

Research summary

To assess whether switching to modified tobacco products reduces the amount of tobacco-specific carcinogens in the body, scientists at the University of Minnesota measured carcinogen uptake in smokers who were using either a “reduced exposure” tobacco product (Swedish snuff or the Omni cigarette) or medicinal nicotine. Those using medicinal nicotine had greater reductions. Reductions of carcinogen uptake from modified cigarettes was modest at best.

Policy implications

The results of this study demonstrate a need for the Food and Drug Administration to be involved in regulation of tobacco products. Regulation of all tobacco products would allow consumers to know how much they are exposed to tobacco toxins, including those that purport to be reduced-exposure products.

About umntturcresearchbrief

The UMN TTURC Research Brief presents timely information on emerging tobacco research from the University of Minnesota. The aims of UMN TTURC are to examine ways to reduce tobacco toxin exposure, determine effective ways to treat smokers who are unable or unwilling to quit smoking, and outline public policy implications for reducing exposure to tobacco toxins.

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Modified tobacco products: are they safer?

For millions of people in this country, quitting tobacco use remains a formidable challenge. While the majority of smokers in the United States want to quit, only 4% of the smokers actually quit for an entire year,¹ and less than 10% are even interested in taking action to stop smoking.² For this population, a potential strategy may be to try products that purportedly reduce tobacco users’ exposure to tobacco toxins while still allowing them to use tobacco products. Examples of such products include the Omni cigarette and Swedish moist snuff (snus).

Although the makers of some of these products claim that they contain lower levels of carcinogens than conventional products marketed in the United States, it is not known whether Omni, snus, and other modified tobacco products actually reduce carcinogen exposure in people—and how they compare with medicinal nicotine. To evaluate the benefits of switching to these products, researchers at the University of Minnesota Transdisciplinary Tobacco Use Research Center (UMN TTURC) measured carcinogen uptake in people who were using them.

Methods

The study involved more than 100 participants: 54 users of smokeless tobacco and 51 cigarette smokers. Participants were randomly assigned to receive either a “reduced exposure” tobacco product (Swedish snus for smokeless tobacco users and Omni cigarettes for smokers) or to quit and use medicinal nicotine (nicotine patch). Every week, from two weeks before to four weeks after the switch, researchers measured the levels of two tobacco-specific lung carcinogen metabolites: 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanol (NNAL) and its glucuronides (NNAL-Gluc). Presence of these metabolites is highly specific to tobacco exposure and indicates that a potent carcinogen, 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK), has been absorbed in the body. NNK has caused lung cancer in rats, mice, and hamsters. Smokers were also assessed for levels of 1-hydroxypyrene (1-HOP), a biomarker for uptake of polycyclic aromatic hydrocarbons (PAHs). Long-term exposure to low levels of some PAHs has caused cancer in laboratory animals.

Findings

In users of smokeless tobacco, total NNAL levels (NNAL and NNAL-Gluc) were significantly lower after

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they switched to snus or to the nicotine patch, but participants using medicinal nicotine had greater reductions. Among smokers, mean total NNAL levels were significantly lower in those who switched to the nicotine patch than in those who used the Omni cigarette. Only those smokers who switched to medicinal nicotine had a reduction in levels of 1-HOP. In users of the Omni product, carcinogen exposure did not decrease as much as was advertised on the manufacturer's web site. (Information on the Omni Web site, which indicated a 53% reduction in NNK and a 15% to 20% reduction in pyrene, was based on machine-measured methods. The Omni site has since been deactivated.)

Conclusions

Switching to reduced-exposure tobacco products or medicinal nicotine can decrease exposure to tobacco-associated carcinogens. However, medicinal nicotine, unlike the modified tobacco products, is likely to result in reduced risk for disease. The extent of reduction of carcinogen uptake from modified cigarettes is modest at best, and oral tobacco products are associated with potential health problems independent of cancer. Furthermore, exposure to other toxins (such as carbon monoxide with cigarettes) can remain the same or, in some products, increase. To date, the only known method to reduce death and disease is tobacco cessation.

Policy implications

The results from this study indicate a need for FDA regulation of tobacco products for these reasons:

- An independent agency is required to validate information that is provided to the consumer. For example, the results from this study showed that machine-determined methods to assess exposure can overestimate the extent of toxin reduction compared with actual human exposure. The consumer has a right to accurate information so that they can make informed decisions.
- Conventional products that are sold in the United States have significantly higher levels of toxins than other modified tobacco products. Although the extent of reduction in exposure to these toxins may not

Toxin Exposure Reductions with Omni Cigarettes: FTC Method vs. Human Exposure

Toxin	FTC Method	Human Exposure
Carbon monoxide	No significant reduction	Increase of 1.4%
NNK	53%	25%
Pyrene	20%	5%

Source: Hatsukami et al. J Natl Cancer Inst 2004;96:844-52

necessarily lead to reduction in disease risk, if the technology is available, all tobacco products should meet standards that would reduce or eliminate toxins in these products.

- It is imperative that the consumer understand that (1) reduced exposure does not necessarily translate to reduced disease risk and (2) the risk for other diseases may remain unchanged or, in some cases, may increase with some of these tobacco products. Direct or implied health claims that are unsubstantiated can mislead a consumer about the "safety" of tobacco use and may diminish a tobacco user's interest in quitting, thereby leading to continued exposure to harm.

Findings from this study were published in the following article: Hatsukami DK et al. Evaluation of carcinogen exposure in people who used "reduced exposure" tobacco products. J Natl Cancer Inst 2004;96:844-52. For more information about this study, please contact Jeanne Mettner, UMN TTURC's communications consultant, at 612.627.1857.

References

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- (2) Wewers ME, Stillman FA, Hartman AM, et al. Distribution of daily smokers by stage of change. Prev Med 2003;36:710-20.