phased out.

ONPs in low- and middle-income countries: a missed opportunity?

The burden of tobacco-related disease is increasingly concentrated in low- and middle-income countries (LMICs), where smoking prevalence is often highest and access to cessation services remains limited [43]. In these settings, ONPs represent a cost-effective and scalable intervention for reducing harm among smokers who are unable or unwilling to quit using traditional methods.

Unlike pharmaceutical nicotine replacement therapies (NRTs), which are often unavailable or unaffordable in

LMICs, ONPs can be competitively priced with cigarettes, are discreet in use, and they represent noncoercive consumer choice. In fact, ONPs allow smokers to take full control of their tobacco use and consequential health impacts. Moreover, by providing a satisfying alternative to cigarettes, ONPs may help counter the rise of unregulated products and illicit tobacco markets, which pose significant criminal and public health risks.

Integrating ONPs into national tobacco control strategies requires thoughtful policy design, including regulatory oversight, public education, and market monitoring. This is particularly relevant for regions such as South-East Asia, where smokeless tobacco use remains widespread. In India, for instance, smokeless tobacco is highly prevalent and oral cancer rates are among the world's highest, yet safer alternatives such as snus or ONPs are unavailable. Pilot programs could be launched to assess acceptability, efficacy, and real-world impact, providing valuable insights for scale-up. International donors and global health organizations should support research and implementation initiatives focused on ONPs, particularly in high-burden countries.

Ethical considerations and public health responsibility

The ethical foundation of public health is rooted in the principles of harm reduction, informed voluntary choice, and equity. Denying access to lower-risk alternatives like ONPs for ideological reasons contradicts these principles and may perpetuate avoidable harm. Abstinence may be an ideal outcome, but it is unachievable for millions of smokers. Recognizing and supporting risk reduction bridges the gap between idealism and pragmatism, ultimately saving lives.

Public health professionals have a duty to provide accurate, evidence-based information about the relative risks of nicotine products. This includes correcting misinformation, countering sensationalist narratives, and ensuring that smokers have access to safer alternatives. Communications should be clear, proportionate, evidence-based, and avoid the pitfalls of absolutism or moral panic.

Conclusion: embracing innovation for a smoke-free future

Tobacco harm reduction is not a panacea, but it is a vital component of a rational and comprehensive tobacco control strategy. ONPs represent a promising innovation with the potential to reduce smoking-related morbidity and mortality, especially among hard-to-reach populations. By embracing these products as part of the solution, rather than viewing them as part of the problem, we can accelerate progress toward a far less hazardous smoke-free world.

Achieving this vision will require courage, collaboration, and a willingness to challenge entrenched dogmas. Policymakers, regulators, researchers, and advocates must come together to craft policies that are guided by science, responsive to local realities, and centered on the needs of those most affected by tobacco harm. The opportunity is ours to seize—let us not waste it.

Declarations

Conflict of Interest, Human and animal rights statement and Informed consent This work does not involve any human or animal subjects, therefore no ethics committee approval or informed consent was required.

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